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May 30, 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 responds to Caplinger's letter regarding the Solicitor General's brief in *Stengel*.[1]

Caplinger's reliance on the Ninth Circuit's decision in *Stengel*—which endorsed a failure-to-warn claim based on a federal duty to report adverse events to the FDA—is misplaced. Caplinger waived any such claim. Medtronic Br. 36-38. And while the Solicitor General erroneously believes that *another* type of failure-to-warn claim, one the Ninth Circuit held expressly preempted, could survive 21 U.S.C. § 360k(a), he recognizes that the claim endorsed in *Stengel* might be expressly preempted, because the state duty to warn and the federal duty to report adverse events might not be "'*genuinely* equivalent'" (SG Br. 14)—as Medtronic argues. Medtronic Br. 38-40. He also recognizes that such claims "implicate some of the concerns recognized in *Buckman*," and thus may be impliedly preempted under 21 U.S.C. § 337(a) (SG Br. 22)—as Medtronic argues. Medtronic Br. 49-54.

Although the Solicitor General wants express preemption to apply only when there are device-specific requirements on "the same subject" as the plaintiff's claim (SG Br. 10-12), he concedes that his position conflicts with *every* federal appellate decision in "every case since *Riegel*." SG Br. 15-16. His position is wrong for the same reason Caplinger's is wrong: It disregards the text of the statute, which preempts "*any* [state] requirement which is different from, or in addition to, *any* [federal] requirement … which relates to … safety or effectiveness." 21 U.S.C. § 360k(a) (emphasis added); *see* Medtronic Br. 22-27. Because premarket approval

[1] We doubt that the brief—advocacy by the current administration—is "supplemental authorit[y]" under Rule 28(j). Given its unexplained departure from positions taken under previous administrations—*cf.* U.S. Br., *Riegel v. Medtronic, Inc.*, 552 U.S. 312 (2008), 2007 WL 3231418; U.S. Br., *Warner-Lambert Co. v. Kent*, 552 U.S. 440 (2008), 2007 WL 4218889—it is owed no deference. *Comm'r v. Schleier*, 515 U.S. 323, 334 n.7 (1995).

established federal requirements "which relate[] to the safety or effectiveness" of Infuse, Caplinger cannot impose any additional *safety or effectiveness* requirements through state law, regardless how she characterizes their "subject." *Cf.* Medtronic Br. 54-56.

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 May 30, 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

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