

Dingell, Stupak Investigating Institutional Review Boards, Questionable Medical Devices

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NEWS RELEASE

Committee on Energy and Commerce

Rep. John D. Dingell, Chairman

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Washington, D.C. — Rep. John D. Dingell (D-MI), Chairman of the Committee on Energy and Commerce, and Rep. Bart Stupak (D-MI), Chairman of the Oversight and Investigations Subcommittee, announced today that their ongoing investigation into Institutional Review Boards (IRBs) will include how IRBs are used for the marketing of questionable medical devices, such as the PAP-IMI and the EPMX device.

“Biomedical research is critical to developing new medical treatments for various diseases. Volunteers in research studies rely on Institutional Review Boards to protect them from undue harm,” Dingell said. “However, it appears that some unscrupulous individuals may have hijacked these protections to market devices which may be harmful and dangerous.”

“It appears that the protections for research volunteers are not only being ignored, but are being manipulated for marketing purposes,” said Stupak. “If IRB approval is being used as a marketing tool, ‘buyer beware’ takes on a whole new meaning. American consumers deserve to be treated better than guinea pigs.”

The two lawmakers wrote to Food and Drug Administration (FDA) Commissioner Andrew von Eschenbach, as well as two private companies that provided IRB approval of a medical device, the PAP-IMI, which the FDA has linked to patient injuries and death. The makers of the PAP-IMI have pointed to the device’s IRB approval as evidence that the device is safe and effective.

In addition to information on the PAP-IMI device, the lawmakers asked the FDA for information on the EPFX device, which is manufactured in Hungary by William Nelson, a fugitive who fled the U.S. in 1996 after he was indicted on felony fraud charges related to his marketing of the EPFX. Nelson continues to distribute the EPFX in the U.S. from Hungary.

Institutional Review Boards formally approve, monitor, and review biomedical and behavioral research involving humans with the alleged aim to protect the rights and welfare of the subjects. The Energy and Commerce Committee opened an investigation into Institutional Review Boards in late summer of this year.

Read letter to the FDA

Read letter to Biomedical Companies

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