IN THE UNITED STATES DISTRICT COURT

FOR THE DISTRICT OF OREGON

RICHARD D. ALTON,

Plaintiff,

v.

3:13-CV-409-PK

OPINION AND ORDER

MEDTRONIC, INC., and MEDTRONIC SOFAMOR DANEK USA, INC.,

Defendants.

PAPAK, Magistrate Judge:

Plaintiff Richard D. Alton filed this action against defendants Medtronic, Inc., and Medtronic Sofamor Danek USA, Inc. (collectively, "Medtronic") on March 11, 2013, alleging claims of fraudulent misrepresentation and fraud in the inducement, strict products liability for failure to warn, strict products liability for defective design, strict products liability for

misrepresentation, products liability for negligence, and breach of express warranty. Each of Alton's claims arises out of complications he suffered following spine surgery in which a medical device designed, produced, and marketed by Medtronic was implanted in his cervical spine. This court has jurisdiction over Alton's claims pursuant to 28 U.S.C. § 1332, based on the complete diversity of the parties' citizenship and the amount in controversy.

Now before the court are Medtronic's motion (#19) to dismiss Alton's claims, Medtronic's motion (#23) for judicial notice, and Alton's motion (#26) for judicial notice. I have considered the motions, oral argument on behalf of the parties, and all of the pleadings and papers on file. For the reasons set forth below, Medtronic's motion (#23) and Alton's motion (#26) for judicial notice are each granted as discussed below, and Medtronic's motion (#19) to dismiss is granted in part and denied in part as discussed below.

LEGAL STANDARDS

I. Request for Judicial Notice

Federal Rule of Evidence 201(d) provides that "[a] court shall take judicial notice [of an adjudicative fact] if requested by a party and supplied with the necessary information." An adjudicative fact is subject to judicial notice when the fact is "not subject to reasonable dispute in that it is either (1) generally known within the territorial jurisdiction of the trial court or (2) capable of accurate and ready determination by resort to sources whose accuracy cannot be reasonably questioned." Fed. R. Evid. 201(b).

II. Motion to Dismiss

To survive dismissal for failure to state a claim pursuant to Rule 12(b)(6), a complaint must contain more than a "formulaic recitation of the elements of a cause of action;" specifically,

it must contain factual allegations sufficient to "raise a right to relief above the speculative level." *Bell Atlantic Corp. v. Twombly*, 550 U.S. 544, 555 (2007). To raise a right to relief above the speculative level, "[t]he pleading must contain something more . . . than . . . a statement of facts that merely creates a suspicion [of] a legally cognizable right of action." *Id.*, *quoting* 5 C. Wright & A. Miller, Federal Practice and Procedure § 1216, pp. 235-236 (3d ed. 2004); *see also* Fed. R. Civ. P. 8(a). Instead, the plaintiff must plead affirmative factual content, as opposed to any merely conclusory recitation that the elements of a claim have been satisfied, that "allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged." *Ashcroft v. Iqbal*, 556 U.S. 662, 129 S. Ct. 1937, 1949 (2009). "In sum, for a complaint to survive a motion to dismiss, the non-conclusory 'factual content,' and reasonable inferences from that content, must be plausibly suggestive of a claim entitling the plaintiff to relief." *Moss v. United States Secret Serv.*, 572 F.3d 962, 970 (9th Cir. 2009), *citing Iqbal*, 129 S. Ct. at 1949.

"In ruling on a 12(b)(6) motion, a court may generally consider only allegations contained in the pleadings, exhibits attached to the complaint, and matters properly subject to judicial notice." *Swartz v. KPMG LLP*, 476 F.3d 756, 763 (9th Cir. 2007). In considering a motion to dismiss, this court accepts all of the allegations in the complaint as true and construes them in the light most favorable to the plaintiff. *See Kahle v. Gonzales*, 474 F.3d 665, 667 (9th Cir. 2007). Moreover, the court "presume[s] that general allegations embrace those specific facts that are necessary to support the claim." *Nat'l Org. for Women v. Scheidler*, 510 U.S. 249, 256 (1994), *quoting Lujan v. Defenders of Wildlife*, 504 U.S. 555, 561 (1992). The court need not, however, accept legal conclusions "cast in the form of factual allegations." *Western Mining Council v. Watt*, 643 F.2d 618, 624 (9th Cir. 1981).

FACTUAL BACKGROUND[1]

Alton's complaint in this matter is voluminous, as are the materials submitted to the court as fit matters for judicial notice. In consequence, I provide here only a brief summary of the material allegations and facts.

On July 2, 2002, Medtronic received pre-market approval ("PMA") from the federal Food and Drug Administration (the "FDA") for its Infuse device (a "Class III" medical device under the classification framework of the Medical Device Amendments of 1976). The Infuse device approved by the FDA consists of a recombinant bone morphogenetic protein referred to as rhBMP-2 used in connection with a collagen scaffold (sponge) and a tapered metallic spinal fusion cage (interbody cage). The Infuse device was specifically approved as of July 2, 2002, for use in surgery on the lumbar spine performed through the abdomen (an anterior approach; this procedure is referred to as anterior lumbar interbody fusion surgery, or "ALIF"). Certain alternate interbody cage designs were approved by the FDA on December 1, 2003. The FDA subsequently approved the Infuse device for use in repairing certain tibia fractures and certain oromaxillary surgeries, and approved the Infuse rhBMP-2 protein component for use in the absence of the sponge or any interbody cage in certain sinus augmentations and alveolar ridge augmentations.

At or around the time it obtained initial FDA approval for the Infuse device, Medtronic began expending large sums of money in efforts to promote so-called "off-label" uses of the device, namely, any application other than those specifically approved by the FDA. These off-

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[1] Except where otherwise indicated, the following recitation constitutes my construal of the allegations of plaintiff Alton's complaint and of the matters properly subject to judicial notice in the light most favorable to Alton.

label applications included the use of the rhBMP protein without the specific interbody cage approved by the FDA as part of the Infuse device in connection with lumbar spine surgeries with a transforaminal or posterior approach (referred to as posterior lumbar interbody fusion or "PLIF" surgery).

Even before it obtained FDA approval for any application of the Infuse device, Medtronic was aware of studies demonstrating that applications of the device other than those ultimately approved by the FDA were associated with significant adverse consequences, sometimes resulting in conditions of the spine that were worse than the condition necessitating surgical intervention in the first instance, in some cases life-threatening conditions. Specifically, off-label applications of the device such as PLIF surgery resulted, in a high percentage of applications, in "exuberant bone growth" (sometimes referred to as "ectopic bone growth") in the location where the bone protein component of the device was applied. Medtronic did not report these adverse results to the FDA, and to the contrary suppressed information regarding adverse consequences in the course of its efforts to promote off-label applications such as PLIF.

As a result of Medtronic's efforts to promote off-label applications of the device and applications of components of the device and of Medtronic's efforts to suppress reports of adverse consequences from such applications, by 2010 the Infuse device and its protein component were more frequently used off label than for approved applications, and became a huge source of profit for Medtronic.

On April 7, 2010, Alton underwent PLIF surgery in which the protein component of the Infuse device was implanted in his lumbar spine without the appropriate interbody cage. At the time he conducted the surgery, Alton's surgeon was unaware of known risks associated with such

application of the protein component of the device, due to Medtronic's suppression of information regarding such risks. Alton subsequently developed uncontrolled exuberant bone growth in his lumbar spine, necessitating further surgery and resulting in significant pain symptoms.

ANALYSIS

I. Parties' Requests for Judicial Notice

By and through its motion (#23) for judicial notice, Medtronic requests that the court take notice of documents constituting: (i) the FDA PMA database listing for the Infuse device indicating a July 2, 2002, decision date approving the device for spinal fusion procedures in skeletally mature patients with degenerative disc disease at one level from L4-S1; (ii) the FDA's PMA letter for the Infuse device dated July 2, 2002, approving the device for spinal fusion procedures in skeletally mature patients with degenerative disc disease at one level from L4-S1; (iii) a supplemental FDA PMA database listing for the Infuse device indicating a March 27, 2013, supplemental decision date approving a modification to the process for using the device, specifically the addition of an alternate water supplier; (iv) a supplemental FDA PMA database listing for the Infuse device indicating a December 1, 2003, supplemental decision date approving a modification to the device, specifically the addition of alternate interbody cage designs; (v) the FDA's PMA letter for the rhBMP-2 protein dated April 30, 2004, approving the protein for the treatment of acute, open tibial shaft fractures stabilized with intramedullary nail fixation in skeletally mature patients; (vi) the FDA's PMA letter for the rhBMP-2 protein dated March 9, 2007, approving the protein for sinus augmentations and for localized alveolar ridge augmentations for defects associated with extraction sockets; (vii) an FDA "Important Medical

Information" advisory regarding the Infuse device and the rhBMP-2 component thereof;[2] and (viii) the FDA's "Summary of Safety and Effectiveness Data" for the Infuse device. By and through his motion (#26) for judicial notice, Alton requests that the court take notice of documents constituting: (i) an FDA "Important Medical Information" advisory regarding the Infuse device and the rhBMP-2 component thereof (identical to the seventh-enumerated document of which Medtronic requests judicial notice); (ii) a "Staff Report on Medtronic's Influence on Infuse Clinical Studies" prepared by the staff of the United States Senate Finance

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[2] The FDA "Important Medical Information" advisory regarding the Infuse device and the rhBMP-2 component thereof includes, *inter alia*, the following statements:

> The InFUSE Bone Graft/LT-CAGE Lumbar Tapered Fusion Device consists of two components containing three parts – a tapered metallic spinal fusion cage, a recombinant human bone morphogenetic protein and a carrier/scaffold for the bone morphogenetic protein and resulting bone. The InFUSE Bone Graft component is inserted into the LT-CAGE Lumbar Tapered Fusion Device component to form the complete InFUSE Bone Graft/LT-CAGE Lumbar Tapered Fusion Device. **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.**

(Emphasis original.)

> The InFUSE Bone GraftILT-CAGE Lumbar Tapered Fusion Device is indicated for spinal fusion procedures in skeletally mature patients with degenerative disc disease (DDD) at one level from L4-S1. DDD is defined as discogenic back pain with degeneration of the disc confirmed by patient history and radiographic studies. These DDD patients may also have up to Grade I spondylolisthesis at the involved level. Patients receiving the InFUSE Bone Graft/LT-CAGE Lumbar Tapered Fusion Device should have had at least six months of nonoperative treatment prior to treatment with the lnFIJSE Bone Graft/LT-CAGE device. The InFUSE Bone Graft/LT-CAGE Lumbar Tapered Fusion Device is to be implanted via an anterior open or an anterior laparoscopic approach.

Committee and dated October 2012;[3] (iii) an August 20, 2012, "Notice of Ruling" issued by the Los Angeles County Superior Court of the State of California denying Medtronic's motion for summary judgment in Case No. BC465313, a products liability action arising out of an application of the Infuse device; (iv) a June 22, 2012, Judgment of Dismissal issued by the Los Angeles County Superior Court of the State of California dismissing product liability claims

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[3] The October 2012 Senate Finance Committee staff report included the following findings:

- Medtronic was heavily involved in drafting, editing, and shaping the content of medical journal articles authored by its physician consultants who received significant amounts of money through royalties and consulting fees from Medtronic. The company's significant role in authoring or substantively editing these articles was not disclosed in the published articles. Medical journals should ensure industry role contributions be fully disclosed.

- Medtronic paid a total of approximately $210 million to physician authors of Medtronic-sponsored studies from November 1996 through December 2010 for consulting, royalty, and other miscellaneous arrangements.

- An e-mail exchange shows that a Medtronic employee recommended against publishing a complete list of adverse events possibly associated with InFuse in a 2005 *Journal of Bone and Joint Surgery* article.

- Medtronic officials inserted language into studies that promoted InFuse as a better technique than taking a bone graft from the pelvic bone (autograft technique) by emphasizing the pain of the autograft technique.

- Documents indicate that Medtronic prepared Dr. Hal Mathews' remarks to the U.S. Food and Drug Administration (FDA) advisory panel meeting prior to InFuse being approved. At the time, Dr. Mathews was a private physician but was hired as a vice president at Medtronic in 2007.

- Medtronic documents show the company unsuccessfully attempted to adopt weaker safety rules for a clinical trial studying InFuse in the cervical spine that would have allowed the company to continue the trial in the event that patients experienced severe swelling in the neck.

against Medtronic in Case No. SC112290; (v) a February 21, 2013, court order issued by a trial court of the State of Colorado in Case No. 12CV40 denying Medtronic's motion to dismiss claims brought against it in connection with an off-label use of the rhBMP-2 protein for spinal surgery without an interbody cage; (vi) a March 5, 2013, court order issued by the Miami-Dade County Circuit Court of the State of Florida denying Medtronic's motion to dismiss in an action against it; (vii) an October 2, 2008 release by the United States Senate Finance Committee of a September 20, 2008, letter from Senator Grassley to Medtronic regarding its financial relationships with private physicians; (viii) a June 22, 2011, release by the United States Senate Finance Committee of a June 21, 2011, letter from Senators Baucus and Grassley to Medtronic regarding evidence and press reports that "doctors conducting clinical trials examining the safety and effectiveness of Infuse . . . were aware that Infuse . . . may cause medical complications, but failed to report this in the medical literature," an "issue . . . compounded by the fact that some clinical investigators have substantial financial ties to Medtronic;" (ix) a December 13, 2011, letter from Senators Blumenthal, Grassley, and Kohl to Medtronic requesting information as to how Medtronic "handles recalls and post-marketing surveillance of [its] products;" and (x) a January 17, 2012 judgment of the United States District Court for the District of Massachusetts in criminal Case No. 09-10330-GAO reflecting the guilty plea of defendant Stryker Biotech, LLC, to distributing a misbranded device.

Neither party requests with particularity that the court take notice of any specific adjudicative fact set forth within any of the identified documents, but rather each party appears to request that the court take notice of the contents of all of the identified documents generally. It is clear that each identified document contains adjudicative facts capable of ready determination,

but equally clear that at least some of the identified documents contain content that does not constitute such an adjudicative fact. Nevertheless, because each identified document sets forth at least some fit matters for judicial notice, the parties' motions are granted, and I take judicial notice of adjudicative facts contained within the identified documents. Other content of the identified documents has been and will be disregarded.

II. Medtronic's Motion to Dismiss

By and through its motion to dismiss, Medtronic chiefly argues that each of Alton's claims is preempted under the federal Food, Drug, and Cosmetic Act of 1938 (the "FDCA"), and in the alternative argues that Alton's design defect claim is barred under Restatement of Torts Section 402A, Comment k, that his breach of express warranty claim necessarily fails because Medtronic has disclaimed all express warranties, and that his fraud claim necessarily fails because it is not pled with adequate particularity. I address each set of arguments in turn below.

A. Preemption Under the FDCA

1. The FDCA Preemption Framework

By and through the Food and Drug Act of 1906 (the "1906 Act"), Congress prohibited the manufacture or shipment through interstate commerce of any adulterated or misbranded food or drug. In 1938, through passage of the FDCA, Congress broadened the coverage of the 1906 Act to include within its scope adulterated or misbranded medical devices and cosmetics. As originally enacted, however, the FDCA did not provide any mechanism for governmental oversight of the process of introducing new medical devices.

In 1976, by and through the Medical Device Amendments of 1976 (the "MDA"), Congress enacted significant amendments to the FDCA. Under the FDCA as modified by the

MDA, medical devices are classified into three categories based on the potential risk they pose. Devices posing the greatest risk are classified as "Class III" devices. *See* 21 U.S.C. § 360c(a)(1)(C).

> Before a new Class III device may be introduced to the market, the manufacturer must provide the FDA with a "reasonable assurance" that the device is both safe and effective. *See* 21 U.S.C. § 360e(d)(2). Despite its relatively innocuous phrasing, the process of establishing this "reasonable assurance," which is known as the "premarket approval," or "PMA" process, is a rigorous one.

Medtronic, Inc. v. Lohr, 518 U.S. 470, 477 (1996). Indeed, the Supreme Court has characterized the premarket approval ("PMA") process as constituting the Congressionally mandated "federal safety review" process. *Riegel v. Medtronic, Inc.*, 552 U.S. 312, 323 (2008) ("Premarket approval. . . is in no sense an exemption from federal safety review--it *is* federal safety review" (emphasis original)).

A manufacturer's obligations under the FDCA do not end with premarket approval. Even after premarket approval issues, manufacturers are required to report to the FDA "no later than 30 calendar days after the day" the manufacturer "receive[s] or otherwise become[s] aware of information, from any source, that reasonably suggests that a device" marketed by the manufacturer:

> (1) May have caused or contributed to a death or serious injury; or
>
> (2) Has malfunctioned and this device or a similar device [likewise marketed by the manufacturer] would be likely to cause or contribute to a death or serious injury, if the malfunction were to recur.

21 C.F.R. § 803.50(a); *see also* 21 U.S.C. § 360i(a) (further detailing the post-approval reporting requirements applicable to device manufacturers); *Riegel*, 552 U.S. at 319; *Stengel v. Medtronic Inc.*, 704 F.3d 1224, 1226-1227 (9th Cir. 2013) (*en banc*). In addition, manufacturers are

required to make periodic reports to the FDA regarding approved devices, such reports to include summaries of:

> (i) Unpublished reports of data from any clinical investigations or nonclinical laboratory studies involving the device or related devices and known to or that reasonably should be known to the applicant.
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> (ii) Reports 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)(2).

The FDCA does not prohibit nor purport to regulate the use by physicians of medical devices for applications that have not been approved by the FDA (so-called "off-label" applications). Indeed, the off-label application of medical devices is not discouraged by the FDA, and is generally accepted to be both necessary and valuable. *See*, *e.g.*, *Buckman Co. v. Plaintiffs' Legal Comm.*, 531 U.S. 341, 350 (2001). However, the FDCA as amended by the MDA expressly prohibits manufacturers from the "introduction or delivery for introduction into interstate commerce of any . . . device. . . that is . . . misbranded." 21 U.S.C. § 331(a). A device is misbranded under the FDCA as amended if, *inter alia*, "its labeling is false or misleading in any particular," 21 U.S.C. § 352(a), or its labeling does not bear "adequate directions for use," 21 U.S.C. § 352(f)(1). Adequate directions for the use of a medical device "means directions under which the layman can use [the] device safely and for the purposes for which it is intended." 21 C.F.R. § 801.5. "Directions for use may be inadequate because, among other reasons, of omission, in whole or in part, or incorrect specification of. . . [s]tatements of all conditions, purposes, or uses for which such device is intended." 21 C.F.R. § 801.5(a). For purposes of the FDCA, the intended use of a medical device is determined on the basis of "the objective intent of

the persons legally responsible for the labeling of [such] device[]." 21 C.F.R. § 801.4.

> [Such] intent is determined by such persons' expressions or may be shown by the circumstances surrounding the distribution of the article. This objective intent may, for example, be shown by labeling claims, advertising matter, or oral or written statements by such persons or their representatives. It may be shown by the circumstances that the article is, with the knowledge of such persons or their representatives, offered and used for a purpose for which it is neither labeled nor advertised. The intended uses of an article may change after it has been introduced into interstate commerce by its manufacturer. If, for example, a packer, distributor, or seller intends an article for different uses than those intended by the person from whom he received the devices, such packer, distributor, or seller is required to supply adequate labeling in accordance with the new intended uses. But if a manufacturer knows, or has knowledge of facts that would give him notice that a device introduced into interstate commerce by him is to be used for conditions, purposes, or uses other than the ones for which he offers it, he is required to provide adequate labeling for such a device which accords with such other uses to which the article is to be put.

Id.

Criminal penalties obtain where manufacturers are found to have violated the FDCA prohibition against misbranding, *see* 21 U.S.C. § 333(a), as do civil penalties in the form of fines payable to the United States, *see* 21 U.S.C. § 333(f). However, there is no private right of action under the FDCA for a manufacturer's violation of its provisions, including the prohibition against the sale or distribution of misbranded devices. *See* 21 U.S.C. § 337(a); *see also*, *e.g.*, *Buckman*, 531 U.S. at 862, n. 4.

The FDCA as modified by the MDA contains an express preemption provision as follows:

> 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.

21 U.S.C. § 360k(a).[4] The FDCA implementing regulations consistently provide, *inter alia*, that:

> State or local requirements 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 [FDCA], thereby making any existing divergent State or local requirements applicable to the device different from, or in addition to, the specific Food and Drug Administration requirements.

21 C.F.R. § 808.1(d).

A trilogy of United States Supreme Court cases provide guidance for analysis of preemption under Section 360k(a). The first of these was *Medtronic, Inc. v. Lohr*, *supra*, decided in 1996. The medical device at issue in *Lohr* was a pacemaker (a Class III device) that had not been approved by the FDA through the rigorous PMA process, but rather had avoided the premarket approval requirement by being designated as "substantially equivalent" to a pre-existing device already on the market through the less rigorous "Section 510(k) process." The Eleventh Circuit had ruled that the *Lohr* plaintiffs' claims of strict products liability for design defect and for negligence in design were not preempted, but that the plaintiffs' claims of negligent manufacture and negligent failure to warn were preempted. Medtronic appealed the Eleventh Circuit's decision that the claims sounding in negligence were not preempted, and the plaintiffs appealed the decision to the extent it upheld Medtronic's preemption defense.

Although all nine *Lohr* justices either expressly or implicitly rejected Medtronic's argument that, where the FDA imposes requirements on a medical device, all common-law

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[4] The provisions of Section 360k(b) are not relevant here.

causes of action arising out of an application of the device are necessarily preempted pursuant to Section 360k(a), *see Lohr*, 518 U.S. at 486-491, 505-508 (Breyer, J., concurring in part and concurring in the judgment), 512-513 (O'Connor, J., concurring in part and dissenting in part, joined by Rehnquist, Ch. J., Scalia, J., and Thomas, J.), only a plurality of four justices adopted Part IV of Justice Stevens' opinion, in which that argument was specifically analyzed, *see id.* at 486-491. Part IV expressed the plurality's opinion that "Medtronic's argument [wa]s not only unpersuasive [but also] implausible," in that any broad construction of FDCA/MDA preemption would have "the perverse effect" of largely immunizing medical device manufacturers from liability to private citizens harmed by their products, notwithstanding the express judgment of Congress that the medical device industry was in need of "more stringent regulation in order 'to provide for the safety and effectiveness of medical devices intended for human use.'" *Id.* at 487, *quoting* 90 Stat. 539. The plurality further opined in Part IV that Section 360k "simply was not intended to pre-empt most, let alone all, general common-law duties enforced by damages actions," and concluded that notwithstanding enactment of the MDA "at least some common-law claims may be maintained" against medical device manufacturers. *Id.* at 491. Justice Stevens and three other justices supported the plurality's opinion in Part IV in part on a reading of Congressional intent pursuant to which the statutory term "requirements" would be given a narrower construction in connection with state-law causes of action than the court had previously ascribed to the same term in the context of the preemption provision of the Public Health Cigarette Smoking Act of 1969. *See id.* at 487-491.

As noted above, all nine justices agreed that some or all of the *Lohr* plaintiffs' common-law claims against Medtronic survived FDCA/MDA preemption, and thus agreed with the

ultimate conclusion reached by the plurality in Part IV. Nevertheless, Justice Breyer expressly stated that he did not join in Part IV of the court's opinion "which emphasize[d] the differences between the MDA [preemption provision] and the preemption [provision of the Public Health Cigarette Smoking Act of 1969], because those differences [we]re not. . . relevant," *id.* at 508 (Breyer, J., concurring in part and concurring in the judgment), and three justices joined in Justice O'Connor's partial dissent which likewise disagreed with the plurality that the statutory term "requirements" should be read more narrowly for FDCA/MDA preemption purposes than for purposes of Public Health Cigarette Smoking Act of 1969 preemption purposes. *See id.* at 510-512 (O'Connor, J., concurring in part and dissenting in part).

All nine *Lohr* justices agreed that the FDA does not impose "requirements" specifically regarding the design of a medical device when the device is approved through the Section 510(k) process, with the consequence that the Section 360k(a) preemption provision is entirely inapplicable to state-law design defect claims arising in connection with a device approved under Section 510(k). *See id.* at 492-494, 508 (Breyer, J., concurring in part and concurring in the judgment), 513 (O'Connor, J., concurring in part and dissenting in part). In consequence, the court affirmed the Eleventh Circuit's decision that the design defect claims were not preempted. *See id.*

More critically for present purposes, all nine justices further held that, on the *arguendo* assumptions that the FDA had placed cognizable requirements on the pacemaker through Section 510(k) approval and that recognition of state common-law claims arising out of applications of the device would constitute imposition of state requirements for preemption purposes, there could be no FDCA/MDA preemption of state claims arising out of the violation of state-law

duties that "parallel" duties arising under the FDCA:

> **Nothing in § 360k denies [the states] the right to provide a traditional damages remedy for violations of common-law duties when those duties parallel federal requirements.** Even if it may be necessary as a matter of [state] law to prove that those violations were the result of negligent conduct, or that they created an unreasonable hazard for users of the product, such additional elements of the state-law cause of action would make the state requirements narrower, not broader, than the federal requirement. While such a narrower requirement might be "different from" the federal rules in a literal sense, such a difference would surely provide a strange reason for finding preemption of a state rule insofar as it duplicates the federal rule. The presence of a damages remedy does not amount to the additional or different "requirement" that is necessary under the statute; rather, it merely provides another reason for manufacturers to comply with identical existing "requirements" under federal law.

Id. at 495 (emphasis supplied); *see also id.* at 508 (Breyer, J., concurring in part and concurring in the judgment; concurring in the quoted holding), 513 (O'Connor, J., concurring in part and dissenting in part; agreeing with the quoted holding). On this basis, the court held that the plaintiffs' negligent manufacture and negligent failure to warn claims were clearly not preempted to the extent premised on state-law duties "equal to, or substantially identical to, requirements imposed" under the FDCA. *Id.* at 496-497. All nine justices concurred in this holding. *See id.* at 508 (Breyer, J., concurring in part and concurring in the judgment; concurring in the cited holding), 513-514 (O'Connor, J., concurring in part and dissenting in part; concurring in the cited holding).

Turning to the question whether the negligent manufacture or negligent failure to warn claims constituted parallel claims that would escape preemption to the extent those claims were premised on the violation of state-law duties of general applicability that were not substantially identical to FDCA requirements, a five-justice majority opined that unless both (i) the state-law duties in question were promulgated "with respect to" a medical device or devices and (ii) the

requirements imposed pursuant to such state-law duties interfere with specific requirements promulgated by the FDA with respect to the medical device or devices, there would be no FDCA/MDA preemption:

> Although we do not believe that th[e] statutory and regulatory language [codified at 21 C.F.R. §§ 801(d) and 808.53-101] necessarily precludes "general" federal requirements from ever pre-empting state requirements, or "general" state requirements from ever being pre-empted. . . , **it is impossible to ignore its overarching concern that pre-emption occur only where a particular state requirement threatens to interfere with a specific federal interest**. **State requirements must be "with respect to" medical devices and "different from, or in addition to," federal requirements.** State requirements must also relate "to the safety or effectiveness of the device or to any other matter included in a requirement applicable to the device," and **the regulations provide that state requirements of "general applicability" are not pre-empted except where they have "the effect of establishing a substantive requirement for a specific device**." Moreover, federal requirements must be "applicable to the device" in question, and, according to the regulations, pre-empt state law only if they are "specific counter-part regulations" or "specific" to a "particular device." The statute and regulations, therefore, require a careful comparison between the allegedly pre-empting federal requirement and the allegedly pre-empted state requirement to determine whether they fall within the intended pre-emptive scope of the statute and regulations.

Id. at 500 (emphasis supplied); *see also id.* at 508 (Breyer, J., concurring in part and concurring in the judgment; concurring in the quoted language). Because the plaintiffs' claims (to the extent not premised on state-law duties substantially equivalent to FDA-promulgated duties) were premised on state-law duties of general applicability rather than on requirements imposed under state law with respect to specific medical devices, the *Lohr* majority held that the claims (so construed) were not preempted:

> [The mandated claim-by-claim] comparison [between purportedly preempting federal requirement(s) and potentially preempted state requirement(s)] mandates a conclusion that the [plaintiffs]' common-law claims are not pre-empted by the federal labeling and manufacturing requirements. The generality of those requirements make this quite unlike a case in which the Federal Government has

> weighed the competing interests relevant to the particular requirement in question, reached an unambiguous conclusion about how those competing considerations should be resolved in a particular case or set of cases, and implemented that conclusion via a specific mandate on manufacturers or producers. Rather, the federal requirements reflect important but entirely generic concerns about device regulation generally, not the sort of concerns regarding a specific device or field of device regulation that the statute or regulations were designed to protect from potentially contradictory state requirements.
>
> **Similarly, the general state common-law requirements in this suit were not specifically developed "with respect to" medical devices. Accordingly, they are not the kinds of requirements that Congress and the FDA feared would impede the ability of federal regulators to implement and enforce specific federal requirements.** The legal duty that is the predicate for the Lohrs' negligent manufacturing claim is the general duty of every manufacturer to use due care to avoid foreseeable dangers in its products. Similarly, the predicate for the failure to warn claim is the general duty to inform users and purchasers of potentially dangerous items of the risks involved in their use. **These general obligations are no more a threat to federal requirements than would be a state-law duty to comply with local fire prevention regulations and zoning codes, or to use due care in the training and supervision of a work force. These state requirements therefore escape pre-emption, not because the source of the duty is a judge-made common-law rule, but rather because their generality leaves them outside the category of requirements that § 360k envisioned to be "with respect to" specific devices such as pacemakers.** As a result, none of the [plaintiffs]' claims based on allegedly defective manufacturing or labeling are pre-empted by the MDA.

Id. at 501-502 (emphasis supplied); *see also id.* at 508 (Breyer, J., concurring in part and concurring in the judgment; concurring in the quoted language).[5]

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[5] Additionally, the four-justice plurality declined to address the plaintiffs' theory that common-law requirements of general applicability could never be construed as imposing requirements for FDCA/MDA preemption purposes, in part on the ground that it was not necessary to consider the argument in light of the court's disposition of the cross-appeals before it. *See Lohr*, 518 U.S. at 502. As an additional ground for declining to address the argument, the plurality opined that "it is apparent that few, if any, common-law duties have been pre-empted by" the MDA preemption provision, and that "[i]t will be rare indeed for a court hearing a common-law cause of action to issue a decree that has the effect of establishing a substantive requirement for a specific device." *Id.* at 502-503 (citation, internal quotation marks omitted). Justice Breyer expressly declined to join in the plurality's opinion to this effect because he was "not convinced that future incidents of MDA pre-emption of common-law claims will be 'few' or

The second Supreme Court case in the FDCA/MDA preemption trilogy was *Buckman Co. v. Plaintiffs' Legal Comm.*, *supra*, decided in 2001. The medical device at issue in *Buckman* was a bone screw (a Class III device) that, like the pacemaker at issue in *Lohr*, had avoided the premarket approval requirement by being designated as "substantially equivalent" to a pre-existing device already on the market through the less rigorous Section 510(k) process. Although the *Buckman* court expressly did not repudiate the analysis set forth in *Lohr*, the court found the plaintiff's cause of action for fraud on the FDA (premised on the theory that the device manufacturer had made fraudulent statements to the FDA resulting in improper approval of the device) was *impliedly* preempted in that the cause of action existed *solely* by virtue of requirements imposed pursuant to the FDCA, the provisions of which are expressly enforceable only by the FDA, and give rise to no private right of action:

> Given this analytical framework, . . . the plaintiffs' state-law fraud-on-the-FDA claims conflict with, and are therefore impliedly pre-empted by federal law. The conflict stems from the fact that the federal statutory scheme amply empowers the FDA to punish and deter fraud against the Agency, and that this authority is used by the Agency to achieve a somewhat delicate balance of statutory objectives. The balance sought by the Agency can be skewed by allowing fraud-on-the-FDA claims under state tort law.

Buckman, 531 U.S. at 348 (footnote omitted). The *Buckman* court clarified that its holding was consistent with the reasoning of the *Lohr* court:

> Notwithstanding the fact that *Medtronic* [*v. Lohr*] did not squarely address the question of implied pre-emption, it is clear that the *Medtronic* [*v. Lohr*] claims arose from the manufacturer's alleged failure to use reasonable care in the production of the product, not solely from the violation of FDCA requirements. *See* 518 U.S. at 481. In the present case, however, the fraud claims exist solely by

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'rare.'" *Id.* at 508 (Breyer, J., concurring in part and concurring in the judgment). Justice O'Connor and the three justices who joined her partial dissent would have rejected the plaintiffs' theory. *See id.* at 514 (O'Connor, J., concurring in part and dissenting in part).

> virtue of the FDCA disclosure requirements. Thus, although *Medtronic* [*v. Lohr*] can be read to allow certain state-law causes of actions that parallel federal safety requirements, it does not and cannot stand for the proposition that any violation of the FDCA will support a state-law claim.

Id. at 352-353.

The third Supreme Court case in the trilogy was *Riegel v. Medtronic, Inc.*, *supra*, decided in 2008. The medical device at issue in *Riegel* was a Class III balloon catheter that had received premarket approval from the FDA following the rigorous PMA process. As a preliminary matter, the *Riegel* court expressly found that the PMA process imposed "requirements" on an approved device for purposes of Section 360k. *Riegel*, 552 U.S. at 322-323. In addition, the *Riegel* majority clarified that it "adhered" to the view of the five justices who did not join in Part IV of the *Lohr* plurality's opinion, that state common-law claims are predicated on the violation of "requirements," and are thus preempted where those underlying requirements are "in addition to or different from" FDA-promulgated requirements. *Id.* at 323-324. However, the *Riegel* court expressly affirmed the reasoning of the *Lohr* court cited above that:

> **State requirements are pre-empted under the MDA only to the extent that they are "different from, or in addition to" the requirements imposed by federal law.** § 360k(a)(1). Thus, § 360k does not prevent a State from providing a damages remedy for claims premised on a violation of FDA regulations; the state duties in such a case "parallel," rather than add to, federal requirements.

Id. at 330 (emphasis supplied), *citing Lohr*, 518 U.S. at 495. Because the plaintiffs' claims were pled as asserting Medtronic's liability for violation of state-law duties "notwithstanding compliance with the relevant federal requirements," the *Riegel* court found the plaintiffs' claims clearly preempted under the plain language of Section 360k(a). *Id.* The court expressly declined to consider the argument, raised for the first time on appeal, that the plaintiffs' claims could be

construed as "parallel" claims. *See id.*

In 2010, the Seventh Circuit persuasively applied the preemption analysis set forth in the Supreme court's FDCA/MDA preemption trilogy to a Class III hip implant approved by the FDA under the rigorous PMA process. The court prefaced its reasoning as follows:

> The central issue in this appeal is whether federal law preempts product liability claims against manufacturers of Class III medical devices where a patient claims that she was harmed by the manufacturer's violation of federal law. That statement of the issue may be a little startling. **The idea that Congress would have granted civil immunity to medical device manufacturers for their violations of federal law that hurt patients is, to say the least, counter-intuitive.** Nevertheless, manufacturers in this case and in others have asserted this theory of defense. As we explain below, **the manufacturer's theory tries to stretch the Supreme Court's decisions in this field beyond the boundaries that were made clear in those decisions**. **Medical device manufacturers who subject their Class III devices to the rigorous premarket approval process are protected by federal law from civil liability so long as they *comply* with federal law. That protection does not apply where the patient can prove that she was hurt by the manufacturer's *violation* of federal law.**

Bausch v. Stryker Corp., 630 F.3d 546, 549-550 (7th Cir. 2010) (italicized emphasis original; bolded emphasis supplied). In the course of analyzing whether state law claims premised on violation of the FDCA could be expressly preempted under Section 360k, the *Bausch* court set out and applied an analytic framework according to which state-law claims are not preempted if based on conduct proscribed by the FDCA but also independently actionable under state law of general applicability, as follows:

> Section 360k 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. Just as a plaintiff in an auto accident may use the other driver's speeding violation as evidence of negligence, plaintiff Bausch claims that she was injured by [defendant] Stryker's violations of federal law in manufacturing the device implanted in her hip. It remains to be seen whether she can prove those allegations, including causation and damages. But if

> she can prove those allegations of harm caused by violations of federal law, her claims under state law would not impose on defendants any requirement "different from, or in addition to, any requirement" imposed by federal law. Her claims are not preempted.

Bausch, 630 F.3d at 553. The *Bausch* court further found that, because the plaintiff's claims were independently actionable under state law, her claims were not impliedly preempted under the reasoning of the *Buckman* court. *See id.* at 558.

Shortly thereafter, the Fifth Circuit applied the Supreme Court's FDCA/MDA jurisprudence to reach a comparable result in connection with a failure to warn claim brought under Mississippi law and predicated in parallel part on the defendant's violation of its duty under the FDCA to report adverse outcomes. *See Hughes v. Boston Scientific Corp.*, 631 F.3d 762, 776 (5th Cir. 2011). The *Hughes* court specifically held that the "failure to warn claim is neither expressly nor impliedly preempted by the MDA to the extent that this claim is premised on [the defendant manufacturer]'s violation of FDA regulations with respect to reporting [adverse outcomes] caused by the device." *Id.* (internal modifications omitted).

The Ninth Circuit's recent *en banc* decision in *Stengel v. Medtronic, Inc.*, *supra*, decided in 2013, cited *Bausch* and *Hughes* with approval and largely adopted (and further developed) the analytic framework proposed in *Bausch*. *See Stengel*, 704 F.3d at 1233 ("In holding that the Stengels' failure-to-warn claim is not preempted, we join the Fifth and Seventh Circuits, which reached the same conclusion with respect to comparable state-law claims in *Hughes* and *Bausch*"); *see id* at 1232 (quoting *Bausch* with approval for the proposition that "[t]he idea that Congress would have granted civil immunity to medical device manufacturers for their violations of federal law that hurt patients is, to say the least, counter-intuitive"). The medical device at

issue in *Stengel* was a Class III pain pump that had received FDA approval following the rigorous PMA process, a malfunction in which had seriously injured one of the plaintiffs. The factual history underlying the *Stengel* claims is broadly analogous to the history underlying the claims at issue here:

> When it received FDA approval of [the Class III pain pump device], Medtronic was not aware of certain risks associated with the device. Before [the injured plaintiff] was paralyzed, however, Medtronic had become well aware of those risks but had failed to inform the FDA, even though the MDA required Medtronic to do so. The FDA discovered the risks, and discovered that Medtronic already knew about them, when it inspected a Medtronic facility in late 2006 and early 2007. The FDA sent a Warning Letter to Medtronic in July 2007, stating that Medtronic had "misbranded" its Class III device by concealing known risks, in violation of 21 C.F.R. §§ 803.50(a)(1), 806.10(a)(1). In response to the FDA's Warning Letter, Medtronic sent a Medical Device Correction letter to doctors in January 2008. Medtronic recalled the device in March 2008. This advice and recall came too late to help [the injured plaintiff], who had been paralyzed in 2005.

Id. at 1227.

The *Stengel* plaintiffs sought to amend their complaint to allege that Medtronic had violated its duty to the FDA to report adverse consequences of reliance on its FDA-approved device, and that its failure to comply with that duty constituted an independently actionable duty to use reasonable care under Arizona negligence law. *See id.* at 1232. The court found this proposed claim not preempted under either Section 360k(a) or *Buckman*:

> **The [plaintiffs]' proposed new claim under Arizona law, insofar as the state-law duty parallels a federal-law duty under the MDA, is not preempted.** Arizona state law has long been concerned with the protection of consumers from harm caused by manufacturers' unreasonable behavior. 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. . . .
>
> We do not decide whether plaintiffs can prevail on their state-law failure-to-warn claim. That question is not before us. But **we do hold, under *Lohr*, *Buckman*, and *Riegel*, that this claim is not preempted, either expressly or impliedly, by the MDA. It is a state-law claim that is independent of the FDA's pre-market approval process that was at issue in *Buckman*. The claim rests on a state-law duty that parallels a federal-law duty under the MDA, as in *Lohr*.** In holding that the Stengels' failure-to-warn claim is not preempted, we join the Fifth and Seventh Circuits, which reached the same conclusion with respect to comparable state-law claims in *Hughes* and *Bausch*.

Id. at 1233 (citations, internal quotation marks omitted; emphasis supplied). Moreover, in interpreting the Supreme Court's "parallel claim" jurisprudence, the *Stengel* court emphasized the continuing importance of the *Lohr* court's holding that FDCA/MDA preemption occurs only where a state-law duty is promulgated "with respect to" a medical device:

> The [*Lohr*] Court held that the MDA did not preempt the [*Lohr* plaintiffs]' state-law claim alleging that Medtronic negligently had failed to warn "plaintiff or her physicians" of the known dangers of its pacemaker. **The generality of the state-law duty to warn was important to the Court's analysis.** The Court wrote:
>
> > The predicate for the failure to warn claim is the general duty to inform users and purchasers of potentially dangerous items of the risks involved in their use. This general obligation is no more a threat to federal requirements than would be a state-law duty to comply with local fire

> prevention regulations and zoning codes, or to use due care in the training and supervision of a work force.
>
> [*Lohr*, 518 U.S.] at 501-02. The state-law duties upon which the [*Lohr* plaintiffs] relied escape preemption "**because their generality leaves them outside the category of requirements that § 360k envisioned to be 'with respect to' specific devices** such as pacemakers." *Id.* at 502.

Id. at 1229 (emphasis supplied; internal modifications omitted), *quoting Lohr*, 518 U.S. at 501-502, 502.

Still more recently than *Stengel*, the Ninth Circuit again addressed the question of FDCA/MDA preemption in *Perez v. Nidek Co.*, 711 F.3d 1109, 1111 (9th Cir. 2013), a panel decision. The *Perez* plaintiffs did not claim to have been injured in any manner, but claimed that the defendants' off-label use of a Class III laser to surgically correct hyperopia was in violation of the California Protection of Human Subjects in Medical Experimentation Act (the "Human Subjects Act") and the California Consumers Legal Remedies Act (the "Consumers Act"). In addition, the plaintiffs brought a claim of "fraud by omission" on the theory that the defendants had failed to advise the plaintiffs that the hyperopic surgeries were an off-label application of the laser. The appeals court found that the plaintiffs had no claim under the Human Subjects Act because the surgeries were not cognizable as medical experiments, and that the plaintiffs lacked standing under the circumstances to sue under the Consumers Act.

As to the claim of fraud by omission, the court found the claim both expressly preempted under Section 360k(a) and impliedly preempted under the reasoning of *Buckman*. The court affirmed its recent *en banc* holding in *Stengel* that the Supreme Court's MDA preemption trilogy collectively stand for the proposition that "the MDA does not preempt a state-law claim for violating a state-law duty that parallels a federal-law duty under the MDA." *Perez*, 711 F.3d at

1117, *quoting Stengel*, 704 F.3d at 1228. However, the *Perez* court distinguished the fraud claim at issue before it from the negligent failure to warn claim at issue in *Stengel* on the basis that the fraud claim, if permitted, would effectively place a greater disclosure requirement on the defendants than was imposed under the FDCA, namely, the requirement that manufacturers and others expressly disclose that the device was not approved for off-label applications. *See id.* at 1118. In consequence, the court found the claim expressly preempted. *See id.* The *Perez* court further found the claim impliedly preempted under *Buckman*, on the grounds that the claim was premised entirely and exclusively on the existence of FDA requirements regarding the approved uses of the device. *See id.* at 1119. The court concluded that:

> Although [the plaintiffs are] not barred from bringing any fraud claim related to the surgeries, [they] cannot bring a claim that rests solely on the non-disclosure to patients of facts tied to the scope of PMA approval. While courts have acknowledged that some fraud and false advertising claims related to FDA status may go forward, [the plaintiffs] cite[] to no case where a court has allowed a plaintiff to bring suit solely for failure to disclose lack of FDA approval.

Id. at 1119-1120.

Although *Lohr*, *Buckman*, *Riegel*, *Stengel*, and *Perez* constitute the universe of FDCA/MDA-preemption case law precedent binding on this court, a number of other courts have also weighed in on the legal issues involved in applying the governing jurisprudence. The decisions vary widely in their constructions and applications. Exemplifying the approach of construing the preemptive effect of FDA premarket approval broadly is *Caplinger v. Medtronic, Inc.*, Case No. CIV-12-630-M, 2013 U.S. Dist. LEXIS 16047 (W. D. Ok. Feb. 6, 2013), a recent decision of the district court for the western District of Oklahoma, in which the court found – with one exception – claims similar to those asserted by Alton in this action and likewise arising

out of complications following use of the Infuse device either preempted under Section 360k(a) and *Riegel*, impliedly preempted under *Buckman*, or both.[6] Before the *Caplinger* court were claims of fraudulent misrepresentation and fraud in the inducement, constructive fraud, strict products liability for failure to warn, strict products liability for defective design, breach of express warranty, breach of implied warranty, negligence, and negligent misrepresentation. The court analyzed the preemptive effect of the FDA's PMA approval of the Infuse device as to each claim in turn.

As to the plaintiff's fraudulent misrepresentation and fraud in the inducement claim, the court reasoned that the claim could have three possible factual underpinnings: (i) alleged misrepresentations and/or omissions in the FDA-mandated warnings and labels accompanying the Infuse device, (ii) alleged misrepresentations and/or omissions in Medtronic's reports to the FDA with regard to Medtronic's practice of marketing off-label applications of the Infuse device to physicians, or (iii) alleged misrepresentations and/or omissions made by Medtronic in the course of marketing off-label applications of the Infuse device to physicians. *See Caplinger*, 2013 U.S. Dist. LEXIS 16047 at *28-33. The court found that to the extent the claim was construed as premised on alleged misrepresentations and/or omissions in the FDA-mandated labels themselves, the claim was clearly expressly preempted under Section 360k(a) and *Riegel*, as effectively seeking to impose labeling requirements in addition to those imposed by the FDA.

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[6] Opinions adopting an analytic approach similar to that followed by the *Caplinger* court include, *e.g.*: *Dawson v. Medtronic, Inc.*, Case No. 3:13-cv-663-JFA, 2013 U.S. Dist. LEXIS 112877 (D.S.C. Aug. 9, 2013); *Houston v. Medtronic, Inc.*, Case No. 2:13-cv-1679-SVH-SH, 2013 U.S. Dist. LEXIS 108996 (C.D. Cal. July 30, 2013); *Otis-Wisher v. Fletcher Allen Health Care, Inc.*, Case No. 1:11-cv-64-jgm, 2013 U.S. Dist. LEXIS 88813 (D. Vt. June 25, 2013).

See id. at *29-30. Similarly, the court found that to the extent the claim was construed as premised on alleged misrepresentations and/or omissions in Medtronic's mandatory reports to the FDA regarding the risk of adverse outcomes from off-label applications of the Infuse device, the claim was clearly impliedly preempted under the reasoning of *Buckman*, as effectively constituting a claim of fraud on the FDA. *See id.* at *30-31.

To the extent the claim could be construed as premised on alleged misrepresentations and/or omissions made by Medtronic to the public and to the plaintiff's physician regarding the safety of off-label applications of the Infuse device, however, the court opined that it "could not be determined" whether the claim was preempted, due to the lack of specificity in the plaintiff's complaint. *Id.* at *32. The court indicated that the claim would not be preempted to the extent so premised, so long as a finding of liability on the claim would not require the imposition of labeling requirements beyond those required by the FDA. *See id.* On that basis, the court denied Medtronic's motion to dismiss the fraud claim on preemption grounds, *see id.* at *31-32, although it nevertheless dismissed the claim on the ground that it was not pled with sufficient particularity to satisfy the heightened pleading requirements of Federal Civil Procedure Rule 9(b), *see id.* at *32-33.

The fraudulent misrepresentation and fraud in the inducement claim was the only claim the *Caplinger* court did not find either expressly or impliedly preempted in its entirety. As to the plaintiff's so-described constructive fraud claim, the court construed the claim as necessarily premised on the allegation that "[s]pecific defects . . . in the Infuse® product. . . rendered it defective and unreasonably dangerous," and on that construction found the claim expressly preempted under Section 360k(a) as seeking to impose "design, manufacturing, labeling,

warning, and marketing requirements different from, or in addition to, federal requirements for the Infuse Device." *Id.* at *34. Apparently in the alternative, the court additionally found that to the extent the constructive fraud claim was premised on alleged misrepresentations made by a Medtronic representative to the plaintiff's surgeons regarding the safety of the Infuse device during the course of the plaintiff's surgery, the claim was not pled with sufficient particularity and subject to dismissal on that basis as well. *See id.* at *34-35.

As to the failure to warn claim, the court analyzed the plaintiff's complaint and determined that the claim was premised on the inadequacy of the FDA-mandated warning labels accompanying the Infuse device. *See id.* at *35-36. Without considering or analyzing whether the plaintiff's allegations would support the proposition that the warning labels were inadequate under the FDCA, independently of state law, and thus without analyzing the possibility that the claim could be a "parallel" claim under *Riegel*, the court found that the claim was therefore necessarily expressly preempted under Section 360k(a) as seeking to impose labeling requirements beyond those required under the FDCA. *See id.* at *36-37.

As to the defective design claim, the court construed the claim as necessarily premised on the allegation that the device was "unreasonably dangerous, even if defendants complied with all FDA regulations addressed to design." *Id.* at 38. On that construction, the court found the claim clearly preempted under Section 360k(a) as seeking to "establish design requirements different from, or in addition to, federal requirements for the Infuse Device." *Id.*

As to the breach of express and implied warranties claims, the court asserted, without analysis, that whether the warranty in question was express or implied, to succeed on a claim of breach the "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." Although I note that the FDA had not (and has not) approved the Infuse device for all applications and has not characterized the Infuse device as "safe and effective" for off-label applications, and further note that the *Caplinger* plaintiff's theory of express warranty was based on assurances made by Medtronic not to the FDA or pursuant to FDA mandate but rather in the context of voluntary communications to the public, on the basis of the unsupported assertion that any warranty claim would require contravention of an FDA finding the court found the claims expressly preempted. *See id.* at *38-40.

As to the negligence claim, the court analyzed the plaintiff's complaint and determined that the claim was based on three independent factual premises: (i) Medtronic's failure to warn the plaintiff and her physicians of the risks posed by off-label applications of the Infuse device, (ii) Medtronic's affirmative promotion and marketing of the Infuse device for unapproved applications, and (iii) Medtronic's failure to comply with unspecified federal law applicable to the sale and marketing of the Infuse device. *See id.* at *40-44. For the same reasons that the court found the plaintiff's failure to warn claim expressly preempted, the court found the negligence claim expressly preempted to the extent premised on a failure to warn. *See id.* at 42. To the extent that the negligence claim could be premised on Medtronic's efforts to market the Infuse device for an off-label application, the court found the claim not expressly preempted because those efforts could constitute misbranding in contravention of the FDCA. *See id.* However, the court asserted without analysis that such efforts could only be improper by virtue of the FDCA prohibition against misbranding – that is, that such efforts could not be in violation of Oklahoma negligence law absent the FDCA prohibition against misbranding – and on that

ground found the claim (to the extent so premised) impliedly preempted under *Buckman*. *See id.* To the extent the claim was premised on Medtronic's violation of unspecified "other" federal law, the court found that the plaintiff had not alleged sufficient facts for the claim to survive a motion to dismiss. *See id.*

Finally, as to the negligent misrepresentation claim, the court construed the claim as necessarily dependent on the proposition that"specific defects in the infuse Device rendered it defective," and on that basis concluded that to permit the jury to consider the claim would "risk interference with the federally-approved design, manufacturing, labeling, and warning requirements." *Id.* at 45. In consequence, the court found the claim expressly preempted under Section 360k(a). *See id.* at 45-46.

Illustrative of cases narrowly construing the preemptive effect of FDA premarket approval is *Cornett v. Johnson & Johnson*, 998 A.2d 543 (N.J. App.Div. 2010), a decision of the court of appeals of the State of New Jersey.[7] At issue in *Cornett* was whether claims asserted under New Jersey law of strict product liability, breach of express and implied warranty, and derivative claims for alleged defects in a Class III medical device with FDA premarket approval (a drug-eluting arterial stent) were preempted under the FDCA as amended by the MDA. *See Cornett*, 998 A.2d at 547. The *Cornett* plaintiffs alleged that the device manufacturer misrepresented the safety risks associated with use of the device at medical conferences and

[7] Opinions adopting an analytic approach similar to that followed by the *Cornett* court include, *e.g.*: *Sanda v. Medtronic, Inc.*, Case No. 13-L-305 (Ill. Cir. Ct. July 18, 2013); *Messner v Medtronic, Inc.*, 39 Misc. 3d 1213(A) (N.Y. Sup. Ct. 2013); *Hofts v. Howmedica Osteonics Corp.*, 597 F. Supp. 2d 830 (S.D. Ind. 2009).

otherwise withheld from the medical community and from the FDA information regarding adverse results from use of the device, all while marketing the device to the medical community. *See id.* at 548-549. The *Cornett* court undertook a diligent and thorough claim-by-claim analysis of each of the plaintiffs' state-law causes of action in turn, to determine whether each imposed requirements different from those imposed by the FDA or, alternatively, constituted a parallel claim under *Lohr*, *Buckman*, and *Riegel*. In connection with the plaintiffs' design defect claim, the court determined that under New Jersey law a jury could find the device to have been defectively designed "without regard to the federal requirements for PMA approval, and without regard to any determination the FDA may have made that the device's design had advantages compared to the alternatives that justified a certain degree of increased risks." *Id.* at 562. In consequence, the court reasoned that New Jersey's products liability law of defective design could require the imposition of "a different standard for the adequacy of the device's design than the federal requirements," and thus that the design defect claim was not a parallel claim but rather was preempted. *Id.* Similarly, the court found plaintiffs' claim for statutory punitive damages for products liability impliedly preempted under *Buckman*, because that claim was premised on the theory that, had the manufacturer disclosed information regarding adverse outcomes from use of the device to the FDA, the FDA would have responded differently to the manufacturer's PMA application. *See id.* at 566-567.

By contrast, the court found the plaintiffs' manufacturing defect, failure to warn, and breach of express warranty claims (as well as claims of wrongful death, loss of consortium, and survivorship that were derivative of those claims) to be neither expressly nor impliedly preempted under the FDCA. As to the manufacturing defect claim, the plaintiffs alleged that the

device manufacturer had departed and deviated from the design approved by the FDA, and limited their allegations of defect to safety risks arising from those deviations. The *Cornett* court found that a New Jersey claim for manufacturing defect based on those allegations was therefore outside the scope of the FDCA/MDA preemption provision as a parallel claim, in that "[t]he [only] additional requirement that this state claim imposed on plaintiffs, proving that the deviations actually rendered the device unsafe or unsuitable for the intended uses, was acceptable because it narrowed the circumstances in which manufacturers could be liable compared to the federal scheme, instead of enlarging them." *Id.* at 562.

In connection with the failure to warn claim, the court noted that New Jersey's products liability law:

> is a strict-liability standard that focuses on "the actual condition of the product" rather than on the reasonableness of the manufacturer's conduct. . . . Thus, the manufacturer has a duty to warn of "dangers" that it knew, or that it "should have known on the basis of reasonably obtainable or available knowledge." . . . It satisfies that duty by giving "an adequate warning or instruction."

Id. at 563 (citations omitted). The court further noted that "[a] warning that has been approved or prescribed by the FDA under the FDCA carries a rebuttable presumption of adequacy." *Id.* (citation, internal quotation marks omitted). The court therefore reasoned that any state-law claim premised solely on the theory that the FDA-approved warning was inadequate would necessarily create a state-law requirement applicable to the manufacturer defendant in addition to those requirements imposed by the FDA, and on that basis would necessarily be preempted under *Riegel*. *See id.* at 563-564. However, the court further reasoned that:

> [W]hen the claim about the failure to warn for approved uses was combined with allegations of nondisclosure, it became a claim within a traditional area of state regulation that would have existed even in the absence of federal requirements.

To that extent, it satisfied *Buckman*'s test for avoiding implied preemption as a claim that amounted to no more than fraud on the FDA. . . . While it is true that the misconduct underlying plaintiffs' claims also constitutes a violation of federal regulations--indeed that is precisely why the claims are parallel--the suit was brought to vindicate plaintiffs' rights, not the FDA's.

* * *

As already noted, 21 *U.S.C.A.* § 360i requires defendants to submit information after approval that reasonably suggested adverse device experiences. Plaintiffs' amended complaint clearly implied that defendants commissioned post-marketing studies that contained reportable adverse experiences, and further alleged that these studies demonstrate the label's inadequacy . . . , even for approved uses. While defendants supposedly withheld them from the FDA and the advisory panel, they allegedly distributed altered versions of them to physicians, to promote both approved and off-label uses with misrepresentations about [possible adverse consequences] and about overall safety. According to plaintiffs' complaint, submission of the studies as federal law required would have caused the FDA to improve the label, and any heightened warnings concerning approved uses would also have increased the safety of off-label uses.

The conduct and consequences that plaintiffs alleged constituted the kind of deliberate nondisclosure needed to overcome [New Jersey products liability law]'s presumption of adequacy for an FDA-approved label. . . . The allegations of plaintiffs' amended complaint must be accepted as true on a motion to dismiss, and as such, the complaint sufficiently pled such deliberate violations of defendants' federal responsibilities to rebut the presumption. . . .

Turning to off-label uses, [New Jersey products liability law] permits claims only relating to a product's intended purpose. As discussed above, federal law does not treat an off-label use as intended when the manufacturer simply has knowledge of it or is promoting it within the safe harbor. Any basis for treating such circumstances as an intended use of the product for [New Jersey products liability law] purposes would be invalid under *Riegel* for imposing duties on the manufacturer in addition to the federal requirements. In other words, under federal law manufacturers are obligated to warn only about intended uses, and, under the safe harbor, evidence of the dissemination of information about an off-label use [is] deemed not to be evidence of an intended use that was different from the use on the label. . . .

On this score, we reject plaintiffs' argument that because § 360k(a) only applies when a medical device is used in a manner that was reviewed and approved by the FDA, then § 360k(a) should not preempt any of their claims against defendants

> arising out of the off-label use of the [device]. . . . Indeed, in *Riegel*, . . . the plaintiffs' claims were found to be preempted by § 360k(a) even though the balloon catheter at issue there had been used off-label. . . . And in *Buckman*, . . . the Supreme Court recognized that off-label usage is not illegal or even disfavored under federal law. . . .
>
> It is, however, only when the manufacturer promotes an off-label use without abiding the requirements or limitations of the safe harbor that federal law regards the off-label use as an intended use, triggering the duty to provide instructions or warnings about that off-label use. . . . All such activity is in violation of the federal requirements, so [New Jersey products liability law] would then be a parallel requirement, while also reflecting a traditional state law cause of action. **A claim that promotion of off-label use beyond the safe harbor was coupled with a failure to warn would not be preempted.**

Id. at 564-565 (citations and internal quotation marks omitted; emphasis supplied).[8] On that basis, the court concluded that, on the face of the plaintiffs' pleading, the failure to warn claim was not preempted:

> [P]laintiffs alleged [that] defendants marketed the[ir] device for [the off-label application that caused one plaintiff's injury]. If that were the extent of the allegation, it would not have succeeded as preempted because, as noted, the lack of federal requirements does not mean off-label marketing is prohibited entirely. To the contrary, the FDA's failure to require adequate off-label warnings for devices promoted within the safe harbor is a deliberative decision in and of itself that warrants preemptive force. But plaintiffs' complaint goes much further. Plaintiffs also allege that defendants affirmatively promoted the off-label use of the [device] in a manner that violated federal law, specifically 21 C.F.R. §§ 99.101, 803.10(c), 803.50, 814.39; that defendants were aware or should have been aware of the dangers inherent in the off-label uses from post-approval studies they performed revealing a significant adverse event rate associated with their device's unapproved uses yet affirmatively represented that there were "no . . . differences [in adverse consequences] between the off-label subgroups and . . . on-label subgroups"; and that while marketing the device in violation of federal law, defendants failed to include adequate warnings about the off-label use they were promoting. Under the liberal standard of review for a motion to dismiss, we conclude that plaintiffs' allegation of off-label promotion without adequate warnings was a sufficient pleading.

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[8] The "safe harbor" referenced by the *Cornett* court was a creature of FDCA provisions that expired in 2006, and are not at issue here.

Id. at 565-566 (footnotes, internal modifications omitted).

In connection with the breach of express warranty claim, the court found that to the extent, if any, that the claim was premised on any warranty created by FDA-approved labeling, the claim was clearly preempted. *See id.* at 566. "However," the court found, "a claim for breach of express warranty based on voluntary statements, meaning any statement that the FDA did not approve or mandate, is not preempted." *Id.* (citations omitted).

The *Cornett* defendants appealed the appeals court's decisions as to the failure to warn and breach of express warranty claims to the New Jersey Supreme Court. That court affirmed the reasoning and decisions of the *Cornett* appeals court below as to those claims. *Cornett v. Johnson & Johnson*, 211 N.J. 362, 386-393 (2012).

A small number of courts construes the preemptive effect of FDA premarket approval still more narrowly than the *Cornett* court where, as here, the device manufacturer is alleged to have affirmatively promoted an off-label application of the device with consequential damage to the defendant. Courts reasoning that claims against such a manufacturer are not subject to Section 360k(a) preemption include *Ramirez v. Medtronic, Inc.*, Case No. CV-13-512-PHX-GMS (D. Ariz. August 21, 2013), a case arising out of an off-label application of the Infuse device.[9] The *Ramirez* court summarized its operative reasoning as follows:

> To review, when the manufacturer has done nothing to alter the intended use of the product, or promote its use in an off-label manner, a claim based only the manufacturer's knowledge of an off-label use appears to be preempted under § 360k because it would seeks to require the manufacturer to depart from the FDA-approved design and label in order to make the separate, unapproved use more safe or effective when the manufacturer is not promoting that use. *See*

[9] The court in *McDonald-Lerner v. Neurocare Associates, P.A.*, Case No. 373859-V (Md. Cir. Ct. August 29, 2013), adopted and followed the analysis set forth in *Ramirez*.

> *Riegel*, 552 U.S. at 330; *Perez*, 711 F.3d at 1117-19. By remaining in compliance with the federal scheme and promoting only the use anticipated by the regulations, the manufacturer has shielded itself from such state law claims.
>
> **The shield drops when the manufacturer violates federal law. "Section 360k 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. Medtronic offers no controlling authority suggesting that the federal government's extensive regulations concerning a medical device apply to off-label uses in cases in which the manufacturer promotes such uses.** Allowance for state law claims premised on Medtronic's off-label promotion and consequent establishment of a new, unregulated use does not impose any requirement on Medtronic relating to Infuse "different from, or in addition to" the requirements set by the federal government. The thrust of [the *Ramirez* plaintiff]'s claims. . . is that in light of Medtronic's promotion of off-label uses, the warning approved by the FDA for "on-label" use was inadequate and harmful to her when she underwent an off-label use promoted by Medtronic. Had Medtronic followed the established procedure and created a new use for Infuse under the MDA, there would be a number of applicable regulations with which the state law might conflict. As it stands, however, a finding against Medtronic on [the plaintiff]'s claims does not entail a finding that Medtronic committed wrongdoing despite compliance with federal law. 21 U.S.C. § 360k(a); *Riegel*, 552 U.S. at 321-22. To be preempted, [the plaintiff]'s claims must conflict with applicable federal law. **In the absence of federal approval of the new use, there is nothing to preempt state law requirements. And in light of the limited breadth courts afford a preemption defense, § 360k should not be read as a broad assertion of exclusive federal power over all things having to do with medical devices.** Section 360k does not foreclose [the plaintiff]'s state law theory.

Ramirez, 2013 U.S. Dist. LEXIS 118822 at *36-38 (emphasis supplied). On that basis, the *Ramirez* court held that a plaintiff alleging state-law claims against a device manufacturer that had allegedly affirmatively promoted the complained-of off-label application is not required to establish that the state-law claims are "parallel" claims under *Lohr*, in that the FDA has not, by definition, imposed device-specific requirements in connection with the promoted off-label use, rendering Section 360k(a) inapposite. *See id.* at *43-44. The *Ramirez* court independently analyzed state-law claims of fraud, failure to warn, design defect, misrepresentation, negligence,

and breach of express warranty and found each, to the extent premised on Medtronic's promotion of off-label application of the Infuse device. to be outside the scope of Section 360k(a). *See id.* at *47-62.

The reasoning of the *Caplinger* court is in some respects difficult to square with the Ninth Circuit's *en banc* decision in *Stengel* that a failure to warn claim pled under Arizona negligence law would be neither expressly nor impliedly preempted, or with that court's adoption of the Seventh Court's reasoning in *Bausch* suggesting that Section 360k(a) preemption is largely unavailable to device manufacturers when they fail to comply with their obligations under the FDCA. To be sure, neither *Stengel* nor *Bausch* was binding on the *Caplinger* court, as *Stengel* is on this court. In addition, however, the *Caplinger* court's reasoning is in numerous instances unpersuasive – as for example where it begs the question by assuming the absence of a cognizable state-law claim in the aid of establishing that no parallel state-law claim had been asserted – and appears in several instances "to stretch the Supreme Court's decisions in this field beyond the boundaries that were made clear in those decisions" in precisely the manner the *Bausch* court found objectionable. *Bausch*, 630 F.3d at 549-550; *see also*, *e.g.*, *Hofts*, 597 F. Supp. 2d at 832 (observing that "some medical device . . . have tried recently to stretch *Riegel* beyond recognition by transforming its protection for FDA-approved devices that *comply* with federal law into a grant of civil immunity for FDA-approved devices that *violate* federal law" and expressly rejecting any such interpretation) (emphasis original).

By contrast, the *Cornett* court's reasoning appears generally consistent with applicable Ninth Circuit precedent, and moreover the *Cornett* court's approach of narrowly construing the preemptive effect of FDA premarket approval appears more consistent than does *Caplinger*'s

with the "basic presumption against preemption" that requires the courts to "assume that a federal statute has not supplanted state law unless Congress has made such an intention 'clear and manifest'" and to "accept the reading that disfavors preemption" where a federal statute may plausibly be read either as having or not as having preemptive effect. *Bates v. Dow Agrosciences L.L.C.*, 544 U.S. 431, 449 (2005), *quoting New York State Conference of Blue Cross & Blue Shield Plans v. Travelers Ins. Co.*, 514 U.S. 645, 655 (1995), *quoting Rice v. Santa Fe Elevator Corp.*, 331 U.S. 218, 230 (1947).

Finally, the reasoning of *Ramirez*, although largely persuasive, appears to me both to depend in part on a flawed premise and to reach a conclusion impliedly rejected by the Ninth Circuit in *Perez*. The flawed premise is in connection with the court's finding that Medtronic violated federal law specifically by promoting off-label applications of the Infuse device. As noted above, Section 331(a) – the provision the *Ramirez* court cited in support of the proposition that "[a] manufacturer is . . . prohibited from promoting a use of the product that is not the specified use" – does not expressly prohibit such promotion, but rather prohibits manufacturers only from the "introduction or delivery for introduction into interstate commerce of any . . . device. . . that is . . . misbranded," 21 U.S.C. § 1331(a), where misbranding is defined in part as labeling a device without including "adequate directions for use," 21 U.S.C. § 352(f)(1), directions for use "may be inadequate because. . . of omission, in whole or in part, or incorrect specification of. . . [s]tatements of all conditions, purposes, or uses for which such device is intended," 21 C.F.R. § 801.5(a), and whether a particular use is intended may be inferred from, *inter alia*, the manufacturer's statements in promotion of the device and its applications, *see* 21 C.F.R. § 801.4. I thus take issue with the reasoning of *Ramirez* to the extent the court presumed

that the state-law claims before it were premised on off-label promotion in violation of the FDCA: the promotion itself did not violate any provision of the FDCA, but rather constituted evidence material to the question whether the Infuse device was misbranded.

Moreover, while the *Ramirez* court's conclusion that Section 360k(a) is inapplicable to state-law claims arising out of off-label applications of a PMA-approved medical device is not clearly incorrect either logically or in light of the Supreme Court's FDCA/MDA preemption jurisprudence, it cannot be reconciled with the Ninth Circuit's holding in *Perez* that claims arising out of a manufacturer-promoted off-label application of a PMA-approved medical device were preempted under Section 360k(a). *See Perez*, 711 F.3d at 1112-113, 1117-1119. Under *Perez*, PMA approval constitutes – impliedly but necessarily – imposition of device-specific requirements on a medical device without regard to the application or use in connection with which the FDA issued such approval. In consequence, I decline to follow the approach adopted by the *Ramirez* court.

2. Application of the FDCA Preemption Framework to Alton's Claims

Under the analytic framework discussed above, state-law claims arising out of the use of a Class III medical device approved by the FDA through the PMA process may be impliedly preempted by the FDCA under the reasoning of *Buckman*, or may be expressly preempted pursuant to Section 360k(a). A claim is impliedly preempted under the reasoning of *Buckman* if it is cognizable only by virtue of the provisions of the FDCA itself, and would not be independently viable under state law absent those provisions. *See Buckman*, 531 U.S. at 348. Conversely, a state-law cause of action escapes implied preemption under *Buckman* if it would state a claim under state law even in the absence of the FDCA. *See id.*

A state-law claim is expressly preempted under Section 360k(a) if recognition of the claim would or could have the effect of imposing on the medical device manufacturer any device-specific requirement or requirements different from or in addition to the requirements imposed by the FDA on the design, manufacture, labeling, or marketing either of the specific device in question or on medical devices generally. *See Lohr*, 518 U.S. at 495, 496-497, 500, 508 (Breyer, J., concurring in part and concurring in the judgment), 513 (O'Connor, J., concurring in part and dissenting in part); *Riegel*, 552 U.S. at 323-324, 330. *Lohr* and its progeny contemplate two types of "parallel" state-law claims that escape express FDCA/MDA preemption: (i) state-law claims that are premised on conduct that both violates the FDCA and is independently actionable under state law, as for example the negligent manufacture and negligent failure to warn claims at issue in *Lohr* to the extent premised on state-law duties "substantially identical" to requirements imposed under the FDCA which all nine *Lohr* justices agreed were clearly not subject to FDCA/MDA preemption, *see* 518 U.S. at 495, 496-497, 508 (Breyer, J., concurring in part and concurring in the judgment), 513-514 (O'Connor, J., concurring in part and dissenting in part), *see also Stengel*, 704 F.3d at 1233, and (ii) state-law claims that are premised on conduct that contravenes state-law duties of such generality as not to present any risk of interference with the federal medical-device regulatory scheme, as for example the negligent manufacture and negligent failure to warn claims which the *Lohr* majority found not preempted to the extent premised on the violation of state-law duties of general applicability that were not substantially identical to FDCA requirements, *see Lohr*, 518 U.S. at 501-502, 508 (Breyer, J., concurring in part and concurring in the judgment), *see also Stengel*, 704 F.3d at 1229. The *sine qua non* of a parallel claim of either type is that recognition of the state-law cause

of action would not impose on the medical device manufacturer any device-specific duty different from, or in addition to, the manufacturer's duties under the FDCA. *See Lohr*, 518 U.S. at 495, 500; *Stengel*, 704 F.3d at 1233.

Alton alleges claims of fraudulent misrepresentation and fraud in the inducement, strict products liability for failure to warn, strict products liability for defective design, strict products liability for misrepresentation, products liability for negligence, and breach of express warranty. Like the *Cornett* and *Caplinger* courts, I examine the preemptive effect of FDA premarket approval on each claim independently, in turn.

a. Fraudulent Misrepresentation/Fraud in the Inducement

Alton's fraud claim – like the category of fraud claims the *Caplinger* court identified as having the potential to escape preemption – is premised chiefly on the allegation that Medtronic intentionally misrepresented material health and safety risk information to the public, to Alton, and to his physicians in the course of affirmatively marketing off-label applications of the Infuse device. *See* Complaint, ¶¶ 266-268. Alton specifically alleges that Medtronic and its agents understood that their representations regarding the health and safety risks of such applications of the device were false at the time they were made, that Medtronic intended Alton and his physicians to rely on those misrepresentations, that Alton and his physicians were unaware of the falsity of Medtronic's representations, and that Alton and his physicians did reasonably rely on Medtronic's misrepresentations in reaching the decision to subject Alton to off-label PLIF surgery in which the protein component of the Infuse device was implanted in his lumbar spine using a posterior approach and without the appropriate interbody cage, with resultant injury to Alton. *See id.*, ¶¶ 269-272. These allegations are sufficient to state an actionable claim under the

Oregon common law of fraud, independently of the FDCA or of any other federal law. *See Webb v. Clark*, 274 Or. 387, 391 (1976) (stating elements of fraud under Oregon law). Alton's fraud claim therefore escapes implied preemption under *Buckman*. *See Buckman*, 531 U.S. at 348.

Alton appears to argue that his fraud claim escapes express preemption as a parallel claim premised on the violation of substantially identical duties arising independently under the FDCA and under the Oregon common law. However, the FDCA neither prohibits off-label applications of an approved device nor prohibits device manufacturers from promoting off-label applications; the FDCA prohibits traffic in misbranded medical devices, but while Alton has alleged sufficient facts to support the conclusion that PLIF surgery involving the protein component of the Infuse device without the approved interbody cage component was an "intended use"of the device, *see* 21 C.F.R. § 801.4, on Alton's misbranding theory (as properly construed), Medtronic's alleged conduct in contravention of the FDCA was not its promotion of the off-label application but rather its "introduction or delivery for introduction into interstate commerce" of the device itself without "adequate directions" for that intended use, *see* 21 U.S.C. §§ 331(a), 352(f)(1), 21 C.F.R. §§ 801.4, 801.5. The alleged conduct underlying Alton's fraud claim therefore could not have been in contravention of Medtronic's duties under the FDCA.

Alton's fraud claim falls instead into the second category of parallel claims contemplated in *Lohr* and its progeny, as a claim premised on conduct that contravenes state-law duties of such generality as not to present any risk of interference with the federal medical-device regulatory scheme. The FDCA does not purport to regulate medical device manufacturers' representations regarding off-label applications of approved medical devices, *see supra*, and in consequence Medtronic's "general obligation[]" to avoid affirmative misrepresentations regarding the risks

associated with such applications with the intent that members of the public rely on those misrepresentations to their detriment is "no more a threat to federal requirements than would be a state-law duty to comply with local fire prevention regulations and zoning codes, or to use due care in the training and supervision of a work force." *Lohr*, 518 U.S. at 501-502. Nothing in *Riegel* or *Perez* suggests to the contrary, in that *Riegel* did not repudiate any aspect of the *Lohr* majority's analysis, *see Riegel*, 552 U.S. at 330, and recognition of the fraud claim at issue here, unlike the fraud by omission claim at issue in *Perez*, would not place Medtronic under any affirmative disclosure requirement in addition to the disclosure requirements promulgated by the FDA, *see Perez*, 711 F.3d at 1118. Under *Lohr*, *Riegel*, and *Stengel*, Alton's fraud claim is a parallel claim, and not preempted under Section 360k(a). *See Lohr*, 518 U.S. at 501-502, 508 (Breyer, J., concurring in part and concurring in the judgment); *Stengel*, 704 F.3d at 1229. Medtronic's motion to dismiss (to the extent argued on preemption grounds) is therefore denied as to Alton's fraud claim.

b. Strict Products Liability Claims

Three of Alton's causes of action allege Medronic's liability under Oregon's statutory products liability scheme, respectively for failure to warn, for defective design, and for misrepresentation, each on a theory of strict liability. The elements of a strict products liability claim under Oregon law are codified at Or. Rev. Stat. 30.920, which provides as follows:

> (1) One who sells or leases any product in a defective condition unreasonably dangerous to the user or consumer or to the property of the user or consumer is subject to liability for physical harm or damage to property caused by that condition, if:
>
> (a) The seller or lessor is engaged in the business of selling or leasing such a product; and

(b) The product is expected to and does reach the user or consumer without substantial change in the condition in which it is sold or leased.

(2) The rule stated in subsection (1) of this section shall apply, even though:

(a) The seller or lessor has exercised all possible care in the preparation and sale or lease of the product; and

(b) The user, consumer or injured party has not purchased or leased the product from or entered into any contractual relations with the seller or lessor.

(3) It is the intent of the Legislative Assembly that the rule stated in subsections (1) and (2) of this section shall be construed in accordance with the Restatement (Second) of Torts sec. 402A, Comments a to m (1965). All references in these comments to sale, sell, selling or seller shall be construed to include lease, leases, leasing and lessor.

(4) Nothing in this section shall be construed to limit the rights and liabilities of sellers and lessors under principles of common law negligence or under ORS chapter 72.

Or. Rev. Stat. 30.920; *see also*, *e.g.*, *Mason v. Mt. St. Joseph, Inc.*, 226 Or. App. 392, 396-398 (2009) (discussing the distinction between strict products liability claims and products liability claims in general). "It is a disputable presumption in a products liability civil action that a product as manufactured and sold or leased is not unreasonably dangerous for its intended use." Or. Rev. Stat. 30.910. Or. Rev. Stat. 30.900 provides that a person may bring a civil action against the manufacturer of a product for personal injury, death, or property damage arising out of "[a]ny design. . . or other defect in a product," "[a]ny failure to warn regarding a product," or "[a]ny failure to properly instruct in the use of a product." Or. Rev. Stat. 30.900.

i. Strict Products Liability for Failure to Warn

The Oregon Court of Appeals has discussed a manufacturer's duty to warn the public

regarding a product as follows:

> [C]omment h of [Restatement (Second) of Torts] section 402A provides:
>
> > "A product is not in a defective condition when it is safe for normal handling * * *. If the injury results from abnormal handling * * *, the seller is not liable. Where, however, [the seller] has reason to anticipate that danger may result from a particular use, * * * [the seller] may be required to give adequate warning of the danger (see Comment j), and a product sold without such warning is in a defective condition."
>
> In turn, comment j provides, in part, that, "in order to prevent the product from being unreasonably dangerous, the seller may be required to give directions or warning, on the container, as to its use." It explains that a seller is required to give warning of a danger when the danger is "not generally known" and if the seller "has knowledge, or by the application of reasonable, developed human skill and foresight should have knowledge," of the presence of the danger. However, under comment j, a seller is "not required to warn with respect to products * * * when the danger, or potentiality of danger, is generally known and recognized." *See Gunstone v. Julius Blum GMbH.a-6873*, 111 Ore. App. 332, 336-37, 825 P.2d 1389, *rev den*, 313 Ore. 354, 833 P.2d 1283 (1992) (the trial court correctly instructed the jury that, if the danger presented by the product in that case was "generally known and recognized," then the manufacturer "had no duty to warn of that danger" and the product "was not unreasonably dangerous due to a lack of warning" (emphasis in original)). Finally, comment j states that, "where warning is given, the seller may reasonably assume that it will be read and heeded; and a product bearing such a warning, which is safe for use if [the warning] is followed, is not in defective condition, nor is it unreasonably dangerous." *See Schmeiser v. Trus Joist*, 273 Ore. 120, 133, 540 P.2d 998 (1975) (citing comment j) (when a warning is actually given, the seller may reasonably assume that it will be read and heeded; a product bearing such a warning, which is safe for use if it is followed, is not in defective condition, nor is it unreasonably dangerous). *See generally Griffith v. Blatt*, 334 Ore. 456, 467, 51 P3d 1256 (2002) (noting the applicability of comments h and j to a product liability claim based on failure to warn); *Waddill v. Anchor Hocking, Inc.*, 149 Ore. App. 464, 474, 944 P.2d 957 (1997), *rev'd on other grounds*, 330 Ore. 376, 8 P3d 200 (2000), *on recons*, 331 Ore. 595, 18 P3d 1096 (2001) (allegations that the defendant had reason to anticipate that danger could result from a particular use of the defendant's product and that the product was sold without any warning as to what could occur as a result of that particular use stated a claim for product liability for failure to warn under comment h).

In *Anderson v. Klix Chemical*, 256 Ore. 199, 207, 472 P.2d 806 (1970), the

> Supreme Court explained that a warning is adequate when it is "in such a form that it could reasonably be expected to catch the attention of the reasonably prudent [person] in the circumstances of its use" and the content of the warning is "of such a nature as to be comprehensible to the average user and to convey a fair indication of *the nature and extent of the danger* to the mind of a reasonably prudent person." (Emphasis added; citation, internal quotation marks omitted.) More specifically as to the latter consideration, in *Schmeiser*, the Supreme Court explained that a "fair and adequate" warning is one that provides the user
>
> > "fair and adequate notice of the possible consequences of use or even misuse. * * * The rule is that when a manufacturer undertakes by printed instructions to advise of the proper method of using [the] chattel, [the manufacturer] assumes the responsibility of giving accurate and adequate information with respect thereto, *including instructions as to the dangers involved in improper use*."
>
> 273 Ore. at 132 (quoting 2 *Hursh and Bailey, American Law of Products Liability* § 8:19, 192, 193 (2d ed 1974)) (emphasis added; internal quotation marks omitted; footnotes omitted in *Schmeiser*).

Benjamin v. Wal-Mart Stores, 185 Or. App. 444, 453-455 (2002) (modifications original).

Alton's strict products liability law claim for failure to warn is premised chiefly on the allegation that Medtronic knew of dangers associated with off-label use of components of the Infuse device and knew that such off-label use was reasonably foreseeable, but did not adequately warn Alton or his physicians about those dangers either in the warnings incorporated into the FDA-mandated labeling of the device or in its communications with the public. *See* Complaint, ¶¶ 279-280, 284-286. Alton further alleges that the bone protein component of the Infuse device that was used in his PLIF surgery was defective when it left Medtronic's control. *See* Complaint, ¶ 282. These allegations are sufficient to state a strict products liability claim for failure to warn under Oregon law. *See* Or. Rev. Stat. 30.900, 30.920; *see also Benjamin*, 185 Or. App. at 453-455. The failure to warn claim is therefore not impliedly preempted under *Buckman*. *See Buckman*, 531 U.S. at 348.

The failure to warn claim is also a parallel claim under the reasoning of *Lohr*, *Riegel*, and *Stengel*. As noted above, Alton's allegations that Medtronic expended large sums of money in affirmative promotion of off-label PLIF surgery involving the protein component of the Infuse device without the approved interbody cage component are sufficient to support the conclusion that such application was an "intended use"of the device. *See* 21 C.F.R. § 801.4. Interpreting Alton's allegations in the light most favorable to him, I therefore conclude for purposes of Medtronic's motion to dismiss that the off-label application that resulted in Alton's injury was an intended use. As such, Alton's allegations describe conduct in contravention of Medtronic's duties under the FDCA, namely its duty to provide "adequate directions" as to that intended use in its product labeling. 21 U.S.C. § 352(f)(1); *see also* 21 C.F.R. § 801.5.

It is clear that Alton's failure to warn claim is preempted under Section 360k(a) to the extent recognition of the claim would constitute imposition of any warning requirement in addition to or different from the "adequate directions for use" that would be mandated under the FDCA for PLIF surgery involving the bone-protein component alone. *See* 21 U.S.C. § 360k(a); *see also Lohr*, 518 U.S. at 495; *Riegel*, 552 U.S. at 330; *Stengel*, 704 F.3d at 1233. However, to the extent that Medtronic's compliance with its FDCA labeling obligations as to the allegedly intended use at issue here would constitute compliance with Oregon's statutory products liability scheme regarding Medtronic's duty to warn in connection with that same allegedly intended use, it is equally clear that his claim would escape express preemption. *See* 21 U.S.C. § 360k(a); *see also Lohr*, 518 U.S. at 495; *Riegel*, 552 U.S. at 330; *Stengel*, 704 F.3d at 1233; *see also Mears v. Marshall*, 149 Or. App. 641, 656-658 (1997) (finding a failure to warn claim cognizable under Oregon's strict products liability law and not preempted under *Lohr*). Moreover, nothing in

Alton's pleading suggests that the failure to warn claim is premised on Medtronic's alleged violation of any state-law duty different from or in addition to Medtronic's FDCA labeling obligations. In consequence, Medtronic's motion to dismiss is denied as to Alton's failure to warn claim. Such disposition shall be without prejudice to Medtronic's ability to raise the issue anew at a later stage of these proceedings, should it become apparent that Alton's theory of Medtronic's liability could risk interference with the federal medical device regulatory scheme.

ii. Strict Products Liability for Defective Design

Alton's strict liability claim for defective design is premised chiefly on the allegations that the Infuse device was defectively designed in that the device was unsafe when used for the PLIF surgery Medtronic allegedly affirmatively promoted at the time it left Medtronic's control, that Alton and his physicians were not aware of such defects in the device's design, that such defects caused the device not to perform as an ordinary consumer would expect, and that the device could have been made safe for such application had Medtronic adopted a reasonable alternative design. *See* Complaint, ¶¶ 297-301. These allegations are sufficient to state a strict products liability claim for design defect under Oregon law. *See* Or. Rev. Stat. 30.900, 30.920; *see also Benjamin*, 185 Or. App. at 460-461. The failure to warn claim is therefore not impliedly preempted under *Buckman*. *See Buckman*, 531 U.S. at 348.

The design of the Infuse device was approved by the FDA through the rigorous PMA process. A finding of Medtronic's liability on Alton's design defect claim would constitute imposition of requirements on the design of the device in addition to those mandated by the FDA through PMA approval. In consequence, the design defect claim is not a parallel claim under the reasoning of *Lohr*, *Riegel*, and *Stengel*, but rather falls squarely within the scope of Section

360k(a). *See* 21 U.S.C. § 360k(a); *see also Lohr*, 518 U.S. at 495; *Riegel*, 552 U.S. at 330; *Stengel*, 704 F.3d at 1233; *but cf. Mears*, 149 Or. App. at 658-659 (finding a defective design claim cognizable under Oregon's strict products liability law and not preempted under *Lohr*, on the ground that the design-related requirements of Oregon's strict products liability scheme are not device-specific); *Ramirez*, 2013 U.S. Dist. LEXIS 118822 at *54-55 (finding a defective design claim premised on an off-label application of the Infuse device not preempted on the ground that the FDA did not determine that the Infuse device was not defectively designed as to intended off-label applications of the device). Because recognition of the design defect claim would tend to undermine the federal medical device regulatory scheme, the claim is preempted, and Medtronic's motion is granted as to Alton's strict products liability claim for defective design.

iii. Strict Products Liability for Misrepresentation

Alton's strict liability claim for misrepresentation is premised chiefly on the allegations that Medtronic affirmatively misrepresented the risks associated with PLIF surgeries using the bone-protein component of the Infuse device with the intention of inducing physicians to use the device for such surgery in reliance on Medtronic's misrepresentations. *See* Complaint, ¶¶ 312-316. It is not clear to me whether these allegations are sufficient to state a claim under Oregon's strict products liability scheme that is meaningfully distinguishable from Alton's strict products liability claim for failure to warn, discussed above, and the parties have not briefed this issue. However, Medtronic does not move to dismiss the misrepresentation claim on any grounds other than preemption, so for purposes of this analysis, I assume that the claim is cognizable under Oregon law as pled. In any event, it is clear that, to the extent the claim is so cognizable, it is not

premised on Medtronic's alleged violation of its obligations under the FDCA, and is therefore not impliedly preempted under *Buckman*. *See Buckman*, 531 U.S. at 348.

Assuming that the misrepresentation claim is cognizable under Oregon's strict products liability law, the claim is also not expressly preempted under Section 360k(a), for the same reasons discussed above in connection with Alton's fraud claim. That is, because the FDCA does not purport to regulate medical device manufacturers' representations regarding off-label applications of approved medical devices, recognition of Alton's misrepresentation claim – premised as it is on Medtronic's alleged affirmative misrepresentations regarding off-label applications of the Infuse device – would not present any risk of interference with the federal medical-device regulatory scheme, and would not constitute imposition of any state-law requirement different from or in addition to the FDA-mandated requirements. *See Lohr*, 518 U.S. at 501-502, 508 (Breyer, J., concurring in part and concurring in the judgment); *Stengel*, 704 F.3d at 1229. Medtronic's motion to dismiss is therefore denied as to Alton's strict products liability claim for misrepresentation.

c. Products Liability for Negligence

Alton's products liability claim sounding in negligence is chiefly premised on the allegations that, in light of Medtronic's affirmative promotion of off-label applications of the Infuse device, it was foreseeable that Alton's physicians would use the device in a promoted off-label manner, that Medtronic's knowledge of the risks associated with such off-label applications of its device gave rise to a "special relationship" between Medtronic and Alton as a result of which Medtronic owed Alton duties to disclose the risks associated with such applications of which it was aware and to exercise reasonable care in preventing the device from creating an

unreasonable risk of harm to Alton, and that Medtronic violated these duties. *See* Complaint, ¶¶ 325-331. These allegations are sufficient to state a cause of action for negligence under Oregon law. *See*, *e.g.*, *Fazzolari v. Portland School Dist.*, 303 Or. 1, 4-7, 17 (1987) (describing elements of cause of action for negligence under Oregon law); *Two v. Fujitec Am., Inc.*, 256 Or. App. 784, 794 (2013) ("A 'product liability civil action' can include both negligence and strict liability claims within its scope"), *citing Mason*, 226 Or. App. at 397. The negligence claim is therefore not impliedly preempted under *Buckman*. *See Buckman*, 531 U.S. at 348.

For the same reasons discussed above in connection with Alton's fraud and failure to warn claims, the negligence claim is a parallel claim escaping express preemption under Section 360k(a), to the same extent as is the failure to warn claim. That is, because the FDCA does not purport to regulate manufacturers' communications regarding off-label applications of PMA-approved devices, to the extent that recognition of the negligence claim would not constitute *de facto* imposition of any state-law requirement on a device different from or in addition to those requirements imposed by the FDA, the claim is not preempted. As was the case in connection with Alton's failure to warn claim, nothing in Alton's pleading suggests that his theory of Medtronic's breach of its alleged duties to him would implicate any such state-law requirement. In consequence, Medtronic's motion to dismiss is denied as to Alton's negligence claim, with the proviso that Medtronic shall not be prejudiced in its ability to raise this issue anew at a later stage of these proceedings, should it become apparent that Alton's theory of Medtronic's liability could risk interference with the federal medical device regulatory scheme.

d. Breach of Express Warranty

Alton's breach of express warranty claim is premised chiefly on the allegation that in the

course of its voluntary communications with physicians and the public regarding off-label applications of the infuse device, Medtronic expressly warranted the safety and efficacy of the device for those applications, including PLIF surgery using only the bone-protein component of the device, with the knowledge that the device was not safe and effective for such application. *See* Complaint, ¶¶ 339-342. Alton's allegations are sufficient to state a claim for breach of express warranty under Oregon law. *See Larrison v. Moving Floors*, 127 Or. App. 720, 724 (1994). The breach of express warranty claim is therefore not impliedly preempted under *Buckman*. *See Buckman*, 531 U.S. at 348.

If Alton's breach of express warranty claim were premised on any statements made in the FDA-mandated labeling of the Infuse device, the claim would be preempted. Here, however, Alton's warranty claim is premised solely on Medtronic's alleged voluntary statements to the public and to the medical community regarding the safety and efficacy of off-label applications of the device, which statements are not subject to FDA regulation. In consequence, recognition of Alton's breach of express warranty claim presents no risk of interference with the federal medical device regulatory scheme, and the claim escapes express preemption under Section 360k(a). *See Lohr*, 518 U.S. at 501-502, 508 (Breyer, J., concurring in part and concurring in the judgment); *Stengel*, 704 F.3d at 1229; *see also Mears*, 149 Or. App. at 659 (finding a breach of express warranty claim cognizable under Oregon law and not preempted under *Lohr*). Medtronic's motion to dismiss (to the extent argued on preemption grounds) is therefore denied as to Alton's breach of express warranty claim.

B. Restatement of Torts Section 402A, Comment k

As noted above, in addition to arguing that Alton's strict products liability claim for

defective design is preempted under the FDCA as amended by the MDA, Medtronic argues that the defective design claim is barred under Restatement of Torts Section 402A, Comment k. Because I find that the claim is expressly preempted under the FDCA, *see supra*, I decline to address Medtronic's argument based on Section 402A, Comment k.

C. Disclaimer of Express Warranties

As noted above, in addition to arguing that Alton's breach of express warranty claim is preempted under the FDCA as amended by the MDA, Medtronic argues that the warranty claim necessarily fails as a matter of law because its FDA-mandated labeling for the Infuse device expressly disclaimed the existence or enforceability of any express warranties. However, Alton's warranty claim is not premised on any warranty set forth in the Infuse labeling or in connection with any FDA-approved application of the Infuse device, but rather on alleged express warranties made to the medical community regarding the safety of non-approved applications of the protein component of the Infuse device. In the event Alton were able to establish the truth of his allegations, any express warranty offered by Medtronic in the course of its voluntary statements to the public and to the medical community regarding off-label applications of the device would not be within the scope of the disclaimer contained in the FDA-mandated labeling. Medtronic's motion to dismiss is therefore denied to the extent premised on that disclaimer.

D. Particularity of Pleading

As noted above, in addition to arguing that Alton's fraud claim is preempted under the FDCA as amended by the MDA, Medtronic argues that the claim is subject to dismissal as having been pled without the particularity requisite under federal procedural law to such claims. Under Oregon law, the elements of a fraud claim are:

> (1) a representation; (2) its falsity; (3) its materiality; (4) the speaker's knowledge of its falsity or ignorance of its truth; (5) his intent that it should be acted on by the person and in the manner reasonably contemplated; (6) the hearer's ignorance of its falsity; (7) his reliance on its truth; (8) his right to rely thereon; and (9) his consequent and proximate injury.

Webb, 274 Or. at 391; *Johnsen v. Mel-Ken Motors*, 134 Or. App. 81, 89 (1995). Federal Civil Procedure Rule 9(b) provides, in relevant part, that "[i]n alleging fraud or mistake, a party must state with particularity the circumstances constituting fraud or mistake. Malice, intent, knowledge, and other conditions of a person's mind may be alleged generally." Fed. R. Civ. P. 9(b). When sitting in diversity, this court applies state law as to the elements of a plaintiff's fraud claim, but applies federal law as to how such elements must be pled:

> It is established law, in this circuit and elsewhere, that Rule 9(b)'s particularity requirement applies to state-law causes of action. While a federal court will examine state law to determine whether the elements of fraud have been pled sufficiently to state a cause of action, the Rule 9(b) requirement that the circumstances of the fraud must be stated with particularity is a federally imposed rule.

Vess v. Ciba-Geigy Corp. USA, 317 F.3d 1097, 1103 (9th Cir. 2003) (citations, internal quotation marks omitted)

The Rule 9(b) particularity requirement is satisfied if the pleading "identifies the circumstances constituting fraud . . . so that the defendant can prepare an adequate answer from the allegations." *Moore v. Kayport Package Express, Inc.*, 885 F.2d 531, 540 (9th Cir. 1989). That is, the allegations must be sufficiently specific "to give defendants notice of the particular misconduct which is alleged to constitute the fraud . . . so that they can defend against the charge and not just deny that they have done anything wrong." *Semegen v. Weidener*, 780 F.2d 727, 731 (9th Cir. 1985).

Medtronic argues for dismissal of Alton's fraud claim for failure to comply with the requirements of Rule 9(b). However, analysis of Alton's supporting allegations establishes that the claim is pled with adequate particularity. The details of Alton's allegations that Medtronic fraudulently concealed the health risks associated with off-label applications of Infuse, and specifically with PLIF surgery using only the bone-protein component of the Infuse device, are pled with voluminous particularity. *See* Complaint ¶¶ 23-38, 78-125, 131-140, 166-216, 267-268. Medtronic is on sufficient notice of the particular misconduct alleged to have constituted fraud to permit it to litigate its defense. Medtronic's motion to dismiss is denied to the extent premised on lack of particularity in the pleading of Alton's fraud claim.

CONCLUSION

For the reasons set forth above, Medtronic's motion (#23) and Alton's motion (#26) for judicial notice are each granted as discussed above, and Medtronic's motion (#19) to dismiss is granted as to Alton's strict products liability claim for defective design and otherwise denied, as discussed above. Alton's strict products liability claim for defective design is accordingly dismissed as preempted under the federal Food Drug and Cosmetics Act.

Dated this 6th day of September, 2013.

/s/ Paul Papak
Honorable Paul Papak
United States Magistrate Judge