

United States Senate

COMMITTEE ON FINANCE

WASHINGTON, DC 20510-6200

October 16, 2007

Via Electronic Transmission

The Honorable Andrew C. von Eschenbach, M.D.
Commissioner
U.S. Food and Drug Administration
5600 Fishers Lane
Rockville, MD 20857

Dear Commissioner von Eschenbach:

The United States Senate Committee on Finance (Committee) has jurisdiction over the Medicare and Medicaid programs. Accordingly, the Committee has a responsibility to the more than 80 million Americans who receive health care coverage under Medicare and Medicaid to oversee the proper administration of these programs, including the payment for medical devices regulated by the Food and Drug Administration (FDA or Agency).

On Monday, October 15, Medtronic Inc. (Medtronic) suspended distribution of its Sprint Fidelis defibrillation leads, which connect implantable defibrillators to patients' hearts, because of the potential for lead fractures. Such fractures can result in unnecessary shocks or loss of output. According to Medtronic's press release, these lead fractures may have contributed to the death of five patients.

As you may be aware, about two years ago, I initiated an inquiry into the recalls of Guidant Corporation's (Guidant) implantable cardioverter defibrillators (ICDs) and allegations that Guidant had kept quiet about the serious malfunctions of some of its ICDs. I am concerned that action may not have been taken in a timely fashion in this case as well. It appears that Medtronic was aware of the potential lead fractures several months before suspending sales of the Sprint Fidelis defibrillation leads.

Accordingly, I am requesting that FDA arrange a briefing for my Committee Staff by no later than October 31, 2007, to discuss the events leading to Medtronic's suspension of distribution of the leads and FDA's actions related to this matter.

Thank you for your immediate attention to this important matter. Any questions or concerns should be directed to Angela Choy or Paul Thacker, at (202) 224-4515. All formal correspondence should be sent via electronic transmission in PDF format to brian_downey@finance-rep.senate.gov or via facsimile to (202) 228-2131 and original by U.S. mail.

Sincerely,

A handwritten signature in blue ink that reads "Chuck Grassley". The signature is written in a cursive style with a prominent loop at the end of the last name.

Charles E. Grassley
Ranking Member