UNITED STATES COURT OF APPEALS
FOR THE SECOND CIRCUIT

SUMMARY ORDER

Rulings by summary order do not have precedential effect. Citation to a summary order filed on or after January 1, 2007, is permitted and is governed by Federal Rule of Appellate Procedure 32.1 and this Court's Local Rule 32.1.1. When citing a summary order in a document filed with this Court, a party must cite either the Federal Appendix or an electronic database (with the notation "summary order"). A party citing a summary order must serve a copy of it on any party not represented by counsel.

At a stated term of the United States Court of Appeals for the Second Circuit, held at the Thurgood Marshall United States Courthouse, 40 Foley Square, in the City of New York, on the 9th day of June, two thousand fifteen.

PRESENT: JOSÉ A. CABRANES,
REENA RAGGI,
DENNY CHIN,
Circuit Judges.

KOLEEN OTIS-WISHER,

Plaintiff-Appellant,

v.

MEDTRONIC, INC., METRONIC SOFAMOR DANEK USA, INC.,

No. 14-3491

Defendants-Appellees,

FLETCHER ALLEN HEALTH CARE, INC., AKA FLETCHER ALLEN HEALTH CARE,

Defendant.

FOR PLAINTIFF-APPELLANT: MICHAEL GANNON (Carey C. Rose, *on the brief*), Affolter Gannon & Rose, Essex Junction, VT.

FOR DEFENDANTS-APPELLEES: ANDREW E. TAUBER (Scott M. Noveck, *on the brief*), Mayer Brown LLP, Washington, DC.

Appeal from an August 19, 2014 judgment of the United States District Court for the District of Vermont (J. Garvan Murtha, *Judge*).

UPON DUE CONSIDERATION WHEREOF, IT IS HEREBY ORDERED, ADJUDGED, AND DECREED that the judgment of the District Court be and hereby is **AFFIRMED**.

Plaintiff-Appellant Koleen Otis-Wisher appeals from an August 19, 2014 judgment of the district court finalizing the June 25, 2013 order granting the motion to dismiss brought by defendants Medtronic, Inc. and Sofamor Danek USA, Inc. (collectively, "Medtronic"). *See Otis-Wisher v. Fletcher Allen Health Care, Inc.*, 951 F. Supp. 2d 592 (D. Vt. 2013). This action arose out of consequences of plaintiff's spinal surgery, in which the treating surgeon utilized Infuse, a Medtronic product approved by the U.S. Food and Drug Administration ("FDA") to augment bone fusion. After the surgery, plaintiff suffered excess bone growth and related pain, movement limitations, voice issues, and difficulty swallowing. Plaintiff brought eight claims against Medtronic for fraudulent misrepresentation, constructive fraud, consumer fraud, negligence, negligent misrepresentation, strict-liability design defect, manufacturing defect, and failure to warn. We assume the parties' familiarity with the underlying facts, the procedural history of the case, and the issues on appeal.

We review *de novo* a district court's dismissal of a complaint pursuant to Federal Rule of Civil Procedure 12(b)(6), accepting as true all factual allegations and drawing all reasonable inferences in the plaintiff's favor. *Carpenters Pension Trust Fund v. Barclays PLC*, 750 F.3d 227, 232 (2d Cir. 2014). To survive a motion to dismiss, the complaint must plead "enough facts to state a claim to relief that is plausible on its face," *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 570 (2007), and "allow[ ] the court to draw the reasonable inference that the defendant is liable for the misconduct alleged," *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009).

Upon *de novo* review of the record on appeal and upon consideration of the arguments advanced by the parties, we affirm the District Court's dismissal.

The federal regulatory regime created by the Medical Device Amendments to the Federal Food, Drug, & Cosmetic Act, 21 U.S.C. § 301 *et seq.*, explicitly preempts any state law requirements "with respect to a device" that "relate[ ] to the safety or effectiveness of the device or to any other matter" governed by the statute and that are "different from, or in addition to" the requirements of

federal law imposed by the FDA. 21 U.S.C. § 360k(a). Common law claims, such as these, challenging the safety of an FDA-approved medical device may survive preemption only if they constitute so-called "parallel" claims, such as claims "premised on a violation of FDA regulations" where state law provides a damages remedy for such violations. *Riegel v. Medtronic, Inc.*, 552 U.S. 312, 330 (2008). The Supreme Court instructs that a state law claim must be "identical" to an existing federal requirement for such a claim to survive § 360k preemption. *Medtronic, Inc. v. Lohr*, 518 U.S. 470, 495 (1996).

Plaintiff's claims for strict liability failure to warn, strict liability design defect, and negligent failure to warn all seek to impose safety-related requirements on the device or its labeling beyond those imposed by the FDA. Accordingly, these claims are expressly preempted under § 360k(a). *See Riegel*, 552 U.S. at 321–30. To the extent her claim for strict liability manufacturing defect is not preempted, *see Riegel v. Medtronic, Inc.*, 451 F.3d 104, 122–24 (2d Cir. 2006), *aff'd on other grounds*, 552 U.S. 312, her assertion of a manufacturing defect is wholly conclusory and, therefore, must be dismissed for failure to state a plausible claim grounded in fact, *see Iqbal*, 556 U.S. at 678.[1] We need not decide whether plaintiff's fraud claims—premised on allegedly misleading off-label promotion—are preempted, because, like the district court, we conclude that these claims are not pleaded with the particularity required under Federal Rule of Civil Procedure 9(b). *See Fin. Guar. Ins. Co. v. Putnam Advisory Co.*, 783 F.3d 395, 403 (2d Cir. 2015).[2]

We also affirm the District Court's dismissal of plaintiff's claim brought pursuant to the Vermont Consumer Protection Act (previously the Vermont Consumer Fraud Act), which defines a "consumer" as a "person who purchases, leases, contracts for, or otherwise agrees to pay consideration for goods or services . . . for his or her use or benefit or the use or benefit of a member of his or her household." Vt. Stat. Ann. tit. 9, § 2451a(a). Plaintiff did not constitute a "consumer" under the statute because she did not, for her personal use, purchase Infuse, which in any event is not available for consumer purchase, but rather was prescribed the medical device by her doctor. Though Vermont has apparently not addressed this issue in the specific context of medical devices, the District Court's ruling here is consistent with that of courts in other jurisdictions interpreting similar consumer protection laws. *See* Appellee's Br. at 63-64 n.24 (collecting cases).

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[1] We "may affirm the district court's judgment on any ground appearing in the record, even if the ground is different from the one relied on by the district court." *Doninger v. Niehoff*, 527 F.3d 41, 50 n.2 (2d Cir. 2008) (internal quotation marks omitted).

[2] The weight of authority both in this Circuit and elsewhere casts doubts on the viability of such claims. *See, e.g.*, *Caplinger v. Medtronic, Inc.*, 784 F.3d 1335, 1341-45 (10th Cir. 2015) (finding no federal regulation that paralleled state common law claims and further concluding that state law off-label promotion claim was preempted by § 360k); *United States v. Caronia*, 703 F.3d 149, 162 (2d Cir. 2012) ("[T]he FDCA itself does not expressly prohibit or criminalize off-label promotion."); *In re Zyprexa Prods. Liab. Litig.*, Nos. 04-MD-1596, 07-CV-1933 (JBW), 2008 WL 398378, at *5 (E.D.N.Y. Feb. 12, 2008) ("[T]here is no state-law equivalent of 'off-label.'").

CONCLUSION

We have considered all of the remaining arguments raised by plaintiff on appeal and find them to be without merit. For the foregoing reasons, we **AFFIRM** the judgment of the District Court.

FOR THE COURT:
Catherine O'Hagan Wolfe, Clerk