



THE COMMITTEE ON ENERGY AND COMMERCE

INTERNAL MEMORANDUM

February 13, 2012

To: Energy and Commerce Committee Members

From: Majority Staff

Re: Reauthorization of MDUFA: What It Means for Jobs, Innovation and Patients

On Wednesday, February 15, 2012, at 10:00 a.m. in 2322 Rayburn House Office Building, the Subcommittee on Health will hold a hearing entitled “Reauthorization of MDUFA: What It Means for Jobs, Innovation and Patients.” At the hearing, the Subcommittee will examine issues pertaining to the reauthorization of the medical device user fee. The following provides background on the hearing witnesses and medical devices.

I. WITNESSES¹

Panel I

Jeffrey E. Shuren, M.D., J.D.
Director
Center for Devices and Radiological Health (CDRH)
Food and Drug Administration (FDA)

Panel II

David Perez
President and Chief Executive Officer
Terumo BCT

Elisabeth M. George
Vice President, Global Government Affairs, Regulations and Standards
Philips Healthcare

Ralph Hall, J.D.
Distinguished Professor and Practitioner
University of Minnesota Law School

Ross Jaffe, M.D.
Managing Director
Versant Ventures

¹ Additional witnesses may be added.

Aaron S. Kesselheim, M.D., J.D., M.P.H.
Assistant Professor of Medicine at Harvard Medical School
Division of Pharmacoepidemiology and Pharmacoeconomics
Brigham and Women's Hospital

Art Sedrakyan, M.D., Ph.D.
Associate Professor
Director, Patient-Centered Comparative Effectiveness Program
Weill Cornell Medical College and New York Presbyterian Hospital

Lisa Swirsky
Senior Policy Analyst
Consumers Union

II. BACKGROUND ON MEDICAL DEVICES

The federal regulatory regime for medical devices has three levels of classification. FDA classifies a device based on its intended use and the level of oversight needed to provide a reasonable assurance of safety and effectiveness. These classifications are Class I, Class II and Class III. Class III devices receive the highest level of oversight while Class I devices the least. Examples of Class I devices include elastic bandages and examination gloves. Powered wheelchairs and most imaging devices are Class II devices. Coronary stents and heart valves are examples of Class III devices.

The federal regime also sets forth the 510(k) clearance process and premarket approval application (PMA) process for the marketing of medical devices. FDA generally uses the 510(k) process to clear Class II devices and PMA process to approve Class III devices.

Congress first authorized a medical device user fee in 2002 and last reauthorized the fee as part of the Medical Device User Fee Amendments of 2007 (MDUFA). Under this user fee authority, FDA collected \$287 million from Fiscal Year 2008 to Fiscal Year 2012. The statute authorizes FDA to collect these funds through three types of medical device user fees. These include application fees, establishment fees and product fees.² Without Congressional action, FDA's ability to collect user fees under MDUFA will end in September 2012, and FDA will have to lay off employees.

The Committee did not receive the proposed medical device user fee agreement by January 15, 2012, as required under law, but FDA did announce in early February that an agreement had been reached with industry. The Committee will not receive the proposed agreement until the completion of certain statutory steps, including a 30-day public notice and comment period. While still unofficial, it is expected that the proposed agreement will provide

² For Fiscal Year 2012, the fee rates are the following: application fees (\$220,050 for PMAs and \$4,049 for 510(k)s), establishment fees (\$2,029), and product fees (\$7,702 for Class III devices).

for \$595 million in user fees for Fiscal Years 2013-2017, and greater predictability, consistency and transparency in the premarket review process.

III. CONCLUSION

Should you have any questions regarding the hearing, please contact Clay Alspach or Ryan Long at (202) 225-2927.