For Immediate Release
Wednesday, September 23, 2009

Grassley works to improve medical device safety

WASHINGTON --- Senator Chuck Grassley said it was good news that the Food and Drug Administration has commissioned the Institute of Medicine to examine the agency's 510(k) system for clearing medical devices.

The 501(k) system is used for reviewing most devices approved by the agency. It is less stringent than FDA's premarket approval process used in reviewing high risk devices, such as implantable defibrillators and pacemakers.

A provision requiring the FDA to commission a study was included in legislation introduced last April by Grassley and the late Senator Ted Kennedy. Their bill, the Drug and Device Accountability Act (S.882), would give the FDA more resources to inspect domestic and foreign manufacturers of prescription drugs and devices.

"A study by the well regarded Institute of Medicine will provide valuable information to improve the FDA's review of medical devices. Questions have been raised about the agency's work in this area," Grassley said.

A January 2009 report of the Government Accountability Office detailing concerns about the FDA's review process for medical devices is attached.

Grassley has conducted active oversight of the FDA during the last five years. He's advocated greater independence in post-market surveillance and sought greater transparency and accountability in the drug and device approval process.

Here is the section of S.882 that called for the study:

SEC. 143. STUDY BY THE INSTITUTE OF MEDICINE REGARDING THE REVIEW OF MEDICAL DEVICES.

(a) In General- The Secretary of Health and Human Services shall enter into a contract with the Institute of Medicine to conduct a study to--

(1) evaluate the organizational structure and operations of the Food and Drug Administration with respect to the review of medical devices for clearance under section 510(k) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360(k)) and for premarket approval under section 515 of such Act (21 U.S.C. 360e);
(2) evaluate the analytical and methodological tools used by such Administration to conduct such reviews; and
(3) identify strengths, weaknesses, and limitations of the system used by such Administration to conduct such reviews.

(b) Report- Not later than September 31, 2010, the Institute of Medicine shall complete the study described under subsection (a) and submit to the Secretary of Health and Human Services, the Committee on Health, Education, Labor, and Pensions and the

Committee on Finance of the Senate, and the Committee on Energy and Commerce of the House of Representatives a report that--

(1) describes the findings of such study; and

(2) makes recommendations regarding the organization structure and operations of the Food and Drug Administration, legislation, and regulation to improve or enhance the review of medical devices by such Administration.

Here is a copy of the FDA's announcement about the study being commissioned:

FDA NEWS RELEASE

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FDA: Institute of Medicine to Study Premarket Clearance Process for Medical Devices

The U.S. Food and Drug Administration today announced that it has commissioned the Institute of Medicine (IOM) to study the premarket notification program used to review and clear certain medical devices marketed in the United States.

The IOM study will examine the premarket notification program, also called the 510(k) process, for medical devices. While the IOM study is underway, the FDA's Center for Devices and Radiological Health (CDRH) will convene its own internal working group to evaluate and improve the consistency of FDA decision making in the 510(k) process.

"Good government conducts periodic reviews and evaluations of its programs," said Jeffrey Shuren, M.D., acting director of CDRH. "Our working group and the IOM's independent evaluation will help us determine how the 510(k) process can be improved to better support FDA's mission to protect and promote the public health."

The 510(k) process was established under the Medical Device Amendments of 1976 with two goals:

- Make safe and effective devices available to consumers
- Promote innovation in the medical device industry.

During the past three decades, technology and the medical device industry have changed dramatically, making it an appropriate time for CDRH to review the adequacy of the premarket notification program in meeting these two goals.

Established by the National Academy of Sciences, the IOM provides independent, objective, evidence-based advice to policymakers, health professionals, the private sector, and the public.

As part of the study, the IOM will convene a committee to answer two principal questions:

- Does the current 510(k) process optimally protect patients and promote innovation in support of public health?
- If not, what legislative, regulatory, or administrative changes are recommended to achieve the goals of the 510(k) process?

The $1.3 million IOM review is slated for completion in 2011, and is one of six priorities Dr. Shuren has outlined for CDRH. Others include:

- Creating an internal task force on the use of science in regulatory decision-making
- Developing an effective compliance strategy
- Optimally integrating premarket and postmarket information
- Increasing transparency in decision-making
- Establishing clear procedures to resolve differences of opinion.

The IOM will hold two public workshops during the next nine months as part of its review, and will publish a final report in March 2011 containing its conclusions and recommendations.

The FDA classifies medical devices into three categories according to their level of risk. Class III devices represent the highest level of risk and generally require premarket approval to support their safety and effectiveness before they may be marketed. Class III devices include heart valves and intraocular lenses.

Class I and Class II devices pose lower risks and include devices such as adhesive bandages and wheelchairs. Most Class II devices and some Class I devices can be marketed after submission of premarket notifications—also called 510(k) applications—that support their substantial equivalence to legally marketed devices that do not require premarket approval.

Devices that present a new intended use or include new technology that presents new questions of safety or effectiveness may not be found substantially equivalent and require premarket approval.

For more information Premarket Notification 510(k)
http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/PremarketSubmissions/PremarketNotification510k/default.htm