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STATEMENT
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COMMITTEE ON OVERSIGHT AND GOVERNMENT REFORM

U.S. HOUSE OF REPRESENTATIVES

"PATHWAY TO FDA MEDICAL DEVICE APPROVAL: IS THERE A BETTER WAY?"

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INTRODUCTION

Mr. Chairman and Members of the Subcommittee, I am Dr. Jeffrey Shuren, Director of the Center for Devices and Radiological Health (CDRH) at the Food and Drug Administration (FDA or the Agency). Thank you for the opportunity to discuss FDA's regulatory pathways for the premarket review of medical devices. FDA recognizes the many important contributions that the medical device industry makes to the economy and to the public health. By increasing the predictability, consistency, and transparency of our premarket review programs, we can help provide better treatments and diagnostics to patients more quickly and stimulate investment in and development of promising new technologies to meet critical public health needs, which may result in increased global market position of U.S. medical devices. In just the last few months, FDA has approved marketing applications for a number of truly innovative medical devices, including the first implantable hearing system, a new device that provides neurosurgeons with another tool to treat brain aneurysms without performing open surgery, and a Humanitarian Device Exemption for the first transcatheter heart valve.

Background

I will begin with a brief overview of our regulatory authorities for medical devices. A medical device, as defined by federal law, encompasses several thousand health products, from simple articles such as tongue depressors and heating pads, to cutting-edge and complex devices such as implantable defibrillators and robotic equipment for minimally invasive surgery.

The Medical Device Amendments of 1976 to the Federal Food, Drug, and Cosmetic Act (FD&C Act or the Act) gave FDA specific authority to regulate the safety and effectiveness of medical devices. Medical devices are assigned to one of three regulatory classes based on risk.

Class I, General Controls, is the lowest risk category of devices and includes items such as adhesive bandages. These devices are subject to the general controls of the Act, which include establishment registration and device listing and compliance with current Good Manufacturing Practice (cGMP), labeling, record-keeping, and reporting requirements.

Class II, Special Controls, is a medium-risk category of devices and includes devices such as intravenous catheters and powered wheelchairs. They are subject to the general controls of the Act as well as Special Controls, which may include special labeling requirements, mandatory performance standards, and post-market surveillance, in order to ensure device safety and effectiveness.

Class III is the highest risk category of devices and includes devices such as heart valves and coronary stents. These devices are subject to the general controls of the Act, plus require approval of a premarket approval application (PMA) containing scientific evidence of the device's safety and effectiveness prior to marketing the device.

Most devices, however, are cleared via the premarket notification [510(k)] process. A 510(k) is a premarket submission to demonstrate that the device to be marketed is "substantially equivalent" to another legally marketed (predicate) device. If a device otherwise subject to premarket review is not substantially equivalent to another legally marketed device, it must go through either the PMA process or the *de novo* classification process (a review process for innovative, lower-risk products).

The Impact of Regulation on Innovation

FDA is charged with a significant task: to protect and promote the health of the American public. To succeed in that mission, we must ensure the safety and effectiveness of the medical products that Americans rely on every day, and also facilitate the scientific innovations that make these products safer and more effective.

These dual roles have a profound effect on the nation's economy. FDA's premarket review of medical devices gives manufacturers a worldwide base of consumer confidence. Our ability to work with innovators to translate discoveries into products that can be cleared or approved in a timely way is essential to the growth of the medical products industry and the jobs it creates. U.S.-based companies dominate the roughly $350 billion global medical device industry. The U.S. medical device industry is one of the few sectors, in these challenging economic times, with a positive trade balance.[1] In

[1] PwC (formerly PriceWaterhouseCoopers), "Medical Technology Innovation Scorecard" (January 2011) at page 8, available at http://pwchealth.com/cgi-local/hregister.cgi?link=reg/innovation-scorecard.pdf.

2000, the U.S. medical device industry ranked 13th in venture capital investment—now, 10 years later, it's our country's fourth largest sector for venture capital investment.[2]

As noted in a January 2011 report on medical technology innovation by PwC (formerly PriceWaterhouseCoopers), the U.S. regulatory system and U.S. regulatory standard have served American industry and patients well. As that report states, "U.S. success in medical technology during recent decades stems partially from global leadership of the U.S. Food and Drug Administration. FDA's standards and guidelines to ensure safety and efficacy have instilled confidence in the industry's products worldwide. Other countries' regulators often wait to see FDA's position before acting on medical technology applications, and often model their own regulatory approach on FDA's."

FDA's FY 2010 Medical Device User Fee Act Performance Report to Congress indicates that FDA's device review performance has been consistently strong. Ninety-five percent of the more than 4,000 medical device applications subject to user fees that FDA reviews every year (FDA reviews over 9,000 submissions annually in total) are reviewed within the goals that were agreed to by the medical device industry under the Medical Device User Fee Amendments of 2007 (MDUFA). Under the 510(k) program—the pathway used by 90 percent of the devices we examine each year—90 percent of our reviews were completed in 90 days or less, and 98 percent of reviews were completed in 150 days or less, as we committed to do under MDUFA.

[2] PriceWaterhouseCoopers/National Venture Capital Association, MoneyTree™ Report, Data: Thomson Reuters, Investments by Industry Q1 1995 – Q4 2010, available at http://www.nvca.org.

There are a limited number of areas in which we are not meeting the goals agreed to with the industry, although our performance in those areas is generally improving. This is the result of several factors, including increasing workload, turnover of key staff, growing device complexity, and poor-quality submissions by industry that require significant time and attention to address. The number of applications for premarket approval (for "breakthrough" devices) has increased by 56 percent over the past two years. In addition, medical devices are becoming more technologically complex, as reflected by the growing number and variety of technical experts with whom FDA must consult during the review process. Finally, a significant number of submissions received by the Agency are incomplete or fail to address basic elements such as the device's proposed indications for use. More than half of the 510(k) submissions received by FDA have quality problems. Although FDA is meeting its performance goals for 510(k)s, these submission quality problems delay the completion of the marketing clearance process and unnecessarily divert resources from more productive activities in the review process.

FDA recognizes that it can do a better job at managing its premarket review programs. We continue to look for ways to improve our ability to facilitate innovation and to speed safe and effective products to patients. We know that medical device development is expensive. And we agree that, in many areas, insufficient clarity, consistency, and predictability on our part contributes to those expenses. This is why we've undertaken a number of initiatives to improve our review processes, and I am happy to highlight a few.

510(k) Action Plan

In recent years, concerns have been raised, both within and outside of FDA, about whether the current 510(k) program optimally achieves its goals of fostering innovation while making safe and effective medical devices available to patients. In light of these concerns, and in keeping with the good government practice of periodically assessing the effectiveness of existing programs, FDA set about to identify problems and their root causes in a methodical manner. In September 2009, we launched a two-pronged, comprehensive assessment of the 510(k) process to determine whether changes should be made to the program so that it can better achieve its goals.

Under the first part of this assessment, FDA created two staff working groups: one to review the 510(k) program and make recommendations to strengthen it; the other, to review how the Agency incorporates new science into its decision-making process, including our PMA program, and recommend how it can do so more predictably. The other part of this assessment is an independent evaluation by the Institute of Medicine (IOM), which is still underway. The IOM is expected to publish its final report in summer 2011.

In keeping with our commitment to transparency, FDA sought public input during the development and review of the two internal reports. We engaged in extensive public outreach, including two public meetings, three town hall meetings, three public dockets, and many smaller meetings with a variety of stakeholder groups. In August 2010, FDA

issued final reports containing 55 recommendations and again sought public comment on the reports and recommendations before taking action.

In January 2011, after reviewing the public comment, the Agency announced the proposed actions it would take to improve the 510(k) process and its use of science in decision-making generally. In particular, these actions are intended to improve the predictability, consistency, and transparency of the 510(k) program and aspects of our PMA program, such as decisions regarding clinical trial protocols, to facilitate innovation while assuring that devices available to patients are safe and effective. A few examples include:

- Streamlining the review process for innovative, lower-risk products, called the *de novo* classification process;
- Publishing guidance for industry to clarify when clinical data should be submitted, in order to increase predictability and transparency;
- Developing a network of external experts who can use their knowledge and experience to help the Agency address important scientific issues regarding new medical device technologies; and
- Establishing a new Center Science Council of senior FDA experts within the Agency's medical device center to ensure more timely and consistent science-based decision-making.

More information about FDA's plans to improve the 510(k) process and the Agency's use of science in decision-making is available on the Agency's web site at *http://www.fda.gov/downloads/AboutFDA/CentersOffices/CDRH/CDRHReports/UCM239450.pdf*.

Innovation Initiative

In addition to our review of the 510(k) program, we recently announced a proposed Innovation Initiative. This Initiative seeks to accelerate the development and regulatory evaluation of innovative medical devices, strengthen the nation's research infrastructure for developing breakthrough technologies, and advance quality regulatory science. As part of this initiative, CDRH is proposing additional actions to encourage innovation, streamline regulatory and scientific device evaluation, and expedite the delivery of novel, important, safe and effective innovative medical devices to patients, including:

- Establishing a priority review program for pioneering technologies;
- Establishing a voluntary, third-party certification program for U.S. medical device test centers, designed to promote early and faster clinical testing during a product's development and assessment stages;
- Issuing guidance on leveraging clinical studies conducted outside the United States;
- Advancing regulatory science through public-private partnerships;

- Creating a publicly available core curriculum for medical device development and testing to train the next generation of innovators; and
- Engaging in formal horizon scanning—the systematic monitoring of medical literature and scientific funding to predict where technology is heading, in order to prepare for and respond to transformative, innovative technologies and scientific breakthroughs.

Facilitating medical device innovation is a top priority for FDA. As part of its 2011 Strategic Plan, FDA's medical device center has set goals to proactively facilitate innovation to address unmet public health needs. A public docket has been set up to solicit public comment on the Innovation Initiative proposals, and a public meeting on the topic took place on March 15, 2011.

MDUFA Reauthorization

In 2002, Congress enacted the Medical Device User Fee and Modernization Act (MDUFMA I), authorizing FDA to collect fees from companies who submit certain applications for marketing of medical devices. In return, MDUFMA I required FDA to pursue a comprehensive set of device review performance goals that were intended to significantly improve the timeliness and predictability of FDA's review of new devices. Five years later, in 2007, MDUFA II was enacted, which reauthorized medical device user fees and identified rigorous new premarket review performance goals for fiscal years 2008 through 2012. These performance goals, which are intended to achieve progressive,

year-by-year improvements in the review processes for medical devices, were developed with input from industry and were a key part of the negotiated package of user fees and other changes made by MDUFA II.

Medical device user fees have constituted an increasing proportion of FDA's program level device review budget since MDUFMA I was originally enacted. In 2003, user fees comprised less than 7 percent of FDA's device-related budget—in 2010, they accounted for almost 20 percent of medical device review costs. The remainder of the cost of administering the medical device review program is funded through Congressional appropriations.

As you know, the statutory authority for MDUFA expires on September 30, 2012. At that time, new legislation will be required for FDA to continue collecting user fees for the medical device program. FDA is currently engaged in negotiations with the regulated industry to prepare recommendations for the reauthorization of MDUFA. In addition, the Agency is holding regular monthly discussions with representatives of patient and consumer advocacy groups, while the negotiations with industry are taking place, as required by the statute. Minutes of both the industry negotiations and the monthly stakeholder meetings are being made publicly available on the FDA website to ensure transparency of the reauthorization process and to facilitate stakeholder involvement in that process. Finally, FDA will hold a public meeting on MDUFA reauthorization later this year.

Issues of concern to industry will appropriately be addressed in these negotiations, and during this process, all other stakeholders, including the scientific and medical community, and patient and consumer groups, will be afforded the opportunity to make their views heard with respect to the reauthorization of MDUFA.

CONCLUSION

Mr. Chairman, I commend the Subcommittee's efforts to understand the impact of FDA's regulatory policies on medical device innovation. FDA is a unique and essential agency—a science-based regulatory agency with a public health mission to promote and protect the health of the American people. This includes ensuring the safety and effectiveness of products that the American people rely on in fundamental, sometimes lifesaving, ways—drugs, vaccines, blood and blood products, medical devices, our nation's food supply, and more. But it also includes working proactively to foster the scientific innovation that will lead to tomorrow's new breakthrough products. We are committed to doing both. FDA strives toward a reasonable and fair approach to regulation that will foster innovation in the medical technology industry while assuring that the medical devices marketed in the United States are safe and effective.

Mr. Chairman, this concludes my formal remarks. I will be pleased to answer any questions the Subcommittee may have.