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RANKING MEMBER

ONE HUNDRED TWELFTH CONGRESS

Congress of the United States

House of Representatives

COMMITTEE ON ENERGY AND COMMERCE
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WASHINGTON, DC 20515–6115

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October 12, 2011

The Honorable Fred Upton
Chairman
Committee on Energy and Commerce
2125 Rayburn House Office Building
Washington, DC 20515

The Honorable Joseph R. Pitts
Chairman
Subcommittee on Health
2125 Rayburn House Office Building
Washington, DC 20515

The Honorable Cliff Stearns
Chairman
Subcommittee on Oversight and Investigations
2125 Rayburn House Office Building
Washington, DC 20515

Dear Chairman Upton, Chairman Pitts, and Chairman Stearns:

Over the past year, the Committee has held four hearings on FDA regulation of medical devices. These hearings primarily served as forums for critics of the FDA who allege that the FDA regulatory process for devices harms patients and has a negative impact on jobs.[1] Some witnesses have even advocated that we change our standards for clearance and approval, a recommendation not supported by Advamed, a leading association of medical device manufacturers.[2] The hearings have not provided a balanced and accurate picture that fully

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[1] Hearing of Subcommittee on Health, "Impact of Medical Device Regulation on Jobs and Patients" (Feb. 17, 2011); Hearing of Subcommittee on Health, "PDUFA V: Medical Innovation, Jobs and Patients" (July 7, 2011); Hearing of Subcommittee on Oversight and Investigations, "Regulatory Reform Series #5 - FDA Medical Device Regulation: Impact on American Patients, Innovation and Jobs" (July 20, 2011); Field Hearing of Subcommittee on Health, "Impact of Medical Device and Drug Regulation on Innovation, Jobs, and Patients: A Local Perspective." (Sept. 26, 2011).

[2] Advamed, "Advamed Statement on the House Energy and Commerce Subcommittee Hearing on FDA Device Regulation" (July 20, 2011).

reflects the role FDA plays in reviewing device applications; nor have they spoken to the potential dangers posed to patients if medical devices are not appropriately regulated.

As the Committee embarks on the reauthorization of the medical device user fee program, we write to urge that we hold hearings that examine medical devices that have developed serious defects after being implanted in patients. Specifically, we believe that looking further into the "metal-on-metal" hip implants and brain stents, two high-profile devices that appear to have resulted in significant harm to human health, would shed further light on the regulation of medical devices. We believe hearings on these topics would provide important information for members to evaluate in the context of the reauthorization of the medical device user fees.

Both items are examples of devices that were found to be associated with major health problems after being approved or cleared by the FDA. As such, we believe they could provide important lessons about the device clearance and approval process as well as the adequacy of our postmarketing safety system.

Brain Stents

Brain stents were a promising new device designed to open up a blocked artery in the brain following a stroke in the hope of preventing additional strokes. The Wingspan Stent System was approved by the FDA in August of 2005 for patients with a greater than 50% blockage in an artery and whose condition was refractory to medical therapy.[3] The device was approved under a humanitarian device exemption (HDE) application. The HDE process allows a manufacturer to bypass the scrutiny of the full premarket approval process if the device is intended to diagnose or treat a disease or condition that affects fewer than 4,000 people, so long as no other non-HDE device is available to treat that disease or condition. A manufacturer applying under the HDE option must comply with certain conditions, including a general prohibition on profit for the HDE device.[4]

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[3] Letter from Mark N. Melkerson, Acting Director, Division of General, Restorative, and Neurological Devices, Office of Device Evaluation, Center for Devices and Radiological Health, FDA, to Ms. Theresa E. Brandner, Director of Regulatory & Quality, Boston Scientific Smart (Aug. 3, 2005).

[4] FDA, "Humanitarian Device Exemption" (accessed Oct. 2, 2011) (online at http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/PremarketSubmissions/HumanitarianDeviceExemption/default.htm). An HDE application is exempt from the effectiveness requirements of a premarket approval, but must contain sufficient information for FDA to determine that the device does not pose an unreasonable or significant risk of illness or injury, and that the probable benefit to health outweighs the risk of injury or illness from its use.

Under the lesser HDE standard of approval, the Wingspan stent system was approved on the basis of registry data for some 45 patients.[5] A recent trial sponsored by the National Institutes of Health including 451 patients demonstrated that 14.7% of patients with a recent stroke who had a stent implanted had a stroke or died within 30 days, as compared to 5.8% of the patients without a stent and only on medical management—more than double the rate of strokes and deaths within 30 days for patients with a stent.[6] According to press reports, thousands of patients have received this implantable device.[7]

Metal-on-Metal Hip Implants

Metal-on-metal hip implants have also garnered close attention over the past year.[8] Artificial hips replace the ball-and-socket structure of the hip with an artificial ball sitting inside an artificial cup placed into the hip. The artificial hip can be constructed from a variety of materials. "Metal-on-metal hips" refer to hips where both the ball and the cup are made of metal. According to the New York Times, of the estimated 250,000 hip replacements each year, nearly one-third are now metal-on-metal hip implants, and an estimated 500,000 patients have received an all-metal replacement hip.[9]

The devices were cleared under the 510(k) clearance process, meaning that the devices had to demonstrate that they were "substantially equivalent" to one or more devices already on the market. Although clinical data can be required under this clearance process, many submissions are cleared without such data. According to press reports, many of the metal-on-metal hip systems were cleared this way.[10] As of December 31, 2010, FDA had cleared for marketing 175

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[5] FDA, "Summary of Safety and Probable Benefit: Wingspan Stent System with Gateway PTA Balloon Catheter" (accessed Oct. 2, 2011) (online at http://www.accessdata.fda.gov/cdrh_docs/pdf5/H050001b.pdf).
[6] Chimowitz et al., "Stenting versus Aggressive Medical Therapy for Intracranial Arterial Stenosis." New England Journal of Medicine (Sept. 7, 2011).
[7] Kolata, Gina "Study is Ended as a Stent Fails to Stop Strokes" (Sept. 7, 2011).
[8] Meier, Barry. "Concerns Over 'Metal-on-Metal' Hip Implants," New York Times (Mar. 3, 2010); Meier, Barry. "As Use of Metal-on-Metal Hip Implants Grows, Studies Raise Concerns," New York Times (Mar. 3, 2010); Meier, Barry. "Hip Makers Told to Study More Data," New York Times (May 10, 2011); Meier, Barry. "In Medicine, New Isn't Always Improved," New York Times (June 25, 2011); Meier, Barry and Roberts, Janet. "Hip Implant Complaints Surge, Even as the Dangers Are Studied", New York Times (Aug. 22, 2011); Meier, Barry. "Metal Hips Failing Fast, Report Says," New York Times (Sept. 15, 2011); Meier, Barry. "Remedy Is Elusive As Metallic Hips Fail at a Fast Rate," New York Times (Sept. 30, 2011).
[9] Meier, Barry and Roberts, Janet. "Hip Implant Complaints Surge, Even as the Dangers Are Studied", New York Times (Aug. 22, 2011).
[10] Id.

submissions for metal-on-metal hips through the 510(k) process, many of which were components of larger systems.[11]

The metal-on-metal hip implant systems have "unique risks in addition to the general risks of all hip implant systems," according to the FDA.[12] Because the metal rubs against the metal, "tiny metal particles may wear off of the device and enter into the space around the implant…[or] even get into the bloodstream."[13] For some patients, these metal particles can cause damage to the bone or tissue surrounding the implant and joint, requiring a surgery to replace the implant. In addition to the local reactions, "high levels of metal ions in the bloodstream may cause symptoms or illnesses elsewhere in the body, including effects on the heart, nervous system, and thyroid gland."[14]

Many of these devices were approved first in the United Kingdom (UK) and elsewhere abroad. The early UK experience suggests that these "unique risks" make the devices much more prone to failure, with as many as one-third of certain models failing in registries in the UK.[15] Indeed, a study in the UK found that the metal-on-metal hips failed early at a rate three times that of hips made of different materials.[16]

In this country, only a small fraction of the 500,000 people who received this device are known to have suffered injury. But the United States does not have a registry for these devices similar to the one in the UK. Since January of this year, FDA has received over 5,000 complaints about the metal-on-metal hips.[17] Two metal-on-metal hip systems have already been voluntarily recalled.[18] These concerns led FDA to order 20 manufacturers of these devices to submit a plan to the FDA to study how frequently they were failing and to examine the health implications of device failures.[19]

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[11] FDA, "Metal-on-Metal Hip Implant Systems" (accessed Oct. 2, 2011) (online at http://www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/ImplantsandProsthetics/MetalonMetalHipImplants/ucm241601.htm)
[12] Id.
[13] Id.
[14] Id.
[15] Meier, Barry. "Metal Hips Failing Fast, Report Says," New York Times (Sept. 15, 2011).
[16] Meier, Barry. "Remedy Is Elusive As Metallic Hips Fail at a Fast Rate," New York Times (Sept. 30, 2011).
[17] Meier, Barry and Roberts, Janet. "Hip Implant Complaints Surge, Even as the Dangers Are Studied", New York Times (Aug. 22, 2011).
[18] FDA, "Recalls Specific to Metal-on-Metal Hip Implant Systems" (accessed Oct. 2, 2011) (online at http://www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/ImplantsandProsthetics/MetalonMetalHipImplants/ucm241770.htm)
[19] Meier, Barry, "Hip Makers told to Study More Data," New York Times (May 10, 2011).

Conclusion

To date, the Committee's hearings on medical devices have examined claims about delays in FDA approval and overregulation.[20] We agree that innovative products that help patients should get on the market quickly, and we are supportive of the efforts by the Administration to improve efficiencies and streamline the approval and clearance process.[21] We are also open to other ways to speed the process.

But while working to reduce inefficiencies at FDA, it is critical that we also protect patient safety. Unfortunately, we believe the hearings to date have provided members with an incomplete record. We should also be examining evidence as to whether FDA device regulation has been ineffective in protecting the public from dangerous medical devices.

Brain stents and metal-on-metal hip implants are recent examples of devices which merit further investigation and hearings to determine whether there are harms associated with underregulation.

In addition, we believe it is imperative that we hold hearings on the recent Institute of Medicine report, which concluded that our current review system needs to be strengthened—not weakened—to ensure that medical devices are safe and effective.[22] This would be in keeping with the Committee's activities in 2006 and 2007, when we examined an Institute of Medicine report that recommended changes to the drug evaluation system. At that time, many of the Institute's recommendations were supported in a bipartisan fashion in the Food and Drug Administration Amendments Act of 2007.[23]

We believe that the reauthorization of the medical device user fees program can and should be a bipartisan process. This is a critical opportunity to improve the efficiency of the process while at the same time strengthening assurances of safety and efficacy. Hearings to ensure that all relevant sides of the issue can be fully examined by the Committee, including the importance of safety, are critical to ensure a balanced perspective for members.

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[20] Committee on Energy and Commerce, Democrats, *Medical Journal Editors Raise Significant Concerns With Validity of Industry-Funded Reports* (July 21, 2011) (online at http://democrats.energycommerce.house.gov/index.php?q=news/medical-journal-editors-raise-significant-concerns-with-validity-of-industry-funded-reports).

[21] FDA, *FDA commissioner outlines steps to spur biomedical innovation, improve health of Americans* (Oct. 5, 2011) (online at http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm274538.htm).

[22] Institute of Medicine, *Medical Devices and the Public's Health: The FDA 510(k) Clearance Process at 35 Years* (July 29, 2011) (online at http://www.iom.edu/Reports/2011/Medical-Devices-and-the-Publics-Health-The-FDA-510k-Clearance-Process-at-35-Years.aspx).

[23] Public Law 110-85 (September 27, 2007).

Sincerely,

Henry A. Waxman
Ranking Member

Frank Pallone
Ranking Member
Subcommittee on Health

Diana DeGette
Ranking Member
Subcommittee on Oversight
and Investigations

John D. Dingell
Member of Congress