Dingell, Stupak to Investigate FDA's Medical Device Approval Process

Lawmakers Question Whether FDA Knowingly Allowed Unsafe & Ineffective Medical Devices into U.S. Market

Washington, D.C. – Reps. John D. Dingell (D-MI), Chairman of the Committee on Energy and Commerce, and Bart Stupak (D-MI), Chairman of the Subcommittee on Oversight and Investigations, today launched an investigation into whether managers within the Food and Drug Administration (FDA) Center for Devices and Radiological Health (CDRH) knowingly corrupted the scientific review process and approved or cleared medical device applications in gross violation of laws and regulations designed to assure the safety and effectiveness of medical devices. Such activity could allow potentially unsafe and ineffective medical devices into the U.S. market.

The investigation was prompted by receipt of an October 14, 2008, letter written on behalf of a large group of CDRH scientists and physicians who state that CDRH managers have "corrupted and interfered with the scientific review of medical devices."

"These allegations are deeply concerning, and we intend to uncover whether any FDA activity has compromised the health and safety of America consumers," said Dingell. "I commend the FDA scientists for courageously sounding the alarm on what appears to be a serious problem. I look forward to pursuing the steps necessary to ensure that the medical devices Americans depend on are safe and effective."

"Our investigations have found that the FDA has allowed contaminated food and unsafe drugs to enter the market, and now serious allegations have been raised about the scientific integrity of the FDA medical device approval process," Stupak said. "Although the FDA has launched its own investigation into this matter, no corrective action has been taken. The committee intends to learn what action the FDA plans to take to ensure the integrity of the medical device approval process and prevent retaliation against the scientists who blew the whistle on these activities."

This Committee has been provided with compelling evidence to support the charges that senior managers within CDRH "ordered, intimidated and coerced FDA experts to modify their scientific reviews, conclusions and recommendations in violation of the law." The CDRH scientists also claim that CDRH managers ordered them "to make safety and effectiveness determinations that are not in accordance with scientific regulatory requirements, to use unsound evaluation methods, and accept clinical and technical data that is not scientifically valid or obtained in accordance with legal requirements, such as obtaining proper informed consent from human subjects."

Additionally, documentary evidence reviewed by this Committee indicates that CDRH scientists who raised concerns up their chain of command have experienced reprisals for their insistence on adherence to a scientific and regulatory basis for medical device review. To protect these CDRH scientists who have risked their careers to bring their concerns to the attention of this Committee, we will not disclose their identities at this time.

Since January 2007, the Committee on Energy and Commerce and its Subcommittee on Oversight and Investigations have been investigating the ability and commitment of the Food and Drug Administration to protect Americans from unsafe food, drugs, and medical devices. For more information about the Committee's ongoing drug safety investigation visit:
http://energycommerce.house.gov/Investigations/FDADrugSafety.shtml

During this Congressional session, Committee leaders released draft legislation aimed at improving the safety of food, drugs, devices, and cosmetics. Work in this draft bill, the "Food and Drug Administration Globalization Act," continues. Committee leaders plan to introduce comprehensive legislation early next session. For more information visit:
http://energycommerce.house.gov/FDAGlobalAct-08/index.shtml

In a letter sent today to FDA Commissioner Andrew C. von Eschenbach, Dingell and Stupak requested a briefing on what actions the Commissioner has taken to date and how the Commissioner intends to resolve all issues raised by the CDRH scientists and physicians.

Visit http://energycommerce.house.gov/Press_110/110-ltr-111708.vonEschenbach.CDRH.pdf to read the letter

Prepared by the Committee on Energy and Commerce
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