PUBLIC CITIZEN LITIGATION GROUP
1600 20th Street NW • Washington DC 20009
202/588-1000 • www.citizen.org

October 8, 2014

Clerk
United States Court of Appeals
for the Tenth Circuit
Byron White Courthouse
1823 Stout Street
Denver, Colorado 80257

Re: *Patricia Caplinger v. Medtronic, Inc.*, No. 13-6061

Dear Clerk:

Pursuant to Federal Rule of Appellate Procedure 28(j), I am writing to inform the Court of pertinent new authority.

On October 7, the Court of Special Appeals of Maryland decided *McCormick v. Medtronic*, a case involving the same medical device as this case. *McCormick* addresses whether state-law tort claims are preempted by the Medical Device Amendments (MDA). The trial court, "relying exclusively on" the district court decision in *Caplinger*, had dismissed the plaintiffs' claims. The appellate court reversed in substantial part. Slip op. 8.

The court began by holding that "the MDA does not expressly preempt state-law claims that are based on a violation of the federal prohibition of false or misleading off-label promotion." *Id.* 27.

Turning to specific claims, the court held that the MDA "does not … preempt claims concerning the misrepresentations that Medtronic allegedly made in voluntary communications with the medical profession or the public." *Id.* 29. Therefore, negligent misrepresentation and fraud claims were not preempted. *Id.* 30.

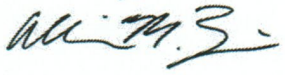
Although the court found that a negligence claim challenging the adequacy of FDA-approved labeling would be expressly preempted, and that one "solely

concern[ing] a failure to disclose material facts" to the FDA would be impliedly preempted, *id.* 31-32, the negligence claim was not preempted insofar as it rested on "failure to disclose material facts concerning the device and … to 'fully disclose' the results of testing on the device, provided that those omissions occurred in the context of off-label promotion and that the omitted facts were necessary to make Medtronic's other statements not misleading." *Id.* 32. Thus, the negligent failure-to-warn claim was not preempted to the extent it was based on "failure to disclose material facts that were necessary to make Medtronic's other statements not misleading in the context of off-label promotion." *Id.* 34.

The court held strict products liability claims preempted in some respects and not others. *Id.* 35-39. Disagreeing with the district court here, the court held federal law does not preempt claims for breach of express warranties that Medtronic made in voluntary communications, apart from the FDA-approved labeling. *Id.* 38-39.

The opinion is attached.

Sincerely,



Allison M. Zieve
Counsel for Patricia Caplinger

Cc: All counsel