U.S. SENATE COMMITTEE ON
Finance
SENATOR CHUCK GRASSLEY, OF IOWA - CHAIRMAN
http://finance.senate.gov

For Immediate Release
Thursday, September 22, 2005

Grassley takes questions directly to medical device manufacturer

WASHINGTON — Sen. Chuck Grassley is asking the Guidant Corporation for information about the way it has complied with agreements it made with the federal government in order to continue doing business with the federal government after one of its subsidiaries settled criminal and civil charges two years ago.

"Taxpayers spend a lot of money through the Medicare and Medicaid programs for medical devices, so I have a responsibility to make sure these products are safe and that the federal agency charged with reviewing their safety is doing its job," Grassley said. "National health care programs shouldn't have to rely on a three strikes and you're out program when lives are at stake."

In recent months, Grassley asked for information from the Food and Drug Administration about its review of medical devices manufactured by the Guidant Corporation. His review of the FDA's regulatory work with regard to these products is ongoing.

Here is the text of the letter Grassley sent today. Previous correspondence can be found at http://finance.senate.gov/press/Gpress/2005/prg091505.pdf.

September 22, 2005

James M. Cornelius
Chairman of the Board
and
Ronald W. Dollens
President and Chief Executive Officer
Guidant Corporation
111 Monument Circle, #2900
Indianapolis, IN 46204-5129

Dear Mr. Cornelius and Mr. Dollens:

The Committee on Finance (Committee) has jurisdiction over the Medicare and Medicaid programs, among other matters. Accordingly, the Committee is responsible to the more than 80 million Americans who receive health care coverage under those programs, including payment for medical devices.

The Food and Drug Administration (FDA) is evaluating the safety and performance of certain implantable defibrillators and pacemakers manufactured by Guidant Corporation (Guidant). Today, Guidant issued another round of warnings to physicians and patients relating to 40 models of implantable pacemakers. This recall comes on the heels of Guidant recalling numerous other models of implantable pacemakers and defibrillators. In recent months, the FDA has classified three Guidant defibrillators as a Class I recall and eight others as a Class II recall. In addition, the FDA classified several models of Guidant pacemakers as a Class I recall.

According to the FDA, a Class I recall means there is a reasonable probability that if a particular device is malfunctioning, the malfunctioning device will cause serious adverse health consequences or death. For a Class II recall, the malfunctioning product may cause temporary or medically reversible adverse health consequences, however, the probability of serious adverse health consequences is remote.

On August 18, 2005, the FDA briefed Committee investigators regarding the aforementioned cardiac device recalls. During the briefing, my Committee staff were informed that the FDA would begin a "comprehensive on-site inspection" the following week at Guidant's manufacturing facilities. The stated purpose of the inspection was to review Guidant's manufacturing practices and record maintenance. Among other issues, the FDA said it would review the timing and completeness of Guidant's regulatory reports, as well as the mechanisms through which Guidant filed its reports.

As you know, on June 30, 2003, Guidant entered into a Corporate Integrity Agreement (CIA) with the Office of Inspector General (OIG), Department of Health and Human Services. According to the preamble of the CIA, Guidant entered into the CIA "to promote compliance by its officers, directors, employees, contractors, and agents with the statutes, regulations, and written directives of Medicare, Medicaid, Food and Drug Administration ('FDA') compliance regulations and all other Federal health care programs (as defined in 42 U.S.C. § 1320a-7b(f)) ('Federal health care program requirements')."

Among other requirements, the CIA specifies that Guidant shall maintain elements of a compliance program, including the following elements: Compliance Officer and Committee, Written Standards (*i.e.*, Code of Business Conduct and Policies and Procedures), Training and Education, Review Procedures, Disclosure Program, Notification of Government Investigation or Legal Proceedings, and Reporting (*i.e.*, Reportable Events). Further, Guidant's Compliance Officer must certify that Guidant is in compliance with all of the requirements of its CIA.
I write to request Guidant's cooperation with the Committee's investigation into, among other concerns, whether or not Guidant has fully and timely complied with all of its CIA obligations.

As Chairman of the Committee, I request that Guidant produce the following documents and information to the Committee:

1. A copy of Guidant's Implementation Report, as submitted to the OIG, in accordance with CIA sec. V.A.

2. A copy of Guidant's Annual Report(s), as submitted to the OIG to date, in accordance

with CIA sec. V.B.

3. A copy of and/or record of all quarterly reports from Guidant's Chief Compliance Officer to the Board of Directors regarding compliance matters.

4. All copies of certifications retained by the Compliance Officer, in accordance with CIA sec. III.C.3.

5. A copy of the disclosure log maintained by the Compliance Officer, in accordance with CIA sec. III.E.

6. A copy of all written notifications of government investigation or legal proceedings provided by Guidant to the OIG, in accordance with CIA sec. III.G.

7. A copy of all reports submitted by Guidant to the OIG related to reportable events, in accordance with CIA sec. III.H.

8. State whether or not Guidant has maintained all documents and records relating to FDA record keeping requirements, or to compliance with the CIA, in accordance with CIA sec. VIII.

Please produce all documents related to requests 1 and 2 by September 30, 2005, unless copies are available sooner. All documents related to requests 3 through 7 are requested by October 7, 2005, unless copies are available sooner. Given Guidant's CIA reporting obligations, these documents should be readily available for production to the Committee. Responsive documents should be produced and delivered in accordance with the attached general instructions and definitions.

Thank you in advance for providing the name and contact information for a person who will act as Guidant's point of contact for the duration of the Committee's investigation.

Sincerely,

Charles E. Grassley
Chairman