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October 10, 2014

BY CM/ECF

Elisabeth A. Shumaker, Clerk
United States Court of Appeals
for the Tenth Circuit
Byron White United States Courthouse
1823 Stout Street
Denver, CO 80257
(303) 844-3157

Re: *Caplinger v. Medtronic, Inc.*, No. 13-6061 (argued Jan. 23, 2014)

Dear Ms. Shumaker:

Medtronic hereby responds to Caplinger's letter regarding *McCormick v. Medtronic, Inc.*, 2014 WL 4976166 (Md. Ct. Spec. App. 2014). *McCormick* does not help Caplinger.

Relying (Reply 2, 9-13) on *Ramirez v. Medtronic, Inc.*, 961 F.Supp.2d 977 (D. Ariz. 2013), Caplinger's principal—but mistaken (Medtronic Br. 19-27)—argument on appeal is that § 360k(a) is inapplicable to claims arising from alleged off-label promotion. But *McCormick* “join[s] the many courts that have rejected *Ramirez*,” which “has been almost universally rejected.” 2014 WL 4976166, at *12 n.13; *accord, e.g., Martin v. Medtronic, Inc.*, 2014 WL 3635292, at *6 (D. Ariz. 2014).

Although *McCormick* found that the plaintiffs' misrepresentation claims survive preemption, it held that they were properly dismissed for failure to plead with particularity. That holding applies here (Medtronic Br. 58-65), where Caplinger's 37-page, 155-paragraph complaint contains no greater particularity than the 45-page, 149-paragraph complaint dismissed in *McCormick*.

That *McCormick* gave the plaintiffs there an opportunity to replead their misrepresentation claims is irrelevant, because this Court lacks jurisdiction to grant such relief. Caplinger's notice of appeal was filed before her motion for leave to amend was denied. JA4. Because Caplinger never filed a new or amended notice of appeal after her motion for leave to amend was denied, that denial is not before this Court. *Coll v. First Am. Title Ins. Co.*, 642 F.3d 876, 884-86 (10th Cir. 2011).

That *McCormick* (given Maryland law) considered only claims predicated on misrepresentations rather than omissions is immaterial, because any “fraud by omission claim is expressly preempted by § 360k(a).” *Perez v. Nidek Co.*, 711 F.3d 1109, 1118 (9th Cir. 2013);

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accord Schouest v. Medtronic, Inc., 2014 WL 1213243, at *5 (S.D. Tex. 2014); *Littlebear v. Advanced Bionics, LLC*, 896 F.Supp.2d 1085, 1091 (N.D. Okla. 2012).

McCormick's conclusion that an express-warranty claim implicating the safety or effectiveness of a device with premarket approval escapes preemption is erroneous (Medtronic Br. 54) and contrary to *Bryant v. Medtronic, Inc.*, 623 F.3d 1200, 1208 (8th Cir. 2010), which holds that such a claim “interferes with the FDA’s regulation of Class III medical devices and is therefore conflict preempted.”

Sincerely,

/s/ Andrew E. Tauber

Andrew E. Tauber
Counsel for Defendants-Appellees
Medtronic, Inc. and Medtronic Sofamor Danek USA, Inc.

cc: All Counsel

CERTIFICATE OF FILING AND SERVICE

I certify that on October 10, 2014, I electronically filed the foregoing using the Court's CM/ECF system, which will serve copies on all parties or their counsel of record.

s/ Andrew E. Tauber

Andrew E. Tauber
Counsel for Defendants-Appellees

CERTIFICATE OF DIGITAL SUBMISSION

I hereby certify that with respect to the foregoing:

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s/ Andrew E. Tauber
Andrew E. Tauber
Counsel for Defendants-Appellees