United States Senate
COMMITTEE ON FINANCE
WASHINGTON, DC 20510–6200

July 20, 2005

VIA FACSIMILE: (301) 827-1960
ORIGINAL BY U.S. MAIL

Lester M. Crawford, D.V.M., Ph.D.
Commissioner
U.S. Food and Drug Administration
5600 Fishers Lane
Rockville, MD 20857

Dear Commissioner Crawford:

Today, the *New England Journal of Medicine* (NEJM), published an extremely troubling article, entitled, "The Controversy over Guidant's Implantable Defibrillators." The article lays out the tragic details behind the death of a young college student, Joshua Oukrop, who died with a failed implantable cardioverter-defibrillator (ICD) in his chest. The ICD-a Ventak Prizm 2 DR Model 1861-was manufactured by Guidant Corporation (Guidant) and the failure was reportedly caused by a short circuit. I understand that both the Food and Drug Administration (FDA) and Guidant are investigating Mr. Oukrop's death presently.

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. According to the NEJM, "[i]n 2003, the Centers for Medicare and Medicaid Services paid for 52,500 ICD implantations; in 2004, it paid for 65,000. With expanded coverage, more than 500,000 Medicare beneficiaries may become eligible for an ICD." As Chairman of the Committee, I am greatly concerned about the public health, safety and regulatory issues associated with medical devices in general and the specific details associated with the death of Mr. Oukrup.

Among other troubling matters, the NEJM reports that "[f]or more than three years, Guidant kept quiet about the serious malfunctions of some of its ICDs and continued to sell defective devices after it made the manufacturing changes to fix the defect." The NEJM also states that "[t]he fallout from the potentially preventable death of Joshua Oukrop has triggered a broad discussion about the propriety of Guidant's actions and the safety of ICDs and medical devices in general. It has also led to debate about the appropriate standards for informing physicians and patients about safety issues and the responsibilities of industry, the FDA, and the medical community."

On July 18, 2005, I requested information from FDA related to the ICD involved with the death of Joshua Oukrop. I asked you why important device performance information reported to the FDA by device manufacturers, and specifically for pacemakers and defibrillators, was not publicly available to patients, health care providers and the scientific community. That same day the Institute of Medicine released a report entitled, *Safe Medical Devices for Children*. This report exposes a fissure in the FDA's safety mission when it comes to surveillance of medical devices for children. It documents how the FDA is neither properly monitoring postmarket studies nor making important postmarket research publicly available. Dr. Crawford, these are the same kinds of problems we've seen with the postmarket review of medicines, as well as with medical devices used for adults. The Institute of Medicine spells out remedies that should be pursued to better protect children who rely on FDA approved medical devices.

It is the shared responsibility of the medical device industry, the FDA, the medical community and Congress, to address the safety issues associated with medical devices. The NEJM reports that the Heart Rhythm Society, a professional association of arrythmia specialists, plans to develop guidelines regarding ICD recalls, manufacturer-notification standards, and when to replace devices. In addition, Guidant is apparently establishing its own panel of experts to recommend guidelines for disseminating information. Please state whether the FDA is reexamining its regulations and procedures for device surveillance. In addition, describe in detail what action the FDA will take, if any, to address both the IOM's report and the safety of ICDs and medical devices in general. Finally, I request that the FDA provide my Committee staff with a detailed briefing on the regulatory history of Guidant's Ventak Prizm 2 DR Model 1861, as well as a status report regarding all investigation(s) associated with the death of Mr. Oukrop, in addition to the information requested in my letter dated July 18, 2005.

Thank you in advance for having your staff coordinate with my staff about this letter by July 22, 2005. I would appreciate your response by August 8, 2005, unless it is available sooner. Any questions or concerns should be directed to . All formal correspondence should be sent via facsimile to and original by U.S. mail. Please do not hesitate to contact me if you have any concerns.

Sincerely,

Charles E. Grassley
Chairman