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STATEMENT
OF
JEFFREY SHUREN, M.D., J.D.
DIRECTOR
CENTER FOR DEVICES AND RADIOLOGICAL HEALTH

FOOD AND DRUG ADMINISTRATION
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BEFORE THE

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U. S. HOUSE OF REPRESENTATIVES

"IMPACT OF MEDICAL DEVICE REGULATION ON JOBS AND PATIENTS"

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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 the effects of medical device regulation on jobs and patients. 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 regulatory pathways, we can help provide better treatments and diagnostics to patients more quickly, stimulate investment in and development of promising new technologies to meet critical public health needs, and increase the global market position of U.S. medical devices.

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, compliance with current Good Manufacturing Practice (cGMP) and 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 approval prior to marketing of a premarket approval application (PMA) containing scientific evidence of the device's safety and effectiveness.

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, more effective, and more affordable.

These dual roles have a profound effect on the nation's economy. FDA medical device approval gives manufacturers a worldwide base of consumer confidence. Our ability to work with innovators to translate discoveries into approvable products 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 2000, the U.S. medical device industry ranked thirteenth in venture capital investment – now, ten years later, it's our country's fourth largest sector for venture capital investment.[2]

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

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."

Some have alleged that delays in FDA approval deprive American patients of needed therapies and push jobs overseas. Yet, as FDA's FY2010 Medical Device User Fee Act Performance Report to Congress indicates, FDA's device review performance has been consistently strong. Ninety-five percent of the over 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.

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. The number of applications for premarket approval and panel-track supplements (for "breakthrough" devices) has increased by 48 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 that 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.

Comparisons Between FDA and the European Union (EU)

As FDA and industry have geared up to negotiate a new user fee agreement under MDUFA, we've seen reports and studies comparing FDA and EU device review performance, with some suggesting that we replace the American system with that of the EU. It is important to note that there are some very basic differences between the two systems that confound comparisons. In contrast to the U.S. medical device regulatory system, the European system:

- does not require government review before a company may market a device;
- does not require demonstration of device effectiveness – the U.S. standard in law is safety and effectiveness; the EU standard is safety and performance, meaning the device must perform as indicated in the device description and is not required to show benefit to the patient;
- allows manufacturers to "forum-shop" their applications among third-party reviewers who are subject to minimal oversight;
- provides minimal information to the public about the evidence supporting company claims; for example, summaries describing the basis for third-party reviewer decisions to grant a CE mark are not provided to the public;
- has no centralized authority for tracking safety information related to medical devices and no EU-wide post-market surveillance system; as a result, the EU is less likely to detect new safety problems as compared to the United States; and
- has no centralized database of information about the performance of the various regulatory systems (such as time spent on premarket review), making it difficult to compare the performance of the EU and U.S. systems.

In 2008, the European Commission acknowledged that there were limitations in its regulatory framework for medical devices and sought public comment on ways to

strengthen its system.[3] As noted by the Commission in its Public Consultation Report: "Experience indicates that the current system does not always offer a uniform level of protection of public health in the European Union. New and emerging technologies have challenged the current framework, highlighting gaps and pointing to a certain scarcity of expertise.... And finally, the legal system has been criticized as being too fragmented and difficult to follow and fraught with national variation."[4]

Different studies report different time frames for U.S. and EU review times for new medical devices, for a variety of reasons. Comparisons of review times between the United States and the EU are particularly difficult when based on flawed assumptions and in the absence of performance data for the EU. For example, the widely cited Makower study, which concluded there was a significant lag in "review times" in the United States as compared to the EU, included within the "review time" the substantial pre-submission assistance to the industry that FDA offers.

For the most complex devices, FDA reviews may indeed take longer from our first contact with a company to approval – in large part, due to our agreement with manufacturers to engage with them far earlier in the product development process than do our European counterparts. Of note, the number of such meetings requested by manufacturers has been steadily increasing over the past few years.

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[3] European Commission, "Recast of the Medical Devices Directives: Public Consultation," available at http://ec.europa.eu/consumers/sectors/medical-devices/files/recast_docs_2008/public_consultation_en.pdf; see generally http://ec.europa.eu/consumers/sectors/medical-devices/documents/revision/index_en.htm.
[4] European Commission, Consumer Affairs, "Revision of the Medical Devices Directives: 2008 - onwards," at http://ec.europa.eu/consumers/sectors/medical-devices/documents/revision/index_en.htm.

An additional factor is that for the higher-risk devices, FDA may ask for more robust clinical data to meet the stronger U.S. regulatory standards. As noted previously, FDA requires a manufacturer to demonstrate that a device is safe and effective, while the European process only requires a demonstration of a device's safety and performance, not its effectiveness. For example, if a manufacturer wishes to market a laser to incise heart tissue to treat arrhythmia (abnormal heart rhythm) in the EU, the manufacturer must show that the laser incises heart tissue only. In the U.S., however, the manufacturer must show that the laser incises heart tissue and also treats the arrhythmia.

Comparisons of safety data are equally problematic. Since the number of approval submissions or "on-market" devices in the EU cannot be determined from publicly available information – nor can the number of recalls or adverse event reports – calculation of accurate rates of safety problems is not possible. According to the industry-funded BCG study on EU and U.S. recalls, 85 percent of medical device safety reports in the EU come from only five member states of the 24 countries reviewed, underscoring the potential for underreporting of safety events in the EU.

We appreciate the concern that some devices come on the market in the EU before they do in the United States. While we want devices to be available to American patients as soon as possible, we believe that, consistent with U.S. law, they need to be both safe and effective. The U.S. system has served patients well by preventing EU-approved devices that were later shown to be unsafe or ineffective from harming American consumers. For example, in 1991, Poly Implant Prosthese (PIP), a company based in southern France,

received a CE mark for silicone breast implants. Unbeknownst to regulators, PIP changed the silicone gel in the breast implants. On March 30, 2010, French regulators issued a recall of all pre-filled silicone breast implants manufactured by PIP. The breast implant recall is said to affect an estimated 35,000 to 45,000 women worldwide. This device was never approved by FDA and therefore never reached the market in the United States.

Yet, FDA recognizes that it can do a better job at managing its premarket review programs. FDA continues to look for ways to improve our ability to encourage 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 initiatives to improve our review processes in order to enhance innovation in the medical device industry.

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 launched in September 2009 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 and recommends 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 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 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.

Innovation Pathway

In addition to our review of the 510(k) program, we recently announced a priority review program for new, breakthrough medical devices. The proposed new Innovation Pathway program for pioneering medical devices is part of a broader effort we have underway designed to encourage cutting-edge technologies among medical device manufacturers.

The Innovation Pathway will seek to accelerate the development and regulatory evaluation of innovative medical devices, strengthen the nation's research infrastructure for developing breakthrough technologies, and advancing 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 rapid improvements to new technologies during a product's development and clinical testing stages;
- 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 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 Pathway proposals, and a public meeting on the topic is scheduled for March 15, 2011.

MDUFA Reauthorization

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.

We look forward to working with Members of the Committee on Energy and Commerce to reauthorize this important legislation.

CONCLUSION

Mr. Chairman, I commend the Subcommittee's efforts to understand the impact of FDA's regulatory policies on medical device innovation. 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. Thank you for your commitment to the mission of FDA, and the continued success of our medical device program, which helps get safe and effective technology to patients and practitioners on a daily basis.

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