



DEPARTMENT OF HEALTH AND HUMAN SERVICES

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Food and Drug Administration  
Silver Spring, MD 20993

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

**FOOD AND DRUG ADMINISTRATION  
DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**BEFORE THE  
COMMITTEE ON HEALTH, EDUCATION, LABOR AND PENSIONS  
UNITED STATES SENATE  
“FDA USER FEE AGREEMENTS:  
STRENGTHENING FDA AND THE MEDICAL PRODUCTS INDUSTRY  
FOR THE BENEFIT OF PATIENTS”**

**March 29, 2012**

**Release Only Upon Delivery**

## **INTRODUCTION**

Mr. Chairman and Members of the Committee, 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). I am pleased to be here today to discuss reauthorization of the Medical Device User Fee Act, or MDUFA.

### Background on MDUFA

The enactment in 2002 of the Medical Device User Fee and Modernization Act (MDUFMA I) was prompted by growing concerns about the medical device review program's capacity and performance. MDUFMA I and MDUFA II (enacted in 2007) authorized user fees for the review of medical device premarket applications, reports, supplements, and premarket notification submissions. These additional resources enabled FDA to make its reviews more timely, predictable, and transparent to applicants. MDUFA fees and mandated appropriations for the medical device program helped FDA expand available expertise, modernize its information management systems, provide new review options, and provide more guidance to prospective applicants.

MDUFA authorizes FDA to collect user fees for certain medical device applications, the registration of certain medical device establishments, and certain other purposes. Small businesses may qualify for a waiver or a reduced fee on certain submissions to FDA.

Of the total \$292,707,540 obligated in support of the process for the review of medical device submissions in FY 2010, MDUFA fees funded about 20 percent. The remainder of the funding was through appropriations. Fees currently charged for device review under MDUFA include \$220,050 for a Premarket Approval (PMA) application for high-risk medical devices (a

business with gross receipts under \$100 million qualifies for the “small business” PMA fee of about \$55,000, and for firms with gross receipts under \$30 million, the firm’s first PMA fee is also waived). For lower-risk devices cleared under the 510(k) review program, manufacturers pay \$4,049 per 510(k) application review (\$2,024 for small businesses).<sup>1</sup> As a point of comparison, PDUFA fees—nearly \$568 million in FY 2010—currently account for about two-thirds of the drug review program’s budget, and the current fee for FY 2012 associated with review of a New Drug Application (NDA) requiring clinical data is \$1,841,500.<sup>2</sup>

The medical device user fee program has produced benefits for public health. A better-resourced premarket device review program has enhanced FDA’s abilities to help bring more safe and effective medical devices to the market, while keeping pace with the increasing complexity of technology and changes in clinical practice. Since MDUFA II was reauthorized in 2007, FDA has approved 106 original PMAs and cleared more than 13,000 devices under the 510(k) program.

For example, approvals have included devices intended to address unmet needs in the pediatric population, such as the first heart pump designed to support the hearts of infants to adolescents until they receive a heart transplant, and the first percutaneous heart valve (approved for both children and adults).

The device program also has approved important new laboratory tests, including an emergency-use diagnostic test in response to H1N1 outbreak in humans, and the first quick test for malaria. Device reviews have significantly contributed to the very important trend toward

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<sup>1</sup> See U.S. FDA, “Medical Device User Fee Rates for Fiscal Year 2012,” 76 *Federal Register* 45,826-45,831 (Aug. 1, 2011), available at <http://www.gpo.gov/fdsys/pkg/FR-2011-08-01/html/2011-19335.htm>.

<sup>2</sup> See U.S. FDA, “Prescription Drug User Fee Rates for Fiscal Year 2012,” 76 *Federal Register* 45,831-45,838 (Aug. 1, 2011), available at <http://www.gpo.gov/fdsys/pkg/FR-2011-08-01/pdf/2011-19332.pdf>.

personalized medicine through clearance of a test system that can assist in assessing the risk of tumor recurrence and long-term survival for patients with relatively high-risk breast cancer.

Other important devices that have become available to patients over the course of MDUFA II include, for example, the Implantable Miniature Telescope (IMT), used for monocular implantation to improve vision in elderly patients with stable severe to profound vision impairment associated with end-stage age-related macular degeneration (AMD)<sup>3</sup>; the Infrascanner™ infrared brain hematoma detector, a non-invasive hand-held device that uses near-infrared spectroscopy to evaluate suspected brain hematomas at the site of injury within the “golden hour” (the period following head trauma when pre-hospital analysis is needed to rapidly assess a patient’s neurological condition)<sup>4</sup>; and the NeuRx DPS™ RA/4 Respiratory Stimulation System, an implantable electronic device that stimulates the diaphragm and allows certain spinal cord injury patients to breathe for at least four hours a day without a mechanical ventilator.<sup>5</sup>

However, neither the FDA nor industry believe that the user fee program has reached the level of performance, or produced the extent of benefits, that it has the potential to achieve.

### MDUFA II Performance

FDA has been meeting or exceeding goals agreed to by FDA and industry under MDUFA II for approximately 95 percent of the submissions we review each year. For example, FDA completes at least 90 percent of 510(k) reviews within 90 days or less. In the few areas where FDA is not yet meeting its MDUFA goals, the Agency’s performance has generally been

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<sup>3</sup> See FDA News Release, “FDA Approves First Implantable Miniature Telescope to Improve Sight of AMD Patients” (July 6, 2010), available at

<http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm218066.htm>.

<sup>4</sup> See Office of Naval Research, “Naval Technology Could be a Lifesaver” (Dec. 21, 2011), available at <http://www.onr.navy.mil/Media-Center/Press-Releases/2011/Infrascanner-brain-TBI-FDA-approval.aspx>.

<sup>5</sup> See FDA News Release, “FDA Approves Diaphragm-Pacing Device” (June 18, 2008), available at <http://www.fda.gov/ForConsumers/ConsumerUpdates/ucm116914.htm>.

improving—despite growing device complexity and an increased workload. FDA’s performance over the course of MDUFA II has not been limited to achieving quantitative goals for the timely review of premarket submissions like PMAs and 510(k)s; we have also accomplished a number of “qualitative” goals set by MDUFA II in 2007, including issuing more than 50 new and updated guidances for industry. Guidance documents are important resources for industry because they describe the Agency’s interpretation of, or policy on, regulatory issues, and as such, are critical to support industry efforts to comply with the law and develop new products that may benefit the public health.<sup>6</sup> The availability of guidance documents also facilitates regulatory predictability and consistency.

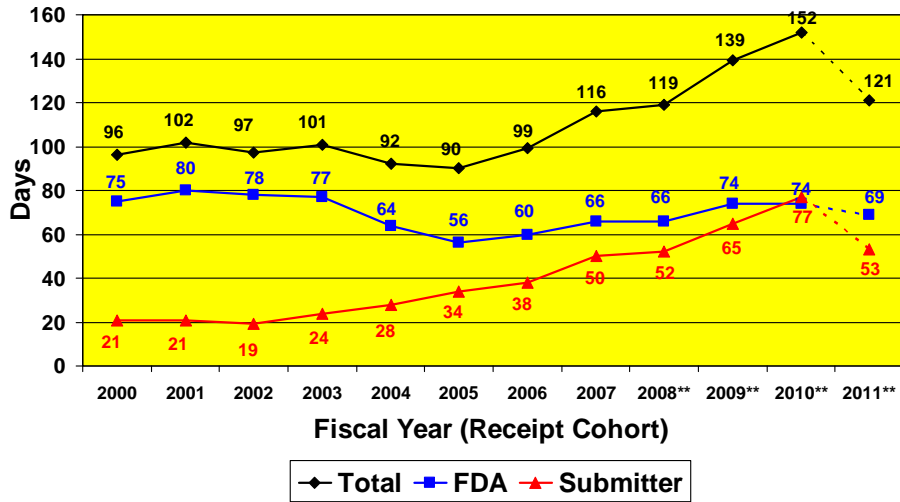
It is important to note that MDUFA metrics reflect FDA time only; they do not reflect the time taken by device sponsors to respond to requests for additional information. *Overall* time to decision—the time that FDA has the application, *plus* the time the manufacturer spends answering any questions FDA may have—has increased steadily since 2001. As the graphs below illustrate, while the time FDA spends reviewing an application has improved (for both low- and high-risk devices), average total days for the review of 510(k)s has been increasing since 2005, and has been increasing for PMA applications since 2004.

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<sup>6</sup> Guidance documents include documents that relate to: (1) the design, production, labeling, promotion, manufacturing, and testing of regulated products; (2) the processing, content, and evaluation or approval of submissions; and (3) FDA’s inspection and enforcement policies. See generally, “Food and Drug Administration Report on Good Guidance Practices: Improving Efficiency and Transparency” (issued Dec. 2011), available at <http://www.fda.gov/downloads/AboutFDA/Transparency/TransparencyInitiative/UCM285124.pdf>.

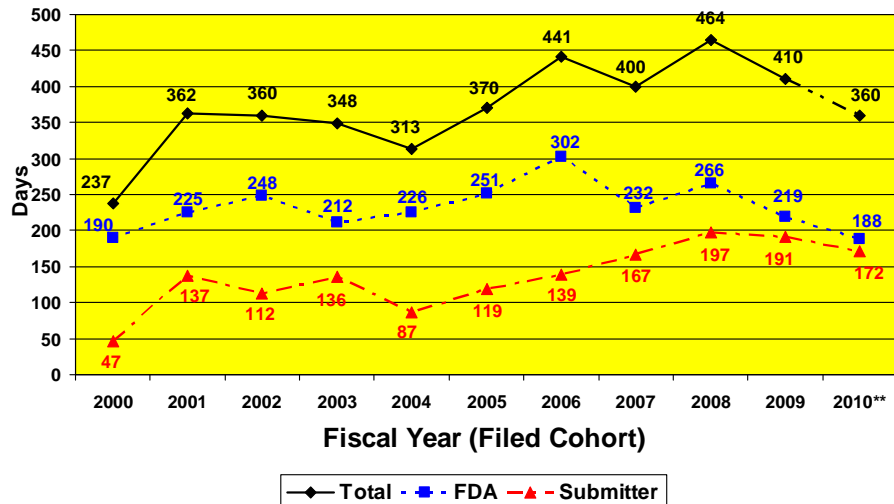
## Average Time to Decision: 510(k)s\*

(Receipt Cohorts as of March 11, 2012)



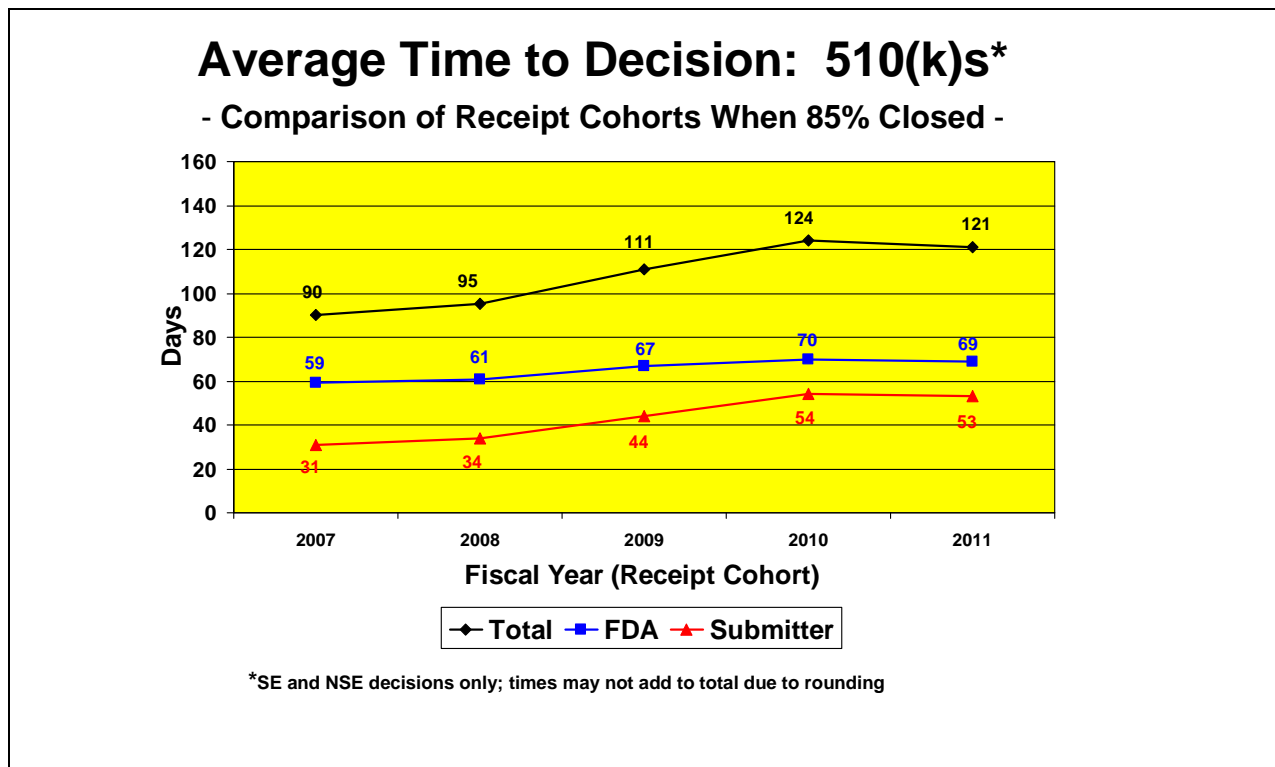
\*SE and NSE decisions only; times may not add to total due to rounding  
 \*\*Cohorts still open; FY 2011 cohort is only 85% closed and average times will increase

## Average Time to Decision: PMAs and Panel-Track Supplements (non-expedited)\*



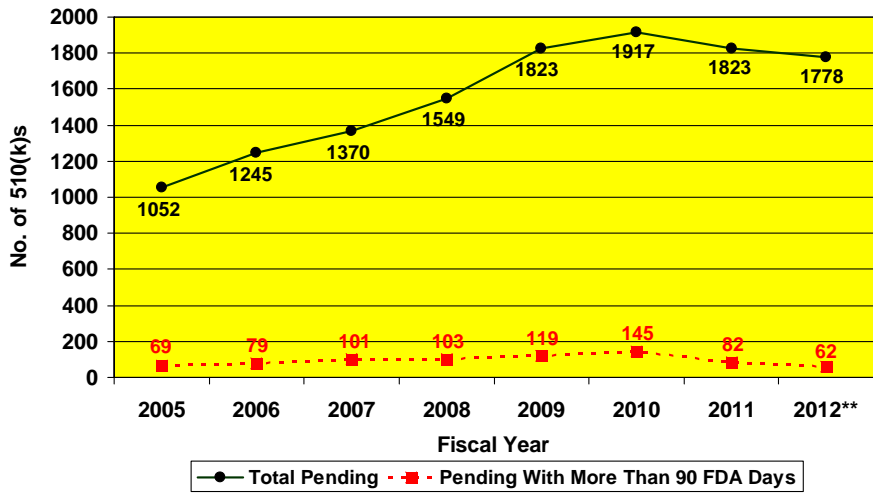
\*Times may not add to total due to rounding; some cohorts still open - data may change  
 \*\*As of January 30, 2012 there were four applications without a decision; the average time to decision will increase as the cohort closes.

FDA bears some responsibility for the increase in total time to decision, and we have been instituting management, policy, and process changes to address this issue. As a result, we are starting to see indicators of improved review performance. For example, the Agency has currently completed review of 85 percent of the 510(k) submissions received in FY 2011. The graph below, illustrating average time to decision during the last five years at this same point (85 percent of 510(k)s reviewed), shows that progress was made, starting last year, in stabilizing 510(k) review times.



In addition, in FY 2011, CDRH for the first time began reducing what previously was an increasing backlog of unresolved 510(k) submissions, as indicated in the chart below—and that trend is clearly continuing as we approach the mid-point of FY 2012:

## 510(k)s Pending\* at End of Year



\*Under review or on hold

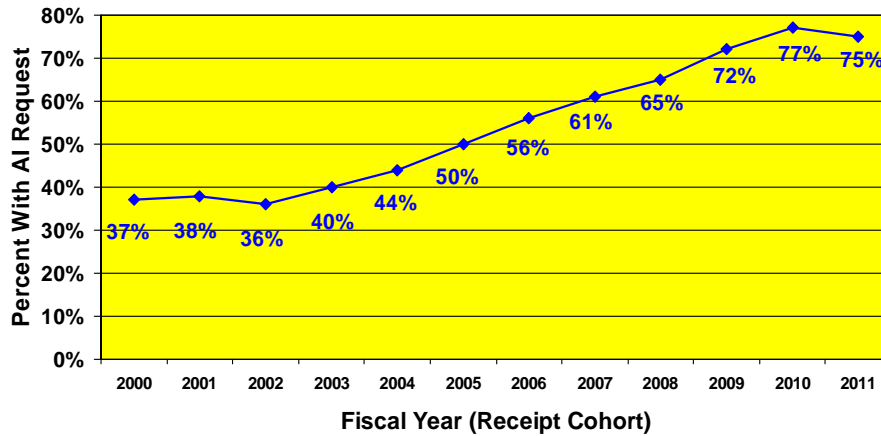
\*\*FY 2012 as of March 11, 2012

Likewise, there had been a continuous annual increase, since FY 2002, in the percentage of 510(k) submissions requiring an Additional Information (AI) letter<sup>7</sup> after the first review cycle, which had contributed to the increasing total time from submission to decision. As indicated in the chart below, however, in FY 2011, the percentage of 510(k)s requiring an AI letter declined for the first time since 2002.

<sup>7</sup> If, after reviewing an application, FDA determines that it cannot approve or clear the application in its current form, FDA sends a letter informing the sponsor of this decision. For 510(k) applications, this is called an “Additional Information” (AI) letter.



## Percent of 510(k)s With Additional Information (AI) Request on 1<sup>st</sup> FDA Review Cycle



### Smart Regulation's Role in Facilitating Medical Device Innovation

FDA recognizes that, if the United States is to maintain its leadership role in this area, we must continue to streamline and modernize our processes and procedures to make device approval not just scientifically rigorous, but clear, consistent, and predictable, without compromising safety. We are committed to continued improvements in the device approval process to address legitimate concerns raised by industry and other stakeholders.

A little over two years ago, CDRH recognized that, given the growing complexities of medical product development, we needed to re-evaluate and modernize our regulatory review processes in order to ensure that patients had timely access to safe and effective medical devices. At that time, CDRH began to undertake a new systematic approach to device regulation, moving away from the traditional misperception that safety and effectiveness and innovation are

incompatible. Rather than focus on *more* regulation or *less* regulation, we began to focus on “smart regulation.”

Our goal has been to ensure that safety and effectiveness and innovation are complementary, mutually supporting aspects of our mission to promote the public health. As part of our process to improve CDRH’s internal systems, we first reached out to stakeholders to hear their concerns and listen to their recommendations about our premarket programs. This is what we heard: industry felt that inadequate predictability, consistency, and transparency were stifling innovation and driving jobs overseas; and consumer groups, third-party payers, and some health care professionals believed that one of our premarket pathways—the 510(k) program—did not provide adequate protection for American patients and did not generate sufficient information for practitioners and patients to make well-informed treatment and diagnostic decisions. In turn, CDRH employees expressed concerns that the 510(k) program had not adapted to the increasing complexity of devices, and that poor-quality 510(k) submissions, poor-quality clinical studies conducted in support of PMA applications, and an ever-growing workload were straining already overburdened premarket programs.

We also began two assessments of our premarket programs to identify issues, their root causes, and the appropriate solutions. One assessment focuses on the 510(k) program. The other looks at how we use science in regulatory decision-making, touching on aspects of several of our premarket review pathways, such as our clinical trials program. In addition, we contracted with the Institute of Medicine (IOM) to conduct an independent evaluation of our 510(k) program.

In August 2010, following extensive public input, we released two reports that identified issues regarding our premarket programs and proposed potential actions for us to take to address the underlying root causes. The number one problem we found was insufficient predictability in

our premarket programs, which can create inefficiencies, increase costs for industry and FDA, and delay bringing safe and effective products to market. We identified several root causes of these issues. They include very high reviewer and manager turnover at CDRH (almost double that of FDA's drug and biologics centers); insufficient training for staff and industry; extremely high ratios of employees to front-line supervisors; insufficient oversight by managers; CDRH's rapidly growing workload, caused by the increasing complexity of devices and the number of overall submissions we review; unnecessary and/or inconsistent data requirements imposed on device sponsors; insufficient guidance for industry and FDA staff; and poor-quality submissions from industry.

While it is true that providing more user fee resources alone won't solve the problems with our premarket programs, insufficient funding is at the root of, or a contributing factor to, several of these problems. Adequate and stable funding is one key component to our and industry's success in bringing safe and effective devices to market quickly and efficiently.

After considering extensive and varied public input on our recommendations, in January 2011, FDA announced a Plan of Action that included 25 specific actions that we would take in 2011 to improve the predictability, consistency, and transparency of our premarket programs. We continued to engage in dialogue about issues of importance to CDRH and to members of the public, including the medical device industry, health care professionals, patients, and consumers,<sup>8</sup> and followed up the Plan of Action with eight additional steps we would take. As of March 2012, 27 actions are already completed or well underway.<sup>9</sup> In February 2011, we

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<sup>8</sup> Numerous public meetings and workshops, including three "town hall" discussions with the Center Director and senior CDRH management, were held in 2011; similar CDRH outreach to stakeholders is ongoing. For more details, see <http://www.fda.gov/MedicalDevices/NewsEvents/WorkshopsConferences/ucm111051.htm>.

<sup>9</sup> More information about FDA's progress in implementing the CDRH "Plan of Action for 510(k) and Science" is available on FDA's website at <http://www.fda.gov/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/CDRH/CDRHReports/ucm276286.htm>.

announced our Innovation Initiative, which included several proposals to help maintain the position of the United States as the world's leader in medical device innovation, including the creation of a new approach for important, new technologies called the Innovation Pathway.

Since then, we have announced additional efforts to improve our premarket programs, including actions to improve our program for clinical trials and the Investigational Device Exemption (IDE) program. The actions we are taking can be grouped into three main areas of emphasis. Overall, our actions seek to:

- Create a culture change toward greater transparency, interaction, collaboration, and the appropriate balancing of benefits and risks;
- Ensure more predictable and consistent recommendations, decision-making, and application of the least-burdensome principle; and
- Implement more efficient processes and use of resources.

Specific steps that we are taking include:

- Issuing guidance clarifying the criteria used to make benefit-risk determinations a part of device premarket decisions. This will provide greater predictability and consistency and apply a more patient-centric approach by considering patients' tolerance for risk in appropriate cases (draft guidance issued August 15, 2011, and final guidance issued on March 27, 2012);
- Creating standard operating procedures for when a reviewer can request additional information regarding a premarket submission and identifying at what management level the decision must be made. These steps are intended to provide greater predictability, consistency, and the appropriate application of the least-burdensome principle by

reducing the number of inappropriate information requests (Standard Operating Procedures issued November 10, 2011);

- Developing a range of updated and new guidances to clarify CDRH requirements for predictable, timely, and consistent product review, including device-specific guidance in several areas such as mobile applications (draft guidance released July 19, 2011) and artificial pancreas systems (draft guidance released December 1, 2011);
- Revamping the guidance development process through a new tracking system, streamlined processes, and, to the greatest extent possible within available resources, core staff to oversee the timely drafting and clearance of documents (December 2011);
- Improving communications between FDA and industry through enhancements to interactive review (some enhancements are already in place);
- Streamlining the clinical trial (IDE) processes by providing industry with guidance to clarify the criteria for approving clinical trials, and the criteria for when a first-in-human study can be conducted earlier during device development. These actions aim to create incentives to bring new technologies to the United States first (guidances issued November 10, 2011) (IDEs are required before device testing in humans that involves significant risks may begin, and they ensure that the rights of human subjects are protected while gathering data on the safety and efficacy of medical products);
- Implementing internal business process improvements to ensure that decisions are made by the appropriate level of management, that decisions are made consistently and efficiently, and that we appropriately apply the least-burdensome principle. For example, CDRH created the internal Center Science Council to actively monitor the quality and performance of the Center's scientific programs and ensure consistency and predictability

in CDRH scientific decision-making (Center Science Council established March 31, 2011);

- Creating a network of experts to help the Center resolve complex scientific issues, which will ultimately result in more timely reviews. This network will be especially helpful as FDA confronts new technologies (Standard Operating Procedures issued September 30, 2011);
- Instituting a mandatory Reviewer Certification Program for new reviewers (program launched September 2011);
- Beginning a pilot Experiential Learning Program to provide review staff with real-world training experiences as they participate in visits to manufacturers, research and health care facilities, and academia (to begin in April 2012);
- Providing industry with specific guidance on how to ensure the quality and performance of clinical trials while applying the least-burdensome principle, so that industry conducts studies that are more likely to support the approval of their products (guidance released August 15, 2011); and
- Streamlining the *de novo* review process, the pathway by which novel, lower-risk devices without a predicate can come to market (draft guidance released October 3, 2011).

Our efforts to improve the premarket review programs at CDRH are ongoing. We recently released our Strategic Priorities for 2012,<sup>10</sup> in which we commit to completing or continuing the work we already started in four priority areas: (1) Fully Implement a Total

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<sup>10</sup> CDRH, “2012 Strategic Priorities,” available at <http://www.fda.gov/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/CDRH/CDRHVisionandMission/ucm288735.htm>.

Product Life Cycle Approach,<sup>11</sup> (2) Enhance Communication and Transparency, (3) Strengthen Our Workforce and Workplace, and (4) Proactively Facilitate Innovation to Address Unmet Public Health Needs. Our plan for 2012 includes time frames associated with each strategy and specific actions we will take to meet those goals or make significant progress toward achieving those goals, including, for example:

- By April 1, 2012, begin the Triage of Premarket Submissions Pilot to increase submission review efficiency and better manage the premarket review workload;
- By September 30, 2012, make recommendations on how to adequately recognize good employee performance and address poor performance;
- By September 30, 2012, create processes and tools that will improve the pipeline for innovative medical devices and transform the way CDRH works with medical device innovators, such as the new Entrepreneurs-in-Residence program;
- By September 30, 2012, develop methods and procedures for the systematic analysis and use of medical device recall information;
- By October 31, 2012, develop a comprehensive strategy to assess real-world device performance;
- By December 31, 2012, conduct an evaluation of CDRH staffing, infrastructure, policies, and practices pertaining to medical device software;
- By December 31, 2012, review remaining Class III pre-amendment medical devices;

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<sup>11</sup> A Total Product Life Cycle (TPLC) approach involves making well-supported regulatory decisions that take into consideration all of the relevant information available to CDRH at any stage of a product's life cycle to assure the safety, effectiveness, and quality of medical devices and the safety of non-device radiation-emitting products. The Center's TPLC database integrates premarket and post-market data about medical devices. For more information, see CDRH's website at <http://www.fda.gov/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/CDRH/CDRHTransparency/ucm199906.htm>.

- By December 31, 2012, fully implement the Experiential Learning Program to enhance premarket reviewer knowledge of how medical devices are designed, manufactured, and utilized by providing real-world learning opportunities; and
- By December 31, 2012, launch the CDRH Leadership Enhancement and Development (LEAD) program to provide CDRH managers and supervisors information and tools to ensure effective leadership.

We believe the actions that we've taken and plan to take in the future will have a positive impact on the device review process by providing greater predictability of data requirements through guidance, reducing unnecessary data requests through training and policy and process changes, implementing policies to appropriately balance benefit-risk determinations, using external experts more extensively (consistent with conflict-of-interest guidelines), creating incentives to conduct clinical studies first in the United States, speeding up IDE approval decisions, implementing the Innovation Pathway 2.0 (a priority review program to expedite development, assessment, and review of important technologies), and instituting efficiencies in the premarket review process.

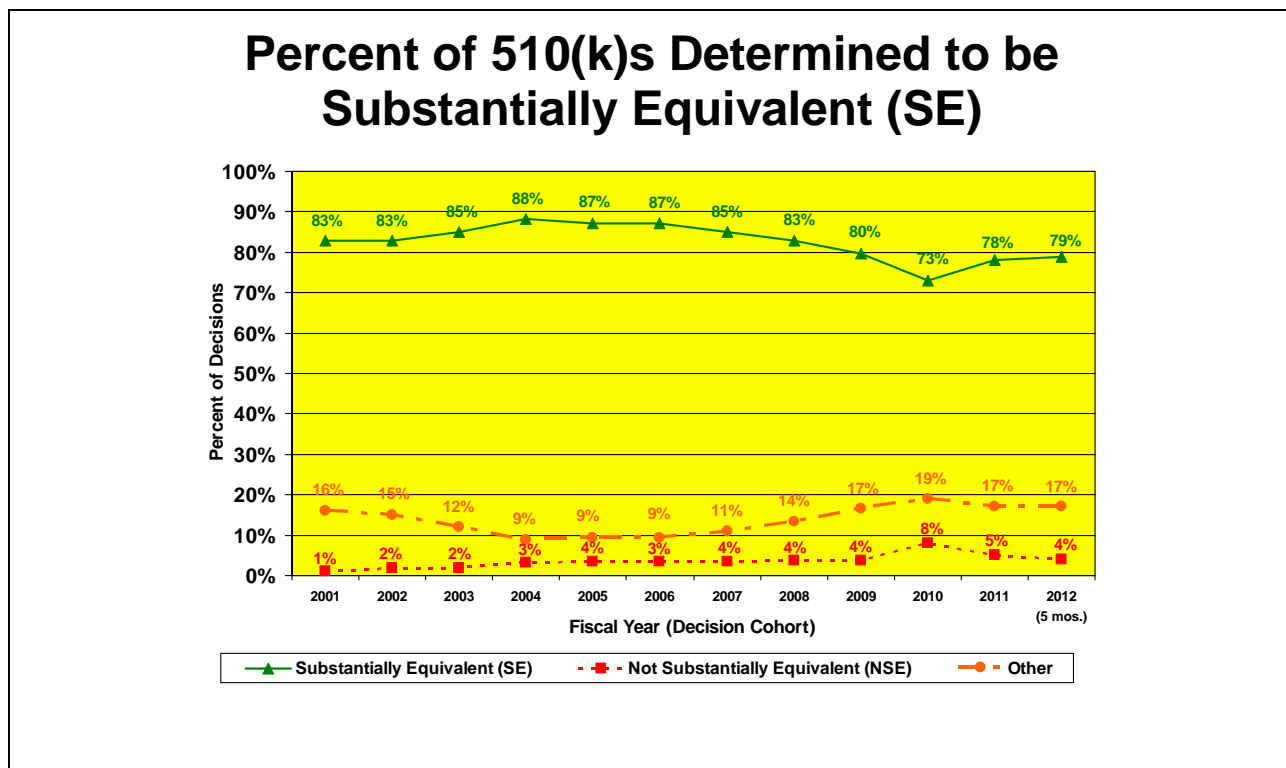
For example, I'm pleased to report that, consistent with our many improvements to the 510(k) program, the recent increase in the "not substantially equivalent" (NSE) rate<sup>12</sup> appears to be turning around. For manufacturers and FDA, NSE determinations often represent an inefficient use of time and resources. NSE determinations require significant Agency resources and time, yet fail to result in the marketing of a new product. As shown in the chart below, from

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<sup>12</sup> Among the reasons that 510(k) submissions result in NSE determinations are: lack of a suitable predicate device; intended use of the new device is not the same as the intended use of the predicate; technological characteristics are different from those of the predicate and raise new questions of safety and effectiveness; and/or performance data failed to demonstrate that the device is as safe and effective as the predicate. The vast majority of NSE decisions are due to the absence of adequate performance data, sometimes despite repeated FDA requests.



a peak of 8 percent in FY 2010, the NSE rate has decreased to 4 percent by the end of the first five months of FY 2012. Just as important, we also may be seeing a reversal in the trend of declining rate in Substantially Equivalent (SE) decisions that clear a 510(k) submission for marketing. After several years of declining percentages, reaching a low of 73 percent in 2010, SE rates increased by 6 percentage points by the end of the first five months of FY 2012, as shown in the chart below.



To best serve patients, both the medical device industry and FDA must have the flexibility to be innovative and entrepreneurial. CDRH must continue making critical improvements to our device program. At the same time, the medical device industry and CDRH must continue to work together to ensure that the Center receives high-quality submissions that contain the information we need to make well-informed and timely decisions. Finally, CDRH

must have adequate and stable resources to get the job done right and quickly. Timely reauthorization of MDUFA, as well as the Congressional appropriations process, is critical to achieving these goals.

### Moving Forward: Reauthorization of MDUFA

When MDUFA was reauthorized in 2007, Congress directed FDA to take additional steps to ensure that public stakeholders would have adequate opportunity to provide input to any program enhancements. In addition to FDA receiving input from stakeholders during an initial public meeting<sup>13</sup> in September 2010, as directed by Congress, we met with stakeholders, including representatives of patient and consumer groups, between January 2011 and February 2012, and made the minutes of those meetings available to the public.<sup>14</sup>

During that 13-month period, we also held discussions with representatives of the medical device industry, as required under the MDUFA II statute, in an effort to develop a package of proposed recommendations for MDUFA reauthorization. Minutes of those consultation meetings were also made available to the public.<sup>15</sup>

We were pleased to announce last month that FDA and representatives from the medical device industry reached an agreement on the proposed recommendations for MDUFA III. That agreement, which would authorize FDA to collect \$595 million in user fees over five years (plus increases based on inflation), strikes a careful balance between what industry agreed to pay and what FDA can accomplish with the amount of funding proposed. We believe that it will result in

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<sup>13</sup> A transcript of the September 2010 public meeting, and related meeting materials, are available on FDA's website at <http://www.fda.gov/MedicalDevices/NewsEvents/WorkshopsConferences/ucm218250.htm>.

<sup>14</sup> The minutes of the stakeholder discussions on MDUFA III reauthorization are available on FDA's website at <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Overview/MedicalDeviceUserFeeandModernizationActMDUFMA/ucm236902.htm>.

<sup>15</sup> The minutes of the industry discussions on MDUFA III reauthorization are available on FDA's website at <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Overview/MedicalDeviceUserFeeandModernizationActMDUFMA/ucm236902.htm>.

greater predictability, consistency, and transparency through a number of improvements to the review process. On March 15, 2012, FDA made public the package of proposed recommendations,<sup>16</sup> requested written public comment on those proposed recommendations, and announced that we would be holding a public meeting on March 28, 2012, at which interested stakeholders could present their views.

The proposed recommendations for MDUFA III address many of the priorities and concerns identified by public stakeholders and the device industry and many of the important challenges identified by FDA. Some of the notable improvements to the MDUFA program in the MDUFA III proposed recommendations include:

- **Review Process, Infrastructure, and Capacity Enhancements:**
  - Facilitating earlier and more transparent and predictable interactions between FDA and the applicant, both during the early product development or “pre-submission” stage as well as during the review process, by implementing a structured process for managing pre-submissions and continuing to incorporate an interactive review process;
  - Providing more detailed and objective “submission acceptance criteria” for determining when a premarket submission is complete and when a premarket submission is incomplete and should not be accepted for review;
  - Improving the process of developing, reviewing, tracking, issuing, and updating guidance documents;
  - Recommending reauthorization of the third-party review program and working with interested parties to strengthen and improve the current program as resources permit;

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<sup>16</sup> The proposed package of recommendations for MDUFA III is available on FDA’s website at <http://www.fda.gov/MedicalDevices/NewsEvents/WorkshopsConferences/ucm292860.htm>.

- Fully implementing guidance on factors to consider when making benefit-risk determinations, meeting with patient groups to better understand the patient perspective on disease severity and unmet medical need, and increasing FDA’s utilization of Patient Representatives to provide patients’ views early in the medical product development process;
- Identifying additional low-risk medical devices to exempt from premarket notification requirements;
- Working with industry to develop a transitional In Vitro Diagnostics (IVD) approach for the regulation of emerging diagnostics;
- Enhancing scientific and regulatory review capacity by hiring additional staff and reducing the ratio of review staff to front line supervisors—FDA is seeking to obtain streamlined hiring authority in order to accomplish this;
- **More Rigorous Review Performance Goals and Shared Outcome Goals:**
  - Adopting streamlined FDA review goals to provide better overall performance and greater predictability, including a commitment to meet with an applicant if FDA’s review of their submission extends beyond the goal date;
  - Eliminating the “two-tier” goal structure of MDUFA II and adopting a more simplified structure, incorporating a single, high-percentage goal for each performance metric;
  - Instituting more rigorous performance review goals:
    - increasing the percentage of 510(k) reviews that are completed in 90 review days from the current 90 percent to 95 percent by FY 2015;

- increasing the percentage of PMA reviews that are completed within 180 review days, from the current 60 percent to 90 percent by FY 2016, for PMAs not requiring external advisory panel review—for PMAs that do undergo panel review, FDA will complete 90 percent of the reviews within 320 review days by FY 2017;
  - Instituting a Substantive Interaction goal for several submission types to track the Agency’s communication with applicants at specified points during the review process;
  - A joint commitment between FDA and industry to accomplish shared outcome goals to reduce the total average calendar time to a decision for PMAs and 510(k)s so that safe and effective devices reach patients and health care professionals more quickly;
- **Enhanced Metrics for Improvements to the Premarket Review Process:**
  - Conducting a comprehensive independent assessment of the premarket review process to identify potential enhancements to efficiency and effectiveness, and incorporating those findings and recommendations into management of the review program;
  - More detailed quarterly and annual reporting of MDUFA III review program performance.

Additional details regarding the proposed recommendations for reauthorization of MDUFA, including the draft MDUFA III Commitment Letter and Legislative Language, are available on FDA’s website at

<http://www.fda.gov/MedicalDevices/NewsEvents/WorkshopsConferences/ucm292860.htm>.

The public comment period for review of the proposed recommendations for MDUFA III began on March 15, 2012. After the conclusion of the public comment period on April 16, 2012, FDA will consider the public's views and comments, revise the proposed recommendations as necessary, and transmit a final package of recommendations to Congress, along with a summary of the views and comments that were received and any changes that were made to the proposed recommendations in response to the public's views and comments. As we continue to work with all interested stakeholders and Congress toward reauthorization of MDUFA in order to provide adequate and stable funding for the program, we will also be moving forward with our ongoing CDRH program improvements, focusing on smart regulation that will facilitate device innovation. As these new policies and processes continue to be implemented, we expect to see notable improvements in the consistency, transparency, and predictability of our premarket review programs.

#### Smart Regulation's Role in Assuring Patient Safety

As we continue to look for ways to improve our ability to facilitate innovation and to speed safe and effective products to patients, we must not lose sight of the benefits of smart regulation to the medical device industry, to patients, and to society. Smart regulation of medical devices results in better, safer, more effective treatments as well as worldwide confidence in, and adoption of, the devices that industry produces.

We at FDA see daily the kinds of problems that occur with medical devices that are poorly designed or manufactured, difficult to use, and/or insufficiently tested. We appreciate the concern that some devices come on the market in the European Union (EU) before they do in the United States. While we want devices to be available to American patients as soon as possible,

consistent with U.S. law, they need to be both safe and effective. The U.S. system has served patients well by preventing devices from entering the U.S. market that were later shown to be unsafe or ineffective.<sup>17</sup>

There are significant differences between the EU and the U.S. medical device review systems. In the EU, manufacturers must demonstrate safety and performance, while in the United States, the standard for approval is safety and effectiveness.<sup>18</sup> In the EU, more than 70 private, non-governmental entities called “Notified Bodies” review and approve devices by giving them a “CE mark.” These decisions are kept confidential and are not released to the public or to EU regulatory bodies. In fact, the EU does not have one centralized regulatory body. Instead, each country can designate an entity as a Notified Body, yet the decision of one Notified Body applies to all EU countries.

Because of these factors, it is impossible to track medical device approvals, adverse events, or recalls in the EU, since there are few to no publicly accessible, centralized systems for collecting and monitoring information about medical device approvals or safety problems. The use of Notified Bodies has been criticized as encouraging “forum shopping” by sponsors to identify those Notified Bodies with the most lax operating standards, and the varying levels of expertise among Notified Bodies has been critiqued.

Some have suggested that the United States adopt the medical device regulatory system of the EU. Yet, outside the United States, pressure is growing toward *greater* premarket scrutiny of medical devices. A June 2011 report from the Belgian Health Care Knowledge Centre (a

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<sup>17</sup> See, e.g., D. Cohen and M. Billingsley, “Europeans Are Left to Their Own Devices,” *British Medical Journal*, 342:d2748 (2011), available at <http://www.bmj.com/content/342/bmj.d2748>.

<sup>18</sup> See “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](http://ec.europa.eu/consumers/sectors/medical-devices/files/recast_docs_2008/public_consultation_en.pdf); European Commission, “Guidelines on Medical Devices: Clinical Evaluation: A Guide for Manufacturers and Notified Bodies” (Dec. 2009), at p. 4, available at [http://ec.europa.eu/health/medical-devices/files/meddev/2\\_7\\_1rev\\_3\\_en.pdf](http://ec.europa.eu/health/medical-devices/files/meddev/2_7_1rev_3_en.pdf).

governmental agency that produces studies to advise policymakers when deciding on health care and health insurance)<sup>19</sup> concluded that “[f]or innovative high-risk devices the future EU Device Directive should move away from requiring clinical safety and ‘performance’ data only to also require pre-market data that demonstrate ‘clinical efficacy,’” and “[t]he device industry should be made aware of the growing importance of generating clinical evidence and the specific expertise this requires.”<sup>20</sup>

In May 2011, the European Society of Cardiology (ESC) issued a “case for reform” of the European medical device regulatory system: that body’s recommendations included creating a unified regulatory system, imposing stronger clinical data requirements, and requiring more accountability for notified bodies.<sup>21</sup> The ESC cited examples of several different cardiovascular technologies that were implanted in patients in the EU that were later proven to be unsafe and/or ineffective through clinical trials required under the U.S. system and were subsequently removed from the European market.

Also in May 2011, a series of feature articles was published in the *British Medical Journal*, criticizing the opacity of the European medical device regulatory system, and raising concerns about the regulation of high-risk devices and how well they are tested before coming on to the European market.<sup>22</sup> Several of the featured articles cited the FDA system’s transparency

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<sup>19</sup> Additional information about the Belgian Health Care Knowledge Centre, and its mission and activities, is available at <https://kce.fgov.be/content/about-the-kce>.

<sup>20</sup> Belgian Health Care Knowledge Centre, “The Pre-market Clinical Evaluation of Innovative High-risk Medical Devices,” KCE Reports 158 (2011) at p. vii, available at [http://www.kce.fgov.be/index\\_en.aspx?SGREF=202677](http://www.kce.fgov.be/index_en.aspx?SGREF=202677).

<sup>21</sup> See “Clinical evaluation of cardiovascular devices: principles, problems, and proposals for European regulatory reform,” Alan G. Fraser, et al., *European Heart Journal*, May 2011.

<sup>22</sup> “The Truth About Medical Devices,” *British Medical Journal*, vol. 342, at pp. 1115-1130 (May 21, 2011), available at <http://www.bmj.com/content/342/7807/Feature.full.pdf> (Deborah Cohen, “Out of Joint: The Story of the ASR,” *British Medical Journal* 2011; 342:d2905; Deborah Cohen and Matthew Billingsley, “Medical Devices: European Patients Are Left to Their Own Devices,” *British Medical Journal* 2011; 342:d2748); see also Fiona Godlee, “Editorial: The Trouble With Medical Devices,” *British Medical Journal* 2011; 342:d3123, available at <http://www.bmj.com/content/342/bmj.d3123.full>; Carl Heneghan, et al., “Medical-Device Recalls in the UK and the Device-Regulation Process: Retrospective Review of Safety Notices and Alerts,” *BMJ Open* (May 2011), available at <http://bmjopen.bmj.com/content/early/2011/05/12/bmjopen-2011-000155.full.pdf>.



as helping physicians to make informed decisions about which devices to use and providing patients with access to information about the devices that will be used on them.

Most recently, France's Directorate General for Health and its consumer safety body AFSSAPS<sup>23</sup> issued a report<sup>24</sup> urging stronger national and European regulation and monitoring of medical devices. In an accompanying statement, France's Minister of Health, Xavier Bertrand, said that EU rules on regulating and monitoring medical devices "must be radically overhauled."<sup>25</sup>

FDA continues exploring ways to get medical products to patients with serious and life-threatening diseases or conditions faster, but lowering U.S. approval standards isn't in the best interest of American patients, our health care system, or U.S. companies whose success relies on the American public's confidence in their products. We are pleased that a U.S. medical device industry trade association, AdvaMed, has stated that it supports maintaining our current rigorous standards of safety and effectiveness for marketing medical devices: "The medical technology industry has long recognized that a strong and well-functioning FDA is vital to maintaining America's preeminence in medical technology innovation, and we support the current regulatory framework in the U.S."<sup>26</sup>

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<sup>23</sup> Agence française de sécurité sanitaire des produits de santé, France's Agency for the Safety of Health Products.

<sup>24</sup> See AFSSAPS, "Poly Implant Prothèse: remise d'un rapport de la DGS et de l'Afssaps aux ministres chargés de la santé – Communiqué," available at <http://www.afssaps.fr/index.php/Infos-de-securite/Communiques-Points-presse/Poly-Implant-Prothese-remise-d-un-rapport-de-la-DGS-et-de-l-Afssaps-aux-ministres-charges-de-la-sante-Communique>.

<sup>25</sup> See "France Calls for Europe-wide Control on Prosthetics following PIP Breast Implant Scare," *The Telegraph* (Feb. 1, 2012), available at [http://www.telegraph.co.uk/health/women\\_shealth/9054282/France-calls-for-Europe-wide-control-on-prosthetics-following-PIP-breast-implant-scare.html](http://www.telegraph.co.uk/health/women_shealth/9054282/France-calls-for-Europe-wide-control-on-prosthetics-following-PIP-breast-implant-scare.html).

<sup>26</sup> Advanced Medical Technology Association (AdvaMed), "AdvaMed Statement on the House Energy and Commerce Subcommittee Hearing on FDA Device Regulation" (July 20, 2011).

## CONCLUSION

Over the course of MDUFA II, and especially during the last two years, CDRH has been working, with extensive input from industry and other stakeholders, to take concrete actions toward creating a culture change toward greater transparency, interaction, collaboration, and the appropriate balancing of benefits and risks; ensuring predictable and consistent recommendations, decision-making, and application of the least-burdensome principle; and implementing efficient processes and use of resources. These actions—geared toward a system of smart regulation—have already started to have a measurable, positive impact on our premarket programs, and we fully expect that positive trend to continue as we proceed to implement the improvements we have committed to make.

While we work with industry, other stakeholders, and Congress in the statutory process toward the reauthorization of medical device user fees, in order to ensure adequate and stable funding of the program, we are also continuing to move forward with CDRH program improvements. MDUFA II is scheduled to expire on September 30, 2012, and FDA is ready to work with you to ensure timely reauthorization of this critical program. If we are to sustain and build on our record of accomplishment, it is critical that the MDUFA reauthorization occurs seamlessly, without any gap between the expiration of current law and the enactment of MDUFA III. At the same time, we must remain mindful that, unlike the PDUFA program in which fees fund more than 60 percent of drug review costs, user fees under MDUFA III (as described in the recently announced agreement) will fund about a third of the total cost of the medical device premarket review process, making it important to keep these resources focused on the performance goals identified in the MDUFA agreement.

Mr. Chairman and Members of the Committee, I share your goal of smart, streamlined regulatory programs. Thank you for your commitment to the mission of FDA, and to the continued success of our medical device program, which helps to ensure that patients and practitioners have access to safe and effective innovative medical technologies on a daily basis. I am happy to answer questions you may have.