ORAL ARGUMENT REQUESTED

No. 13-6061

IN THE UNITED STATES COURT OF APPEALS
FOR THE TENTH CIRCUIT

PATRICIA CAPLINGER,

Plaintiff-Appellant,

v.

MEDTRONIC, INC., ET AL.,

Defendants-Appellees.

On Appeal from a Final Judgment of the United States District Court for the Western District of Oklahoma, Hon. Judge Miles-Lagrange

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BRIEF FOR PLAINTIFF-APPELLANT

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August 9, 2013

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LOCAL RULE 28.2(c)(1) STATEMENT

There are no prior or related appeals.

GLOSSARY

FDA	Food and Drug Administration
FDCA	Food, Drug, and Cosmetic Act
MDA	Medical Device Amendments of 1976, 21 U.S.C. § 360c, *et seq.*
PMA	Premarket approval

JURISDICTION

Plaintiff-appellant Patricia Caplinger filed her original complaint on June 4, 2012, and an amended complaint on July 23, 2012. Appx. 1, 3. The district court had jurisdiction under 28 U.S.C. § 1332(a) based on the complete diversity of citizenship of the parties: Ms. Caplinger is a citizen of Missouri, and Medtronic, Inc. and Medtronic Sofamor Danek USA, Inc. (hereafter collectively referred to as "Medtronic") are citizens of Minnesota and Tennessee, respectively, where they are incorporated and have their principal places of business. *See* Appx. 5, ¶¶ 1-3 (amended complaint). The action meets the amount-in-controversy requirement of § 1332(a) because Ms. Caplinger's complaint seeks recovery of damages exceeding $75,000. *See id*. 5, ¶ 4.

The district court entered its order dismissing all of Ms. Caplinger's claims on February 6, 2013. Appx. 70. On March 6, 2013, within 28 days of the dismissal order, Ms. Caplinger moved for reconsideration, invoking Federal Rules of Civil Procedure 59 and 60. On March 8, 2013, while that motion was pending (and within 30 days of the original dismissal order), she filed a notice of appeal. This court ordered the appeal abated under Federal Rule of Appellate Procedure 4(a)(4)(B)(i) because of the pendency of the motion under Rules 59 and 60. The district court denied Ms. Caplinger's motion for reconsideration on April 8, 2013. Appx. 74. The denial of the motion made Ms. Caplinger's notice of appeal

effective under Rule 4(a)(4)(B)(i), and this Court lifted the abatement order and reactivated the appeal on April 18, 2013. *Id.* 4.

STATEMENT OF ISSUES

1. Whether the district court erred in holding that 21 U.S.C. § 360k(a), the preemption provision of the Medical Device Amendments of 1976 (MDA)—which preempts state laws that impose requirements relating to the safety or effectiveness of medical devices only if they are "different from, or in addition to" requirements imposed by federal law—forecloses Ms. Caplinger's state-law claims based on injuries caused by Medtronic's marketing and promotion of a medical device for a use that has not been approved by the Food and Drug Administration (FDA). *See* Appx. 59 (district court order on motion to dismiss).

2. Whether the district court erred in holding that § 360k(a) preempts Ms. Caplinger's state-law claims for failure to warn, design defect, fraudulent misrepresentation, fraud in the inducement, constructive fraud, and negligence, where those claims are based on state-law duties that parallel federal requirements imposed on Medtronic under the MDA. *See* Appx. 59-69 (district court order on motion to dismiss).

3. Whether the district court erred in holding that Ms. Caplinger's claims for fraudulent misrepresentation / fraud in the inducement and for negligence are preempted, in part, under the reasoning of *Buckman Co. v. Plaintiffs' Legal*

Committee, 531 U.S. 341 (2001), which held that a purported claim of "fraud on the FDA" was contrary to federal policy but recognized that claims based on breaches of state-law duties that parallel federal law are not preempted. *See* Appx. 60-61, 67-68 (district court order on motion to dismiss).

4. Whether the district court erred in holding that Ms. Caplinger's claims for breach of warranty are impliedly preempted on the ground that they conflict with FDA regulation, where the claims do not call into doubt the correctness of any FDA decision and the FDA has indicated that warranty claims are not preempted. *See* Appx. 65-66 (district court order on motion to dismiss).

5. Whether the district court erred in holding that Ms. Caplinger's claims for fraudulent misrepresentation / fraud in the inducement and, in part, for constructive fraud were not pleaded with requisite particularity. *See* Appx. 61-63 (district court order on motion to dismiss).

STATEMENT OF THE CASE AND OF FACTS

A. Nature and Course of the Proceedings

This action is a personal injury case in which plaintiff Patricia Caplinger seeks to recover under principles of state common law for injuries she suffered as the result of the malfunctioning of a medical device called the Infuse Bone Graft, manufactured by defendant Medtronic. The Infuse device is used to treat degenerative disc disease in spinal fusion surgery. *See* Appx. 9, ¶ 18 (amended

complaint). The FDA approved the device for use in surgery performed through the abdomen, but has not approved it for use in surgery performed through the back. *Id*. 10, ¶ 26. When used through the back, the device causes exuberant bone growth onto or around the spinal cord. The bone growth can compress nerves, causing intractable pain, weakness, and foot drop. *Id*. 6-7, ¶ 9.[1]

In Ms. Caplinger's case, the device caused exuberant bone growth and foot drop, which in turn caused a tear in a ligament of her right knee. Because of the exuberant bone growth, Ms. Caplinger has had to undergo additional spinal surgery and knee surgery, and the continuing exuberant bone growth will likely require additional surgeries in the future. *Id*. 21, ¶¶ 67-70.

Ms. Caplinger sued Medtronic, raising claims that the device was defectively designed for the use for which it was marketed to her physician and that Medtronic had provided insufficient warnings to her and her doctor about the risks associated with the device. *See generally* Appx. 5-41. Among Ms. Caplinger's theories of recovery were that Medtronic failed to warn about risks of which it knew and, indeed, downplayed the risks associated with the device, that

[1] Foot drop "is a general term for difficulty lifting the front part of the foot. … [It] is a sign of an underlying neurological, muscular or anatomical problem." Foot drop may be temporary or permanent. An individual with foot drop may need to wear a brace on the ankle and foot to hold the foot in a normal position. Mayo Clinic, Definition of Foot Drop, http://www.mayoclinic.com/health/foot-drop/DS01031.

the product was defectively designed because its risks outweighed its benefits when promoted for use through the back, and that Medtronic had fraudulently concealed and misrepresented the safety risks of the product, which it promoted for unapproved use through the back, in violation of FDA regulations. The complaint also recited FDA requirements that Medtronic had violated, thereby causing the device to be misbranded. *Id*. 39, ¶ 155.

Medtronic moved to dismiss on the ground that Ms. Caplinger's state-law claims are preempted by the MDA because they seek to impose requirements on the device that are "different from, or in addition to," requirements imposed by the MDA, 21 U.S.C. § 360k(a), or because they are impliedly preempted under the reasoning of *Buckman Co. v. Plaintiffs' Legal Committee*, 531 U.S. 341 (2001). Appx. 53-56. Ms. Caplinger responded that insofar as her claims are premised on conduct that violated federal requirements, such as the prohibition against a manufacturer promoting a device for a use that has not been approved by the FDA and requirements that device manufacturers report to FDA adverse incidents involving their products, the claims are not preempted because they parallel federal requirements and neither differ from nor add to those requirements. *Id*. 56-58.

The district court granted Medtronic's motion to dismiss, holding that all of Ms. Caplinger's claims are either expressly or impliedly preempted and that the

fraud claims are, in part, not pleaded with adequate specificity. The court dismissed the action in its entirety. *Id*. 70, 71.

B. Background and Facts

1. Federal Medical Device Regulation

Although the development and marketing of prescription drugs have been the subject of extensive regulation by the FDA since the enactment of the Food, Drug, and Cosmetic Act (FDCA) in 1938, medical devices, which range in complexity from elastic bandages to artificial hearts, were outside the scope of the FDA's regulatory authority until the enactment of the MDA in 1976. *See Medtronic, Inc. v. Lohr*, 518 U.S. 470, 475-76 (1996). The MDA divided all medical devices into three categories—classes I, II, and III—and established a tripartite scheme for their regulation. *See id.* at 476-77.

Under the MDA, class III devices are those that treat serious medical conditions or pose serious risks of causing injury to patients. 21 U.S.C. § 360c(a)(1)(C).[2] Like new drugs, new class III devices that are not substantially similar to devices already on the market when the MDA was enacted must receive premarket approval (PMA) from the FDA. *See Lohr*, 518 U.S. at 477; *Riegel v. Medtronic, Inc.*, 552 U.S. 312, 318-19 (2008). The PMA process involves a

[2] Class I devices are basic items such as bandages, and class II includes such devices as hearing aids, which are more complex and have greater potential to cause harm if defective or misused.

detailed review of a device's safety and efficacy for particular uses, including all studies and investigations available to the manufacturer, as well as the device's proposed uses, its design, and its labeling. *See Riegel*, 552 U.S. at 318. PMA thus represents an FDA finding that the device is safe and effective "under the conditions of use included in the proposed labeling." 21 U.S.C. § 360e(d)(1)(A); *see also id*. § 360e(d)(2)(A), (B) (requiring the FDA to deny approval if a device is not safe and effective for the uses specified in the labeling). In addition, PMA is conditioned on the manufacturer's compliance with ongoing obligations under the FDA's regulations, including the requirement that the manufacturer report adverse incidents involving the device to the FDA. 21 U.S.C. § 360i(a)(1), (3); *see Riegel*, 552 U.S. at 319. In particular, a manufacturer must report incidents in which a device "malfunctions" and those in which the device may have caused or contributed to a death or "serious injury." 21 C.F.R. § 803.50(a); *see also id*. § 803.3 (defining "malfunction" and "serious injury"). The FDA makes such reports available to the public. *See id*. § 803.9.

In contrast to new class III devices that are subject to the PMA process, class III devices that were already in existence when the MDA was enacted are subject to less stringent standards. Such devices, as well as devices that are their "substantial equivalents," are grandfathered, and approval to market such products may be obtained through a truncated review process generally referred to as the

"510(k) process" (so named after the MDA section providing for such review). *See Lohr*, 518 U.S. at 477-79. Section 510(k) review focuses on the question of substantial equivalency and does not entail a thorough examination of the device's safety and efficacy, or of its design except to the extent necessary to determine whether it is substantially equivalent to a grandfathered device. *Riegel*, 551 U.S. at 322.

Whether a device is introduced through the PMA or 510(k) process, it can be marketed only for the use(s) approved or cleared by the FDA and specified in its labeling. *See* 21 U.S.C. § 360e(d)(1)(A) (in evaluating a PMA application, FDA "shall rely on the conditions of use included in the proposed labeling"); *id.* § 360c(a)(2)(B) (providing that the safety and effectiveness of a device must be determined "with respect to the conditions of use prescribed, recommended, or suggested in the labeling of the device"). Thus, for example, a manufacturer cannot promote a device approved as a knee implant for use as a hip implant. Although the FDA does not regulate physicians, who may use a device approved for one use for a different use, *see id.* § 396, a class III device *intended by the manufacturer* for an unapproved, or "off-label," use is adulterated and misbranded. *Id.* §§ 351(f)(1)(B), 352(f); *see* FDA, Guidance for Industry: Good Reprint Practices of 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).[3] And federal law prohibits manufacturing or marketing an adulterated or misbranded product. 21 U.S.C. § 331(a), (b), (c), (g).[4]

Unlike the statutory provisions establishing the otherwise comparable PMA requirements for new prescription drugs, the MDA contains an express preemption provision codified at 21 U.S.C. § 360k(a). Section 360k(a) states:

> Except as provided in subsection (b) of this section, no State or political subdivision of a State may establish or continue in effect with respect to a device intended for human use any requirement—
>
> (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.

2. Medtronic's Infuse Bone Graft Device

Infuse is a bio-engineered bone-filling material used in spinal fusion surgery as an alternative to grafting a patient's own bone, typically from the patient's hip.

[3] Available at www.fda.gov/regulatoryinformation/guidances/ucm125126.htm.

[4] In 1997, Congress created a "safe harbor" from this strict prohibition for device manufacturers who disseminated to health-care providers peer-reviewed articles or reference publications "concerning the safety, effectiveness, or benefit of a use not described in the approved labeling." 21 U.S.C. §§ 360aaa, 360aaa-1. To take advantage of the safe harbor, the manufacturer had to apply for approval of the additional use. *Id.* § 360aaa-3(a). The safe harbor provision expired in 2006 and, in any event, is not implicated by the facts in this case.

It uses a genetically engineered protein called rhBMP-2 to help fuse vertebrae in the lower (lumbar) spine to treat degenerative disc disease. Appx. 9, ¶ 18.

As a class III medical device, the Infuse product could not be marketed until Medtronic obtained PMA from the FDA, which it did in 2002. *Id*. 10, ¶ 26. The FDA approved Infuse for use only in surgery in which the surgeon approaches *from the front* (anterior) of the patient, to treat degenerative disc disease in the lower, or lumbar, region of the spine (at levels L4 through S1),[5] as the FDA approval letter expressly states. *Id*. 80; *see also id*. 75 (FDA database listing). Infuse is not approved for use in spinal surgery in which the surgeon proceeds through the patient's *back* (posterior). Use of Infuse for posterior lumbar fusion surgery is an off-label use that creates an undue risk of unwanted bone growth, intractable pain, weakness, and foot drop, among other things. *Id*. 6, ¶ 9; 11, ¶ 31.

Nonetheless, Medtronic aggressively promoted Infuse for off-label use in posterior-approach surgeries. As the Department of Justice, the Senate, and a leading journal of spinal medicine have documented, Medtronic's illegal promotion included paying kickbacks and other incentives to physicians to influence clinical studies, prevent publication of adverse events, and encourage the off-label use. *See generally id*. 12-20, ¶¶ 35-63.

[5] Medtronic later received PMA to market Infuse for use in certain dental surgeries and for repair of certain tibial fractures. Appx. 11, ¶¶ 27-28.

Medtronic was a defendant in two qui tam lawsuits alleging that it violated the False Claims Act, 31 U.S.C. § 3729, by paying illegal kickbacks to physicians for promoting the off-label use of Infuse in the spine, which resulted in the submission of false or fraudulent claims to federal health care programs. Appx. 13, ¶ 39. In July 2006, Medtronic agreed to pay $40 million to the United States to settle these lawsuits. *Id*. 14, ¶ 42.

Despite the settlement, Medtronic continued to illegally market Infuse for the unapproved use in posterior-approach spinal surgery. In 2008, following a Wall Street Journal article about Medtronic's practices (*see* Armstrong & Burton, *Medtronic linked to surgery problems*, Wall St. J., Sept 4. 2008), members of the Senate expressed serious concerns about continued wrongdoing by Medtronic. Appx. 15-17, ¶¶ 48-54. For example, Senator Charles Grassley wrote: "Fourth, earlier this month the WSJ reported on problems with off-label use of Medtronic's Infuse. Infuse is a bone graft replacement technology that uses a protein which creates bone. Specifically, it was reported that Medtronic gave payments to physicians, in the form of consulting agreements, as a means of increasing sales of Infuse. The allegations that Medtronic has been disguising [as] consulting agreements … inducements or kickbacks for physicians to use Infuse are equally troubling." *Id*. 17, ¶ 53.

In 2011, the Senate Committee on Finance began an investigation into whether Medtronic was continuing to misrepresent the adverse events that result from Infuse and rhBMP-2, as well as the possibility that Medtronic improperly influenced clinical trials and reporting regarding rhBMP-2 by payments to physicians. *Id*. 17, ¶ 55.

In June 2011, The Spine Journal, a leading U.S. medical journal, published a special edition dedicated to addressing serious patient safety and ethical concerns related to the use of Infuse in the spine. *Id*. 18, ¶ 58.[6] The journal reviewed thirteen peer-reviewed articles about rhBMP-2 by industry-sponsored authors, including many sponsored by Medtronic, and found that these articles had inaccurately reported the safety by underestimating the risks. In an editorial summarizing the journals' findings, five prominent physicians, including spine surgeons at Stanford University, wrote that the earlier industry-sponsored trials and reports were "remarkable for the complete absence of reported rhBMP-2- related clinical adverse events," including reported instances of adverse back and leg pain events, radiculitis, bone resorption, retrograde ejaculation, urinary retention, and implant displacement, *id*. 19, ¶ 60, as well as sterility and cancer risks, *id*. They concluded

[6] The Spine Journal articles are available at http://www.spine.org/Pages/ConsumerHealth/NewsAndPublicRelations/NewsReleases/2011/pressrelease1_062811.aspx.

that the trials and reports suffered from idiosyncratic trial design, reporting bias, and peer-review and publication shortfalls. *Id*. According to the editorial and accompanying articles, the thirteen industry-sponsored articles reported only successful fusions and low rates of complications with Infuse, "which led to the 'off-label' use of Infuse" and "may have promoted widespread poorly considered on- and off-label use, eventual life-threatening complications and deaths." *Id*. 19, ¶ 61.

3. Patricia Caplinger's Injuries

On August 25, 2010, Patricia Caplinger had surgery to correct a degenerative disc condition. The surgeon used the off-label posterior approach to place the Medtronic Infuse bone graft into the lumbar region of Ms. Caplinger's spine. A Medtronic representative was present during the surgery, and she was actively involved and provided information regarding Infuse as it applied to Ms. Caplinger's particular surgery. *Id*. 20-21, ¶¶ 64-66.

In October and November 2010, Ms. Caplinger's symptoms returned and worsened. She also experienced a foot drop condition in her right leg resulting from exuberant bone growth caused by the use of Infuse. In December 2010, the foot drop condition caused a tear of the anterior cruciate ligament in her right knee, which required surgery in February 2011. MRI and CT imaging of Ms. Caplinger's

lumbar spine confirmed exuberant bone in her lumbar spine caused by the use of Infuse and requiring revision surgery on September 9, 2011. *Id*. 21, ¶¶ 67-69.

Ms. Caplinger continues to suffer exuberant bone growth and the resulting pain, weakness, and foot drop condition. A June 2012, CT imaging confirmed that exuberant bone growth is continuing and will likely require additional surgery. *Id*. 21, ¶ 70.

4. The Lawsuit and the District Court's Decision

Ms. Caplinger filed this lawsuit on June 4, 2012, seeking to recover for her injuries under state products liability law.[7] Her amended complaint states claims for failure to warn, design defect, breach of express and implied warranty, negligence, negligent misrepresentation, fraudulent misrepresentation, fraud in the inducement, and constructive fraud. The complaint also sets forth various FDA regulations violated by Medtronic's conduct but does not allege claims for relief directly under federal law. *Id*. 5-41 (amended complaint).

Medtronic moved to dismiss, principally on the ground that Ms. Caplinger's claims are foreclosed by the MDA's preemption provision, 21 U.S.C. § 360k(a), which, as explained above, prohibits state laws from imposing "requirements" on

[7] The district court assumed that Oklahoma law would apply here, but Ms. Caplinger believes that Missouri law applies. The choice-of-law issue, however, should not affect the resolution of the preemption issues.

devices that are "different from, or in addition to" requirements imposed under the MDA. Ms. Caplinger, relying principally on the Supreme Court's decisions in *Lohr* and *Riegel*, argued that her claims are not preempted by § 360k(a) because they are based on conduct of Medtronic that violated state-law duties that parallel federal requirements imposed under the MDA. Thus, her claims are not based on state-law duties that are "different from, or in addition to," those of the MDA.

The district court granted the motion to dismiss. Appx. 70. Although the court acknowledged that some state-law claims for injury caused by a PMA medical device are neither expressly nor impliedly preempted, the court held that each of Ms. Caplinger's claims is either expressly or impliedly preempted. The court also held that Ms. Caplinger's fraud claims are not pleaded with adequate specificity under Federal Rule of Civil Procedure 9(b).

To begin with, the court disagreed with Ms. Caplinger's contention that the fact that she was injured by off-label use of the device is pertinent to the preemption analysis. Appx. 58-59. Turning to the specific claims alleged, the court found that a claim premised in any way on the notion that Infuse was unreasonably dangerous for the unapproved posterior use, or that Medtronic had failed to provide adequate warnings for that unapproved use, are expressly preempted by 360k(a) because such a claim would impose additional design or labeling requirements on the device. And the court held that a claim tied to Medtronic's off-label promotion

and concealment of the dangers of the unapproved use—conduct that violated applicable federal laws and regulations—is impliedly preempted under *Buckman*.

Specifically, the court held that the fraudulent misrepresentation/fraud in the inducement claim and the constructive fraud claim are expressly preempted under § 360k(a) to the extent that they are based on statements made in the device's labeling or premised on a duty to market Infuse without defects that rendered the device unreasonably dangerous. The court further held that the fraudulent misrepresentation claim is impliedly preempted to the extent that it is based on statements or omissions during marketing or promotion of the device for off-label use in posterior-approach surgery. And the court found that the claims are not alleged with adequate specificity to the extent that they are based on misrepresentations and omissions made in promoting Infuse for off-label use or made by Medtronic's representative during Ms. Caplinger's surgery. *Id.* 60-63.

The court also held that the strict liability failure to warn and design defects claims are expressly preempted by § 360k(a), and that the warranty claims are impliedly preempted under a conflict preemption theory because, the court believed, they would require a jury to contradict the FDA by finding that Infuse was not safe and effective. It held that the negligence claim is expressly preempted to the extent it is based on a failure to warn and impliedly preempted under the reasoning of *Buckman* to the extent it is based on the marketing and promotion of

Infuse. And the court held that, to the extent that the negligence claim is based "on some other violation of federal law," the complaint fails to state facts sufficient to survive a motion to dismiss. Finally, the court held that the negligent misrepresentation claim is expressly preempted under § 360k(a). *Id.* 63-69.

Ms. Caplinger moved for reconsideration or, in the alternative, for leave to file a second amended complaint. *Id*. 4. The motion brought to the court's attention the en banc decision in *Stengel v. Medtronic, Inc*., 704 F.3d 1224 (9th Cir. 2013), decided after the briefing on the motion to dismiss, in which the Ninth Circuit unanimously held that similar claims involving another Medtronic device were based on state-law duties that paralleled federal requirements and, therefore, were neither expressly nor impliedly preempted. The motion noted that the *Stengel* decision was consistent with decisions of other federal courts of appeal. With respect to the dismissal of the fraud claims for failure to plead with specificity, the motion referred the court to specific allegations in the complaint but also sought leave to amend in light of an October 2012 report of the U.S. Senate Finance Committee on Medtronic's influence on Infuse clinical studies, which provides additional detail that would enable Ms. Caplinger to plead the claims with greater specificity. The district court denied the motion. Appx. 74.

SUMMARY OF ARGUMENT

The district court's preemption analysis reflects a fundamental misreading of the scope of both express preemption under § 360k(a) of the MDA and implied preemption. Section 360k(a) by its plain terms preempts only state laws that impose requirements that are "different from, or in addition to," requirements under the MDA. As the U.S. Supreme Court's decision in *Lohr* makes clear, if no relevant federal requirements are in place, state law is not preempted. The FDA does not approve devices in a general sense; it approves them for specific uses. Here, the FDA has not approved Infuse for use in posterior-approach surgery. Accordingly, the FDA has imposed no requirements on the design, labeling, or promotion of Infuse *for posterior use*. As in *Lohr*, in the absence of federal requirements, § 360k(a) does not preempt Ms. Caplinger's state-law claims.

In addition, both *Lohr* and *Riegel* hold that states may impose requirements that parallel or are identical to requirements imposed under the MDA, and that claims based on conduct that violates state-law duties are thus not preempted if that same conduct violates federal device requirements. Ms. Caplinger's claims that Medtronic's conduct—such as off-label marketing and promotion, failure to disclose adverse events, and misrepresenting the safety of the device for an intended (albeit unapproved) use—caused injury cognizable under state products liability law are exactly the kinds of claims that the Supreme Court has held *not*

preempted by § 360k(a). The state-law duties underlying these claims, for failure to warn, design defect, fraud, and breach of warranty, do not require Medtronic to do anything that federal law does not also require. Thus, they do not fall within § 360k(a)'s prohibition on state laws that impose requirements that differ from or add to applicable federal requirements.

In addition, Ms. Caplinger's claims for misrepresentation in connection with the marketing and promotion of Infuse for off-label use in posterior-approach surgery, breach of warranty, and negligent marketing and promotion are not impliedly preempted under the reasoning of *Buckman*. *Buckman* narrowly held that a particular type of claim—a claim of "fraud on the FDA"—premised solely on a violation of a duty to a federal agency falls outside the scope of a state's traditional power to regulate matters of health and safety. The Supreme Court concluded that such a claim is impliedly preempted because it intrudes on the agency's power to police fraud against it. But *Buckman* recognized that states may make conduct actionable when that conduct violates both a duty to the agency and a duty to the plaintiff that falls within the scope of traditional state-law regulation of matters of health and safety. Ms. Caplinger's claims are not preempted under *Buckman* because they are not premised solely on a breach of a duty owed to the agency, but rather arise from a breach of a traditional state-law duty owed to her—the duty to warn of dangers of a manufacturer's products and to refrain from

misrepresentations concerning them—that coincides with federal reporting requirements and federal restrictions on off-label promotion.

A broader approach to implied preemption here would not only negate the Supreme Court's repeated statements that states may make violations of federal requirements under the MDA actionable, but would also run counter to the presumption against preemption, which strongly counsels against both express and implied preemption of state laws that fall within the scope of the states' traditional police powers. *See Altria Group, Inc. v. Good*, 555 U.S. 70, 77 (2008). Claims that a manufacturer failed to warn of and misrepresented the dangers of a medical device, unlike claims of "fraud on the FDA," are exactly the types of claims as to which the presumption against preemption is the strongest. Preempting such claims would far exceed the scope of congressional intent in enacting the MDA, which, as the Supreme Court has now twice held, was *not* to immunize manufacturers against claims that they injured patients by engaging in conduct that violated state-law duties and standards of care that *parallel* duties imposed by the MDA.

ARGUMENT

I. Standard of Review

"Because the sufficiency of a complaint is a question of law, [this Court] review[s] de novo the district court's grant of a motion to dismiss pursuant to Federal Rule of Civil Procedure 12(b)(6)." *Russell v. United States*, 551 F.3d 1174,

1178 (10th Cir. 2008) (citation omitted). The court accepts as true all well-pleaded facts and construes all reasonable allegations in the light most favorable to the plaintiff. *Id.* The Court "also review[s] de novo the legal question of whether federal law preempts state law." *Col. Dep't of Pub. Health & Env't, Hazardous Materials & Waste Mgmt. Div. v. United States*, 693 F.3d 1214, 1221 (10th Cir. 2012).

"Concerning the failure to plead fraud with particularity under [Federal Rule of Civil Procedure] 9(b), [the Court] also review[s] a dismissal de novo." *U.S. ex rel. Lemmon v. Envirocare of Utah, Inc*., 614 F.3d 1163, 1167 (10th Cir. 2010).

II. Ms. Caplinger's State-Law Claims Are Not Expressly Preempted by § 360k(a).

Section 360k(a) preempts state-law requirements only when they are "different from, or in addition to," federal medical device requirements. The duties underlying Ms. Caplinger's state-law claims do not fall within the scope of § 360k(a). First, Medtronic's Infuse device was subject to no federal requirement regarding use in posterior-approach surgery, as that use was not approved by the FDA. Ms. Caplinger's claims are therefore not preempted to the extent that they stem from injuries caused by Medtronic's off-label promotion of Infuse. Second, § 360k(a) does not preempt state law to the extent that it parallels federal device requirements. Thus, Ms. Caplinger's claims are not preempted for the additional reason that they are based on state-law duties that impose liability for conduct that

also violates federal requirements, such as those addressing off-label marketing and promotion, adverse event reporting, and labeling.

A. The Supreme Court Has Defined the Scope of Express Preemption Under § 360k(a).

By its express terms, the MDA's preemption provision, § 360k(a), preempts only state laws that impose requirements with respect to devices that are "different from, or in addition to," requirements applicable to the same devices under the MDA. The FDA has underscored the plain language of the statute by promulgating a regulation implementing it, which provides that state laws are preempted "only when the Food and Drug Administration has established specific counterpart regulations or there are other specific requirements applicable to a particular device under the act," 21 C.F.R. § 808.1(d), and that even when such specific requirements exist, the MDA "does not preempt State or local requirements that are equal to, or substantially identical to, requirements imposed by or under the act," *id.* § 808.1(d)(2).

The Supreme Court has twice considered the scope of the MDA's preemption provision. First, in *Lohr*, 518 U.S. 470, the Court considered state-law design, labeling, and manufacturing claims concerning a Medtronic device marketed through the FDA's 510(k) process. The Court unanimously held that § 360k(a) did not preempt the Lohrs' design claim, stating that state law is not preempted if no relevant federal requirement is in place. *Id*. at 492-94 (majority

opinion) (design defect claim not preempted where federal law places no design requirements on the device); *id*. at 513 (O'Connor, J., concurring in part) (same).

In addition, the Court unanimously held that § 360k(a) does not preempt state-law actions that seek to enforce duties that parallel requirements imposed under the MDA. Such actions, the Court held, do not impose requirements that are "different from, or in addition to," those imposed by the MDA. *See id.* at 495-97 (majority opinion); *id.* at 513 (O'Connor, J., concurring in part and dissenting in part). As the majority opinion explained, "[n]othing in § 360k denies Florida the right to provide a traditional damages remedy for violations of common-law duties when those duties parallel federal requirements." *Id*. at 496; *see id.* at 513 (O'Connor, J., concurring in part and dissenting in part) ("[T]he Lohrs' claims are not preempted by § 360k to the extent that they seek damages for Medtronic's alleged violation of federal requirements. Where a state cause of action seeks to enforce an FDCA requirement, that claim does not impose a requirement that is 'different from, or in addition to,' requirements under federal law.").

Further, *Lohr* explains that a state may impose liability for a manufacturer's conduct that violates requirements imposed by federal law, even if the showing required to establish liability requires proof of "additional elements of the state-law cause of action," such as that the manufacturer engaged in "negligent conduct" or "created an unreasonable hazard for users of the product." *Id*. at 495. Such

elements "make the state requirements narrower, not broader, than the federal requirement," and are not "additional or different" requirements for purposes of § 360k(a). *Id*.

Second, in *Riegel v. Medtronic, Inc.*, 552 U.S. 312, the Supreme Court considered the scope of § 360k(a) in a case that, like this one, involved a class III Medtronic device marketed under a PMA, rather than the abbreviated 510(k) review at issue in *Lohr*. As in *Lohr*, the Court took a two-step approach to determining whether state-law claims are preempted. First, it looked to whether the FDA had established requirements applicable to the device. *Id*. at 321-22. Second, in light of such requirements, the Court considered whether the state-law duties at issue would impose requirements different from or in addition to the relevant federal requirements. *Id*. at 323.

Riegel concluded that, in contrast to the 510(k) process, the PMA process establishes requirements that are "specific to individual devices." *Id*. Under § 360k(a), therefore, state-law requirements that are different or in addition to those device-specific PMA requirements are preempted. *Id*. At the same time, *Riegel* reiterated *Lohr*'s unanimous holding that § 360k(a) does not preempt state-law claims that parallel federal requirements: "§ 360k(a) does not prevent a State from providing a damages remedy for claims premised on a violation of FDA regulations; the state duties in such a case 'parallel,' rather than add to, federal

requirements." *Id*. at 330 (citing *Lohr*). Put differently, states can impose liability on medical device manufacturers for violation of state-law duties that parallel federal requirements, but they cannot impose liability "notwithstanding compliance with relevant federal requirements." *Id.*

Together, the Supreme Court's decisions in *Lohr* and *Riegel* establish unequivocally that § 360k(a) does not preempt state-law claims in the absence of a relevant federal device requirement and that § 360k(a) does not preempt state-law claims premised on the breach of state-law duties of care that incorporate or parallel federal regulatory requirements. Such state-law duties, by definition, do not contain specific requirements that are "different from, or in addition to," federal requirements.

B. In the Absence of an Applicable Federal Requirement, § 360k(a) Does Not Preempt State Law.

1. Because the FDA Has Imposed No Requirements on Posterior-Approach Use of Infuse, Claims Arising from Marketing and Promotion for That Off-Label Use Are Not Preempted.

a. This case involves claims based on a specific use of the Infuse device: its use for posterior spinal fusion surgery. The FDA has never approved the device for that use and hence has never imposed requirements on the design and labeling of the device for that use. In the absence of device-specific requirements applicable to the use at issue, state-law claims challenging, with respect to the device as

marketed for *that use*, the device's design, the adequacy of Medtronic's warnings concerning the device, and the truthfulness of Medtronic's representations about the device do not impose requirements that are different from or in addition to requirements of federal law within the meaning of § 360k(a).

As explained above, in both *Lohr* and *Riegel*, the Supreme Court held that the touchstone for preemption under § 360k(a) is the existence of requirements specifically applicable to a device, which preempt state requirements that impose different or additional requirements with respect to the subject-matter covered by the federal requirements. *See Riegel*, 552 U.S. at 322-23; *Lohr*, 518 U.S. at 493-94, 498-502. In *Lohr*, the Court emphasized that preemption under § 360k(a) turns on the existence of *specific* federal and state requirements on the same subject matter and noted that "it is impossible to ignore [the statute's] overarching concern that pre-emption occur only where a particular state requirement threatens to interfere with a specific federal interest." 518 U.S. at 500; *id.* at 492-94 (state-law design defect claims not preempted because 510(k) clearance process did not result in imposition by the FDA of specific requirements applicable to device design).

In *Riegel*, the Court reiterated that preemption under § 360k(a) requires specific federal requirements applicable to the device, which then operate to preempt different or additional state-law requirements addressing the same subjects. *See* 552 U.S. at 322-23. Thus, the Court held that state-law design defect

and failure-to-warn claims are preempted *to the extent* that they would impose requirements different from or in addition to the specific design and labeling requirements imposed by federal law on PMA devices and address the same subject-matter as those requirements. *See id.* at 325. The Court's analysis in *Riegel* rests heavily on the notion that the adequacy of the design and labeling of devices for approved uses are matters specifically reviewed and approved by the FDA in the PMA process. *Id*. at 318, 323.

When a manufacturer markets a device for an unapproved use, however, it acts outside the scope of the FDA's device-specific design and labeling requirements, for, as to that use, the FDA has not reviewed and approved the safety and effectiveness of the device and the adequacy of the warnings and instructions for use contained in its labeling. Indeed, the MDA specifically provides that, for purposes of PMA, the FDA evaluates only the particular uses described in the manufacturer's proposed labeling for the device: "[T]he safety and effectiveness of a device are to be determined—(A) with respect to the persons for whose *use the device is represented or intended*; (B) with respect to the *conditions of use* prescribed, recommended, or suggested in the labeling of the device; and (C) weighing any probable benefit to health from the *use of the device* against any probable risk of injury or illness *from such use*." 21 U.S.C. § 360c(a)(2) (emphasis added). The FDA's decision to grant or withhold PMA depends on whether it finds

a reasonable assurance of safety and effectiveness "*under the conditions of use prescribed, recommended, or suggested in the proposed labeling thereof*," *id.* § 360e(d)(2) (emphasis added), and approval authorizes the manufacturer to market the device only for that use.

Here, while PMA for the Infuse device imposes specific design and labeling requirements that Medtronic must meet when marketing Infuse for its *approved* use in anterior spinal surgery, the PMA imposes no design or labeling requirements on Infuse as a device *intended by Medtronic for use in posterior spinal surgery*. The FDA's PMA for *other* uses of Infuse does not require that a device intended for use in posterior spinal surgery "take any particular form for any particular reason," *Lohr*, 518 U.S. at 493, nor does the PMA specify labeling requirements for a device marketed for that unapproved use. When it granted PMA, the FDA neither considered nor approved the safety and effectiveness of Infuse's design for posterior surgery or the adequacy of the device's labeling for that use. The PMA decision thus established no requirements applicable to the Infuse device intended by Medtronic for posterior-approach spinal fusion. Under the reasoning of *Lohr* and *Riegel*, therefore, there are no specifically applicable federal requirements that preempt state requirements applicable to the design or labeling of the device to the extent it is intended for use in, and marketed for use in, posterior spinal surgery.

b. The district court stated that, "under § 360k(a)(1), the question is not whether there are federal requirements applicable to a particular *use* of a device; the question is whether there are federal requirements applicable 'to the *device*.'" Appx. 58-59 (quoting *Riley v. Cordis Corp.*, 625 F. Supp. 2d 769, 779 (D. Minn. 2009)). But the court (and the opinion in *Riley*) overlooked that, under the MDA, the question whether a federal requirement is, in the words of § 360k(a), "applicable under this chapter to [a] device" necessarily depends on the use for which the device is intended. The Infuse device's PMA unquestionably provides design and labeling requirements that are "applicable to the device" *when it is manufactured and marketed for the uses specified in its labeling*. But the PMA does not impose design or labeling requirements that are "applicable" to Infuse when Medtronic markets the device for an unapproved use. Absent any such *applicable* requirement, the fact that the device may be subject to other *inapplicable* requirements is irrelevant.

The district court's contrary conclusion would distort the evident purposes of § 360k(a) as described in both *Lohr* and *Riegel*: protecting the FDA's determinations of a device's safety and effectiveness, incorporated in specific requirements imposed in the PMA process, from second-guessing by state laws. *See Riegel*, 552 U.S. at 325; *Lohr*, 518 U.S. at 500. When a manufacturer markets a device for an unapproved use, no such FDA determinations are implicated

because the FDA has not assessed the safety and effectiveness of the device for that use and has not imposed federal design and labeling requirements to ensure the adequacy of the device for that use. Extending preemption under § 360k(a) to claims against manufacturers who market devices for unapproved uses would grant them a windfall: protection from state-law liability for engaging in conduct that is not only unauthorized by federal law, but actually prohibited.

2. Claims Arising from the Statements of Medtronic's Representative at Ms. Caplinger's Surgery Are Not Preempted.

Ms. Caplinger's negligence and constructive fraud claims are not preempted by § 360k(a) for the additional reason that the FDA has issued no requirements applicable to the interactions of Medtronic's representatives with physicians in the operating room. Ms. Caplinger has alleged that a Medtronic representative attended Ms. Caplinger's surgery for the purpose of providing information regarding use of Infuse for posterior-approach lumbar spine fusion, and that, through its representative, Medtronic breached its duty to Ms. Caplinger by failing to disclose the significant danger presented by that unapproved use of Infuse. Appx. 17, ¶ 66; 25-26, ¶¶ 104-11; 31, ¶135.

> The FDA does not regulate interactions between corporate representatives and physicians on-site at a particular surgery, and where it does not mandate special physician training for a [device], it does not specify how such an interaction at surgery must be performed. These localized situations are traditional matters for the common law, not the FDA's regulatory approval process. Such a claim does not challenge the

> design, manufacture, and labeling of the [] device so as to implicate Riegel preemption, but rather challenges negligence by a corporate agent acting as a de facto physician's assistant during a surgical procedure.

Adkins v. Cytyc Corp., 2008 WL 2680474, at *2-*3 (W.D. Va. 2008). Accordingly, Ms. Caplinger's claims arising from the omissions and misrepresentations of Medtronic's representative at Ms. Caplinger's surgery are not preempted by § 360k(a).

C. Ms. Caplinger's State-Law Claims Are Not Preempted to the Extent That They Are Based on State-Law Duties That Parallel Federal Requirements Under the MDA.

1. The district court held that § 360k(a) expressly preempts Ms. Caplinger's failure to warn, design defect, negligence, and negligent misrepresentation claims, and, in part, her fraud claims. The decision is wrong, however, not only because of the absence of applicable federal requirements, but because it cannot be squared with the Supreme Court's repeated recognition that § 360k(a)'s preemption of state requirements that are "different from, or in addition to," federal requirements does not extend to claims that seek to enforce state-law duties that are "equal to, or substantially identical to," or "parallel" to federal requirements. *Lohr*, 518 U.S. at 496-97. The archetype of such a non-preempted claim is one "premised on the violation of FDA regulations." *Riegel*, 552 U.S. at 330.[8]

[8] The district court's discussion of the breach of warranty claim is not clear as to whether the court believed the claim to be both expressly and impliedly

Ms. Caplinger's claims fall precisely into that category. They do not seek to impose liability on Medtronic for anything approved by the FDA in the PMA process (such as the design or labeling of the device for anterior use), and thus they neither seek a finding that anything "the FDA required and approved through the PMA process [was] inadequate under state law" nor "require[] a showing that the FDA requirements themselves were deficient." *Gomez v. St. Jude Med. Daig Div.*, 442 F.3d 919, 931, 933 (5th Cir. 2006). Moreover, Ms. Caplinger's claims are not premised on the theory that Medtronic owed her a duty that required something *more* than compliance with the FDA's requirements and restrictions regarding adverse event reporting, off-label marketing, and misbranding.

Rather, Ms. Caplinger claims that exactly the same conduct that violated federal device requirements violated Medtronic's state-law duties. On the most

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preempted or only impliedly preempted. The court stated that the claim was preempted because it is premised on the notion that Infuse was safe and effective for off-label use and such a finding "would be contrary to the FDA's approval." Appx. 65-66. Because the FDA approval was not based on off-label use (indeed, off-label uses are by definition uses that have not been FDA-approved), this reasoning, whether intended to convey express or implied preemption, is untenable, and the court's holding on this point is incorrect. Moreover, breach of express warranty claims are not expressly preempted because they are not based on "requirements" imposed under state law but on duties voluntarily undertaken by a manufacturer. *Bates v. Dow AgroSciences*, 544 U.S. 431, 444-45 (2005); *Cipollone v. Liggett Group, Inc*., 505 U.S. 504, 525 (1992). And because the product was marketed for an unapproved use, the breach of implied warranty claim is not expressly preempted because the state-law duties parallel federal requirements, as discussed *infra* at pp. 32-37.

fundamental level, Ms. Caplinger's strict products liability and negligence claims, based on allegations that the Infuse device was defective because it was not reasonably safe for the use for which it was marketed in this case and that Medtronic failed to provide sufficient warnings of the risks entailed in that use, parallel the basic requirements of the MDA: A device may not be marketed for a particular use unless the manufacturer has shown it to be safe and effective for that use, has provided a label that contains adequate warnings for that use, and has obtained PMA from the FDA to market the device for that use. 21 U.S.C. §§ 360e(a), 360e(d)(1)(A), 360e(d)(2)(A)-(B). Absent those conditions, federal law does not permit the promotion or marketing of the device for the use at issue.

As applied to a device that has been promoted and marketed for an unapproved use, state law claims asserting that the device's design was defective or its warnings inadequate for that unapproved use are based on duties that parallel those federal requirements.[9] Such claims do not seek to impose liability for any

[9] Under Missouri law, "[t]he elements of a cause of action for strict liability failure to warn are: (1) the defendant sold the product in question in the course of its business; (2) the product was unreasonably dangerous at the time of sale when used as reasonably anticipated without knowledge of its characteristics; (3) the defendant did not give adequate warning of the danger; (4) the product was used in a reasonably anticipated manner; and (5) the plaintiff was damaged as a direct result of the product being sold without an adequate warning." *Moore v. Ford Motor Co*., 332 S.W.3d 749, 756 (Mo. 2011).

conduct *permitted* by federal law, but instead for conduct that *violates* federal requirements that a device not be marketed or promoted for a use as to which it has not been found to be safe and effective under the conditions of use described in its approved labeling. *See also* Appx. 83 (FDA approval letter stating that "[f]ailure to comply with the conditions of approval invalidates this approval order"). As the Supreme Court has twice made clear, § 360k(a) does not bar states from providing remedies for conduct constituting "a violation of FDA regulations." *Riegel*, 552 U.S. at 330; *Lohr*, 518 U.S. at 495 (majority opinion); *id*. at 513 (O'Connor, J., concurring in part); *see also Bausch v. Stryker Corp*., 630 F.3d 546, 546 (7th Cir. 2010) (explaining that manufacturers of PMA devices "are protected by federal law from civil liability so long as they comply with federal law," but "[t]hat

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"The elements of a claim for failure to warn based in negligence are: (1) the defendant designed the product at issue; (2) the product did not contain an adequate warning of the alleged defect or hazard; (3) the defendant failed to use ordinary care to warn of the risk of harm from the alleged defect or hazard; and (4) as a direct result of the defendant's failure to adequately warn, the plaintiff sustained damage." *Id*. at 764.

In contrast to failure to warn, "design defect theories address the situation in which a design is itself inadequate, rendering the product unreasonably dangerous without regard to whether a warning is given—such as a lawn mower designed without a guard or deflector plate." *Id.* at 757.

protection does not apply where the patient can prove that she was hurt by the manufacturer's violation of federal law").[10]

Ms. Caplinger's failure to warn claim parallels the applicable federal requirements in other ways as well. Ms. Caplinger alleges that Medtronic failed to provide adequate warnings to her and her physician by, among other things, minimizing the risks of Infuse for posterior-approach spinal fusion, failing to submit required reports of data from clinical investigations, and marketing and promoting a device without adequate directions for its intended use (that is, the unapproved use in posterior-approach surgery). Appx. 31-32, ¶¶ 114-19. The acts and omissions that violated the state-law duty to warn also violated requirements imposed on Med-tronic by the FDA as a condition of the device's PMA for another

[10] The duties imposed by state product liability law as applied to a device marketed for an unapproved use are actually narrower than those imposed by federal law: Federal law flatly prohibits marketing or promoting a device for an unapproved use, while state law imposes liability only if the plaintiff proves that the product was in fact defectively designed for that use, that the warnings provided with respect to the risks of that use were in fact inadequate, and/or that the manufacturer was negligent with respect to the device's design or warnings for that use. *Lohr* makes clear that a state-law claim requiring the plaintiff to prove that a device marketed in violation of federal law "created an unreasonable hazard for users of the product" or that its design or labeling was "the result of negligent conduct" is not preempted under § 360k(a). 518 U.S. at 495. As the Court explained, the existence of "elements of the state-law cause of action [that] make the state requirements narrower, not broader, than the federal requirement" would "surely provide a strange reason for finding pre-emption" of a state-law products liability claim. *Id.*

use (anterior-approach surgery), including the prohibition against misbranding. *See* 21 U.S.C. §§ 331, 351(f), 352; 21 C.F.R. §§ 801.5 (labeling must contain adequate directions for intended use), 803.50 (requiring adverse event reporting), 814.80 (prohibiting manufacturing, distributing, or advertising in a manner inconsistent with the conditions of PMA), 814.84 (requiring submission of periodic reports of data from clinical investigations); *see also* Appx. 84-86 (FDA Conditions of Approval).

Moreover, although the FDA allows a manufacturer to distribute some information about off-label uses without running afoul of the prohibition against off-label promotion, a manufacturer may do so only if it discloses "all significant risks or safety concerns known to [it] concerning the unapproved use." FDA, Guidance for Industry, *supra* page 8. A manufacturer distributing journal articles concerning an unapproved use must also disclose "any author known to the manufacturer as having a financial interest in the product or manufacturer or who is receiving compensation from the manufacturer, along with the affiliation of the author, to the extent known by the manufacturer, and the nature and amount of any such financial interest of the author or compensation received by the author from the manufacturer." *Id*. If the manufacturer fails to disclose the risks of the author's financial interest, the device is misbranded. *Id*. The duty underlying Ms. Caplinger's failure-to-warn claim is parallel in this way as well, because without

those disclosures, Infuse both was misbranded under federal law and failed to satisfy the duty to warn under state law. *See Cornett v. Johnson & Johnson*, 48 A.3d 1041, 1057 (N.J. 2012) ("To the extent, however, plaintiffs' failure to warn claim is founded on promotion by defendants of off-label uses of the device beyond the safe harbor, the claim is not preempted.").

Likewise, Ms. Caplinger's fraud claims, which are premised on misrepresentations about the safety and effectiveness of the unapproved use, rely on state-law duties that parallel these federal requirements. Appx. 26-30, ¶¶ 92-111.[11] As in the case of the failure-to-warn claim, the misrepresentations that form

[11] The elements of a claim for fraudulent misrepresentation are: (1) a representation; (2) its falsity; (3) its materiality; (4) the speaker's knowledge of its falsity; (5) the speaker's intent that it should be acted on by the person and in the manner reasonably contemplated; (6) the hearer's ignorance of the falsity of the representation; (7) the hearer's reliance on the representation being true; (8) his right to rely thereon; and, (9) the hearer's consequent and proximately caused injury. *Droz v. Trump*, 965 S.W.2d 436, 441 (Mo. Ct. App. 1998).

The elements of constructive fraud are the same, except for the fourth element, as "it is not necessary for the plaintiff to plead and prove that the defendant had knowledge of the falsity of his or her representation, but only that he or she was ignorant of its truth." *Id*.

The elements of a claim for negligent misrepresentation are "(1) the speaker supplied information in the course of his business; (2) because of the speaker's failure to exercise reasonable care, the information was false; (3) the information was intentionally provided by the speaker for the guidance of limited persons in a particular business transaction; (4) the hearer justifiably relied on the information; and (5) due to the hearer's reliance on the information, the hearer suffered a pecuniary loss." *Coverdell v. Countrywide Home Loans, Inc*., 375 S.W.3d 874, 884 (Mo. Ct. App. 2012).

the basis for the fraud claims also violate requirements imposed on Medtronic by the FDA as a condition of the device's PMA for anterior-approach surgery: the prohibition against marketing a device with labeling that is "false and misleading in any particular," 21 U.S.C. § 352 (defining misbranding), the requirement that Medtronic report adverse events, 21 C.F.R. § 803.50, and the prohibition against manufacturing, distributing, or advertising in a manner inconsistent with the conditions of PMA, *id*. § 814.80. *See also* FDA, Guidance for Industry, *supra* page 8 (stating that journal reprints of articles concerning off-label uses may be distributed to physicians if accompanied by a "permanently affixed statement disclosing . . . all significant risks or safety concerns").

To be sure, the Infuse labeling was FDA approved. It was approved, however, for marketing of the device for anterior-approach surgery—not for posterior-approach surgery. *See* Appx. 75, 80 (FDA database listing, approval letter). To the extent that Medtronic misrepresented the approval status of Infuse for posterior-approach surgery, concealed safety concerns, failed to submit adverse event reports, and violated other FDA requirements for disclosure of risks and prohibitions against off-label promotion and against misbranding, *see id*. 12-20, ¶ 35-63; 39, ¶ 155, it violated both federal and state-law duties. Because the duties and standards of care that Ms. Caplinger's claims posit demand no more than that Medtronic do what federal law already requires, the claims "simply parallel[] or

enforce[] the federal regulatory requirements without 'threatening' or interfering with them." *Gomez*, 442 F.3d at 932 (quoting *Lohr*, 518 U.S. at 495). Accordingly, they are not preempted by § 360k(a).

2. A finding of no preemption here is consistent with the decisions of each of the other federal courts of appeals to consider preemption under § 360k(a) since *Riegel*. Those courts have held that § 360k(a) does not preempt a state-law duty to warn that parallels the manufacturer's federal duty to monitor PMA products on the market and to report adverse events to the FDA. *See Stengel*, 704 F.3d 1224 (9th Cir.); *Hughes v. Boston Scientific Corp*., 631 F.3d 672, 770-71 (5th Cir. 2011) (no preemption of state-law duty to warn that parallels FDA medical device reporting regulations); *see also Bass v. Stryker Corp*., 669 F.3d 501, 510 (5th Cir. 2012) (no preemption of state-law duty that parallels FDA good manufacturing practices regulations); *Bausch*, 630 F.3d at 555 (7th Cir.) (same); *Howard v. Sulzer Orthopedics, Inc*., 382 Fed. App'x 436, 441 (6th Cir. 2010) (same).

In the cases where courts of appeals have held state-law claims concerning PMA devices to be preempted, the plaintiffs failed to "set forth any specific problem or failure to comply with any FDA regulation that [could] be linked to the injury alleged." *Wolicki-Gables v. Arrow, Int'l, Inc*., 634 F.3d 1296, 1301-02 (11th Cir. 2011). For example, in *In re Medtronic, Inc., Sprint Fidelis Leads Products Liability Litigation*, 623 F.3d 1200 (8th Cir. 2010), the Eighth Circuit explained

that the plaintiffs alleged that all of the devices at issue were defectively manufactured because Medtronic used a process called spot welding, but they "conceded" that the PMA authorized spot welding. *Id*. at 1207. On those facts, the court held that "*as pleaded and argued*, the manufacturing defect claims are not parallel, they are a frontal assault on the FDA's decision" to approve the product and authorize use of spot welding. *Id*.; *see Stengel*, 704 F.3d at 1232 ("At no point did [*In re Medtronic*] address a state-law claim based on a state-law duty that paralleled a federal-law duty. . . ."). Similarly, in *Walker v. Medtronic, Inc.*, 670 F.3d 569 (4th Cir. 2012), the court held that the plaintiff had failed to allege a state-law duty that paralleled a federal requirement on the specific facts of the case. Because the plaintiff's argument, the court explained, would require that the device "never deviate from its programmed flow rate by more than plus or minus 15 percent, and the terms of the device's premarket approval do not contemplate this result, she is actually contending that the device should have been designed differently." *Id*. at 580. Notably, unlike this case, the device at issue in *Walker* "was undisputedly designed, manufactured, and distributed in compliance with its FDA premarket approval." *Id*. at 581.

"Section 360k(a) provides immunity for manufacturers of new Class III medical devices to the extent that they *comply* with federal law, but it does not protect them if they have *violated* federal law." *Bausch*, 630 F.3d at 553 (emphasis

added). Accordingly, here, where Medtronic's violations of state-law duties also constitute violations of federal law, § 360k(a) does not preempt Ms. Caplinger's claims.

3. Ms. Caplinger's complaint alleged various ways that Medtronic had violated federal requirements, listing a number of specific statutory and regulatory provisions. Appx. 39, ¶ 155. This list is more than sufficient to adequately plead parallel claims. In fact, the Supreme Court's decisions make clear that, to avoid preemption, a plaintiff does not need to plead in her complaint the federal requirements that her claims parallel. In *Lohr*, where the Court unanimously held that the failure-to-warn claims were not preempted to the extent that they paralleled FDA requirements, 518 U.S. at 495 (majority opinion); *id*. at 513 (O'Connor, J., concurring in part and dissenting in part), the complaint did not itself plead that the state-law duties paralleled federal duties, *id*. at 495 ("Although the precise contours of their theory of recovery have not yet been defined (the pre-emption issue was decided on the basis of the pleadings), it is clear that the Lohrs' allegations may include claims that Medtronic has, to the extent that they exist, violated FDA regulations.").

Likewise, in *Bates*, 544 U.S. 431, which concerned the "similarly worded" preemption provision of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), the plaintiff argued before the Supreme Court that the state-law duties he

invoked paralleled the generally applicable statutory requirements "that a pesticide label not contain 'false or misleading' statements, or inadequate instructions or warnings." *Id*. at 447 (citation omitted). Again, there is nothing in the opinion to suggest that the *complaint* pleaded that the claims paralleled federal law. Again, the Court held, unanimously, that state-law requirements that parallel federal labeling requirements are not preempted by the provision. *Id*. at 447 (majority opinion); *id*. at 456 (Thomas, J., concurring in part and dissenting in part). The Court remanded for consideration of whether the common-law duties were "equivalent to FIFRA's misbranding standards." *Id*. at 447.

Here, Ms. Caplinger has specified statutory and regulatory provisions that establish requirements that parallel the state-law duties on which her claims are based. *See* Appx. 39, ¶ 155. The complaint thus provides greater detail about the parallel nature of the claims than in *Lohr* and *Bates*. Moreover, even if further specificity were required, the complaint here, unlike in *Wolicki-Gables*, sets forth both specific facts and failures to comply with regulations "that can be linked to the injury alleged." 634 F.3d at 1301-02. The district court's dismissal of the claims on the basis of express preemption should therefore be reversed.

III. Ms. Caplinger's Claims for Fraud, Breach of Warranty, and Negligence Are Not Impliedly Preempted.

A. The Court Erred in Holding that the Fraud and Negligence Claims Are Impliedly Preempted, in Part, Under *Buckman v. Plaintiffs' Legal Committee.*

The district court also erred in holding that two of Ms. Caplinger's claims—for fraudulent misrepresentation and negligence insofar as those claims are based on off-label promotion—are impliedly preempted under the Supreme Court's decision in *Buckman*. *Buckman* sets forth a narrow implied preemption rationale applicable to claims of "fraud on the FDA." *See* 531 U.S. at 348. That rationale is inapplicable here because Ms. Caplinger did not make such a claim, and her claims do not pose the concerns of conflict with federal policy that *Buckman* identified with regard to a "fraud-on-the-agency" claim. Indeed, Ms. Caplinger's claims are wholly unlike the claim that the Supreme Court held to be impliedly preempted in *Buckman*.

1. In *Buckman*, the plaintiffs claimed that the defendant had violated a duty to the FDA by committing a fraud on the agency. Specifically, the plaintiffs alleged that the defendant "made fraudulent representations to the Food and Drug Administration … in the course of obtaining approval to market" the product and that "[h]ad the representations not been made, the FDA would not have approved the devices, and plaintiffs would not have been injured." *Id*. at 343. The Court's

opinion repeatedly characterizes the claim before it as a "fraud-on-the-FDA" or "fraud-on-the-agency" claim. *Id*. at 347, 348, 350, 351, 352.

As described by the Court, the critical failure of the *Buckman* "fraud-on-the-FDA" claim was that the claim was not based on anything resembling "traditional state tort law principles of the duty of care owed by" the defendant to the plaintiff, *id*. at 352, but rested entirely on alleged duties arising from "the relationship between a federal agency and the entity it regulates," *id*. at 347. Thus, the sole interest that the claim sought to advance was to "punish and deter fraud against the [FDA]." *Id*. at 348. That objective, the Court stressed, was one in which the states had no independent interest, and it was also one already fully served by the "federal statutory scheme[, which] amply empowers the FDA to punish and deter fraud." *Id*. Allowing state law to "[p]olic[e] fraud against federal agencies," *id*. at 347, would interfere with the federal statutory scheme by "skew[ing]" the "balance sought by the [FDA]" in enforcing prohibitions on fraud in the PMA process, *id*. at 348. Thus, "[s]tate-law fraud-on-the-FDA claims inevitably conflict with the FDA's responsibility to police fraud consistently with the Administration's judgment and objectives." *Id*. at 350.

Here, by contrast, the essence of Ms. Caplinger's claims is not that Medtronic breached duties *to the FDA*, but that it breached duties *to her*—such as the duty to use ordinary care to warn of the product's risks and the duty not to

conceal information known to Medtronic about the problems associated with off-label posterior-approach use. Appx. 27, ¶ 94; 36, ¶ 139. Although the same Medtronic conduct that violated duties owed to Ms. Caplinger under state law also violated requirements imposed under federal law, the federal requirements are relevant only to show that the state-law duties impose no different or additional obligations, and thus are not preempted under § 360k(a). The federal requirements are not elements of the state-law causes of action, which rest on "traditional state tort law principles." 531 U.S. at 352; *see also supra* n.9 (defining negligent failure to warn under state law). As the Court stressed in *Buckman*, where an alleged breach of duty does not arise "solely by virtue of [federal] disclosure requirements," a plaintiff may maintain a "state-law caus[e] of action that parallel[s] federal safety requirements." 531 U.S. at 353.

Ms. Caplinger's claims also differ from the *Buckman* fraud-on-the-FDA claim in another important respect: They do not require any hypothetical consideration about what regulatory action the agency would have taken if the agency had not been "defrauded." Members of the Court in *Buckman* expressed concern about the possibility that fraud-on-the-agency claims would require "speculation as to the FDA's behavior in a counterfactual situation" and interfere with federal policy by "second-guessing the FDA's decisionmaking." *Id*. at 354 (Stevens, J., concurring in the judgment). But unlike the claim in *Buckman*, Ms.

Caplinger's claims based on Medtronic's violation of FDA reporting requirements, restriction on off-label promotion, and prohibition against misbranding do not rest on the theory that Medtronic fraudulently obtained premarket approval by concealing information from the FDA. In fact, they do not challenge in any way the PMA that approved Infuse for use in anterior-approach surgery. They therefore do not require a court to explore the issue of reliance by the FDA, to reconstruct what the agency would have done if it had not been misled, or to second-guess the agency's regulatory action or reaction in any way.

2. A finding that *Buckman* is inapplicable here is consistent with the reasoning of the federal courts of appeals. The Fifth Circuit in *Hughes*, the Seventh Circuit in *Bausch*, and the Ninth Circuit in *Stengel* held that parallel claims, not expressly preempted by the MDA, are also not impliedly preempted under *Buckman*. *Hughes*, 631 F.3d at 775; *Bausch*, 630 F.3d at 556-58; *Stengel*, 704 F.3d at 1233. Those courts understood that where a plaintiff pleads a state-law tort claim that is based on the defendant's violation of *state-law* duties owed to the plaintiff, *Buckman* does not apply. Particularly where the state-law duties parallel federal requirements, such claims in "no way" "conflict with the federal regulations," and thus there is no basis "for them to be impliedly preempted." *Bausch*, 630 F.3d at 557. Likewise, the Sixth Circuit recently held that where the alleged breach of a state-law duty arises from the same act as a violation of federal law, "[t]his is

simply not grounds for preemption" under *Buckman*. *Fulgenzi v. PLIVA, Inc*., 711 F.3d 578, 587 (6th Cir. 2013).[12] And the Second Circuit in *Desiano v. Warner-Lambert & Co.*, 467 F.3d 85 (2d Cir. 2007), *aff'd by an equally divided Court sub nom. Warner-Lambert Co. v. Kent*, 552 U.S. 440 (2008), held that *Buckman* is limited to cases where the plaintiff pursues a fraud-on-the-agency claim and does not extend to "claims that sound in traditional state tort law." *Id*. at 94. The Second Circuit explained that traditional tort claims differ fundamentally from the claim in *Buckman* because the underlying source of the duty enforced by traditional state law is a duty owed by the defendant to the plaintiff, not a duty grounded in the relationship between a federal agency and a regulated entity. *Id*.

[12] *Fulgenzi* involves a drug, but its reasoning concerning *Buckman* applies equally to a case involving a device. *Buckman* generally applies to both drugs and medical devices because the decision does not turn on any differences in the regulatory schemes. *See, e.g., Lofton v. McNeil Consumer & Specialty Pharm.*, 672 F.3d 372, 379-80 (5th Cir. 2012); *Lefaivre v. KV Pharm. Co*., 636 F.3d 935, 943 (8th Cir. 2011).

In another Sixth Circuit case, *Cupek v. Medtronic, Inc*., 405 F.3d 421 (6th Cir. 2005), decided before *Riegel* and *Bates*, the court affirmed a district court decision to deny leave to amend a negligence-per-se claim, where the plaintiff's theory was that "Medtronic's alleged failure to comply with 21 C.F.R. § 814.84 invalidated the FDA's approval of [the device]." District Court Order, Case No. C-1-97-105 (S.D. Ohio Dec. 10, 2001). The Sixth Circuit agreed with the district court that this claim was a "disguised fraud on the FDA claim," impliedly preempted under *Buckman*. *Cupek*, 405 F.3d at 424. The district court here, however, did not suggest either of the claims dismissed under *Buckman* could be characterized as "fraud-on-the FDA" claims.

As in these cases, Ms. Caplinger's state-law claims that Medtronic's actions not only violated federal regulations but also breached duties owed to her (as opposed to duties to the FDA) differ from a fraud-on-the-agency theory in that, under the latter theory, "proof of fraud against the FDA is *alone sufficient* to impose liability." *Id.* Here, Medtronic's conduct constitutes wrongdoing *toward Ms. Caplinger*. Accordingly, as in *Hughes*, *Bausch*, and *Stengel*, Ms. Caplinger's claims are not impliedly preempted.

3. Reading *Buckman* broadly to preempt Ms. Caplinger's claims would not only undermine the holdings in *Riegel* and *Lohr* that states may offer remedies for violations of state-law duties that parallel federal-law requirements, it would also run afoul of the presumption against preemption—the principle that the "historic police powers of the States [are] not to be superseded by the Federal Act unless that was the clear and manifest purpose of Congress." *Lohr*, 518 U.S. at 485 (citation omitted). As the case law shows, the presumption against preemption applies both to assertions of express and implied preemption. *See Wyeth v. Levine*, 555 U.S. 555, 565 (2009) (implied preemption); *Altria Group*, 555 U.S. at 77 (express and implied preemption). The presumption "applies with particular force when Congress has legislated in a field traditionally occupied by the States." *Altria Group*, 555 U.S. at 77. And when states provide remedies for patients injured by medical products, they are operating in just such a field—the "regulation of health

and safety." *Wyeth*, 555 U.S. at 565 n.3. Moreover, providing remedies for patients injured by medical devices falls within the traditional authority of the states over matters of health and safety, and the presumption is thus fully applicable to assertions that such remedies are preempted. *See id*. at 565 (citing *Lohr*, 518 U.S. at 485); *Altria*, 555 U.S. at 77 (same).

Properly confined to "fraud-on-the-agency" claims or other claims that are similarly premised solely on the alleged violation of a duty owed by the defendant to a federal agency under federal law, *Buckman* does not conflict with the presumption against preemption because "[p]olicing fraud against federal agencies is hardly 'a field which the States have traditionally occupied,' *Rice v. Santa Fe Elevator Corp.*, 331 U.S. 218, 230 (1947), such as to warrant a presumption against finding federal pre-emption of a state-law cause of action." *Buckman*, 531 U.S. at 347. While *Buckman*'s reasoning forecloses application of the presumption against preemption to claims that serve only to police obligations owed to the federal government, it does not weaken the presumption as applied to "traditional state tort law" claims, *id*. at 353—that is, claims that rest on the enforcement of duties of care that a manufacturer owes to users of its products. Thus, *Buckman*'s holding that the presumption did not apply rested on the fact that "that case involved state-law fraud-on-the-agency claims, and the Court distinguished state

regulation of health and safety as matters to which the presumption does apply." *Wyeth*, 129 S. Ct. at 1195 n.3.

Given the applicability of the presumption against preemption, this Court, in construing both § 360k(a) and *Buckman*, has a "duty to accept the reading disfavoring preemption." *Bates*, 544 U.S. at 449. Preemption is appropriate only if congressional intent to displace traditional state tort remedies is "clear and manifest." *Id.* (citations omitted). Neither § 360k(a), which on its face preempts only state laws that add to or differ from specific requirements imposed by federal law on devices, nor *Buckman*, which calls for preemption only of actions that interfere with federal policy by imposing liability solely on account of breaches of duties owed only to the federal government, reveals a manifest congressional intent to preempt state-law claims, like Ms. Caplinger's, that parallel federal requirements. Indeed, far from conflicting with federal policy, such claims "would seem to aid, rather than hinder, the functioning" of federal law. *Bates*, 544 U.S. at 451.

B. The Breach of Warranty Claim Is Not Impliedly Preempted.

Ms. Caplinger also asserted a claim for breach of express and implied warranty, alleging that Medtronic warranted that off-label "use[] in posterior procedures was safe and effective." Appx. 34, ¶ 129. The district court again found preemption, stating that the claim "interferes with the FDA's regulation of Class III

medical devices" because, to succeed on her claim, "plaintiff must persuade a jury that the Infuse Device was not safe and effective, a finding that would be contrary to the FDA's approval." *Id*. 65. The district court was wrong.

To begin with, the court was wrong that a finding that Infuse is safe and effective for the use to which it was put in Ms. Caplinger's surgery would be contrary to the FDA's approval, because the *FDA has never approved Infuse for posterior use*. A finding that Medtronic breached its own warranty obligations to provide a product safe and effective for that use thus would not in any way contradict the FDA's finding that Infuse is safe and effective for the use specified in its label. *See Cornett*, 48 A.3d at 1059 ("[T]o the extent plaintiffs allege defendants have deviated from the labeling and instructions for use through voluntary statements to third parties in the course of its marketing efforts, this [breach of warranty] claim is not preempted.").

Moreover, the FDA itself disagrees that warranty claims interfere with its regulation of medical devices. First, in the FDA letter informing Medtronic that Infuse was approved for anterior use, the FDA stated that it "does not evaluate information related to contract liability warranties, however you should be aware that any such warranty statements must be truthful, accurate, and not misleading, and must be consistent with applicable Federal and State laws." Appx. 82. This statement shows not only that the FDA was unconcerned that state laws enforcing

warranties would interfere with its regulation of the device, but that it encouraged compliance with them. Second, an FDA regulation addressing the scope of preemption lists as a type of state-law requirement that is *not* preempted requirements under the Uniform Commercial Code, such as "warranty of fitness." *See* 21 C.F.R. § 808.1(d)(1). The district court dismissed the regulation, noting that in *Riegel* the Court rejected reliance on it. Appx. 66. In *Riegel*, however, the issue was the meaning of the statutory language of § 360k(a). Here, the court was considering whether the claim "interferes" with FDA regulation of medical devices. Whereas § 808.1(d)(1) may not have been useful to the Supreme Court in discerning the plain meaning of § 360k(a), an FDA regulation surely is useful in discerning whether a state law interferes with FDA regulation of medical devices. Given the strong indications that the FDA does not find state warranty law an obstacle to federal regulation, the district court erred in holding otherwise.

IV. The District Court Erred in Dismissing the Fraud Claims on the Alternative Ground That They Lacked Particularity.

The district court dismissed the fraudulent misrepresentation/fraud in the inducement claim and the constructive fraud claim to the extent that they were based on Medtronic's off-label promotional efforts or the statements of the Medtronic representative who attended Ms. Caplinger's surgery on the alternative ground that the claims were not pleaded with adequate specificity under Federal

Rule of Civil Procedure 9(b). Appx. 61-62, 63. This aspect of the decision below should also be reversed.

The complaint details the ways in which Medtronic misrepresented the safety and effectiveness of Infuse for off-label posterior use. It describes journal and newspaper articles, lawsuits by the Department of Justice, an investigation of the U.S. Senate Finance Committee, and letters from senators discussing Medtronic's off-label promotion, concealment of risks, and payment to physicians as kickbacks for off-label promotion and use. *See id*. 12-20, ¶¶ 35-63. The materials referenced, some of which are directly quoted in the complaint, elaborate further. In addition, the constructive fraud allegations set forth that on August 25, 2010, Lisa Mitchell, a Medtronic representative, was in the operating room during Ms. Caplinger's surgery, that she breached her duty by failing to disclose that using the Infuse device for Ms. Caplinger's posterior-approach surgery was unreasonably dangerous, and that Ms. Caplinger's injuries resulted. *See* Appx. 20-21, ¶¶ 64-66; 29-30, ¶¶ 103-11. The complaint thus sets forth the time, the place, the misrepresentation, the identity of the person making the misrepresentation, and the consequences thereof. *See Tal v. Hogan*, 453 F.3d 1244, 1263 (10th Cir. 2006).

These allegations are sufficient at this stage to survive a motion to dismiss. "The federal rules do not require a plaintiff to provide a factual basis for every allegation. Nor must every allegation, taken in isolation, contain all the necessary

information. Rather, to avoid dismissal under Rule[] 9(b) . . . plaintiffs need only show that, taken as a whole, a complaint entitles them to relief." *U.S. ex rel. Lemmon*, 614 F.3d at 1173. "The complaint must provide enough information to describe a fraudulent scheme to support a plausible inference that" fraudulent misrepresentations were made with respect to the safety of the off-label use of Infuse in posterior-approach surgery and Medtronic's promotion to induce that off-label use. *Id*. Ms. Caplinger's complaint satisfies that standard.[13]

CONCLUSION

For the foregoing reasons, this Court should reverse the decision of the district court and remand for further proceedings.

Respectfully submitted,

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August 9, 2103

[13] Even if the fraud claims do not satisfy Rule 9(b), the necessity of a remand with respect to Ms. Caplinger's other claims under a proper understanding of express and implied preemption under the MDA would allow amendment of the fraud claims to provide greater specifics, given that the district court denied the post-judgment motion for leave to amend because it considered amendment futile in light of its erroneous views on preemption.

STATEMENT REGARDING ORAL ARGUMENT

Plaintiff-appellant Patricia Caplinger respectfully requests that the Court hear oral argument in this appeal. Oral argument would be useful to the Court because the case presents issues concerning the application of the Supreme Court's decisions in *Riegel v. Medtronic, Inc.*, 552 U.S. 312 (2008), and *Buckman v. Plaintiffs' Legal Committee*, 531 U.S. 341 (2001), that have not yet been considered by this Court and that would benefit from the full exploration that oral argument would allow.

CERTIFICATE OF COMPLIANCE WITH TYPE-VOLUME LIMITATION, TYPEFACE REQUIREMENTS, AND TYPE-STYLE REQUIREMENTS OF FED. R. APP. P. 32(a) AND WITH THIS COURT'S ELECTRONIC FILING REQUIREMENTS

1. This brief complies with the type-volume limitation of Fed. R. App. P. 32(a)(7)(B) because it contains 13,149 words, excluding the parts of the brief exempted by Fed. R. App. P. 32(a)(7)(B)(iii) and the Rules of this Court.

2. This brief complies with the typeface requirements of Fed. R. App. P. 32(a)(5) and the type-style requirements of Fed. R. App. P. 32(a)(6) because it has been prepared in a proportionally spaced typeface using Microsoft Office Word 2010 in 14-point Times New Roman.

3. This brief complies with the requirements for redaction of private information; it is identical to the paper copy of the brief; and the electronic file containing it has been scanned for viruses with an updated version of a commercial virus scanning program (VIPRE Business, version 6.2.5530.0, 2013 update) and is free from viruses.

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August 9, 2013

CERTIFICATE OF SERVICE

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