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STATEMENT

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"Continuing America's Leadership: The Future of Medical Innovation for Patients"

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Chairman Alexander, Ranking Member Murray, and Members of the Committee, I am Jeffrey Shuren, Director, Center for Devices and Radiological Health (CDRH) at the Food and Drug Administration (FDA). I am pleased to be here today to discuss FDA's work to promote patient access to innovative medical devices while ensuring appropriate patient protections.

INTRODUCTION

Advances in medical technology are transforming established medical practice and bringing completely new models of treatment, prevention, and diagnosis to patients right now. New devices include not only improvements over existing technology – devices that make less-invasive treatments possible and provide new options to patients whose condition would have been considered untreatable in the past – but also technologies that will be keystones in emerging fields, such as precision medicine. Genetic testing offers the promise of targeting the right treatment to the right patients, reducing ineffective treatment decisions, and speeding the delivery of therapies that work. Health information technology can empower people with chronic diseases to manage their own health and well-being by putting medical "apps" right into the hands of patients. FDA has responded to the promises – and challenges – posed by these devices with flexible, risk-based approaches to its oversight role and with strong performance in bringing new, safe and effective products to market.

At the same time, FDA needs to ensure it is delivering on its oversight role. This role requires that FDA facilitate patient access to new medical technology while providing the oversight to minimize unnecessary risks and ensure devices provide clinical benefit. At one end of the spectrum, unnecessary regulatory burden could drive innovators to seek more favorable

environments, potentially depriving American patients of timely access to needed therapeutic and diagnostic devices. At the other end of the spectrum, lax oversight could lead to patient harm from devices that have not been tested and shown to be safe and effective, and affect the marketplace by reducing confidence in the health care system that devices will do what they are intended to do without harming the patients they are intended to benefit. A flexible, risk-based approach to oversight of medical technology is critical to striking the right balance.

FDA's existing framework establishes flexibility that has allowed FDA to develop innovative approaches to medical device oversight, approaches that reduce unnecessary burden without compromising assurances that devices marketed to American patients are safe and effective. Improvements to FDA's device program have already resulted in decreased review times and timely patient access to important new devices. And while other changes are too new to evaluate, early signs are positive and point to additional improvements in timely access for U.S. patients to safe and effective devices.

Glossary of Key Terms

510(k) -	An application to FDA for market clearance of Class II devices and a small number of Class I devices. The manufacturer must demonstrate that the device is "substantially equivalent" to a legally marketed device. FDA currently reviews 510(k)s for fewer than 10 Class III devices that were legally marketed before 1976. FDA is in the process of reclassifying or finalizing calls for PMAs for these devices.
***De Novo* -**	A premarket request for FDA to classify a novel device into Class I or Class II.
IDE -	Investigational Device Exemption: An application to conduct studies of devices on human subjects.
MDUFA -	Medical Device User Fee Act: An agreement between FDA and industry that FDA will take certain actions and attain performance goals in exchange for industry user fees.
PMA -	Premarket Approval Application: The application to FDA for Class III devices. The manufacturer must demonstrate a reasonable assurance of safety and effectiveness to gain approval of a PMA.

The U.S. Regulatory Environment for Devices: 2010 – 2015

Performance of FDA's Device Program

In the early part of this decade, many policymakers and FDA stakeholders called for reform of FDA's device program, arguing that FDA regulation was driving companies to relocate overseas or market their devices abroad before introducing them in the United States. To support their arguments, critics pointed to contemporary surveys of device manufacturers and FDA's own data showing a decline in the performance of its premarket program from 2000 to 2010. Although FDA raised questions about the methodology used in some of these studies,[1] the underlying premise that industry's perception of FDA oversight can affect decisions about introducing new technology in the U.S. marketplace is important. This premise, as well as FDA's own awareness of the Agency's worsening performance numbers, moved FDA to implement a number of new

[1] These arguments often rely on studies published early in this decade to support these assertions—the methodology of which FDA has questioned. *See* Letter from Jeanne Ireland, Assistant Commissioner for Legislation, FDA, to Ranking Member Henry A. Waxman (July 11, 2011) *http://democrats.energycommerce.house.gov/sites/default/files/documents/Waxman-FDA-Concerns-Regarding-Makower-Study-of-Medical-Device-Regulation-2011-7-18.pdf.*

policies and programmatic changes over the past five years to improve its performance and to adapt its oversight to the global marketplace, and to new technologies. Added funding and increased capacity, as the result of the 2012 reauthorization of MDUFA also helped reverse the direction of the Agency's medical device premarket program.[2]

Today, the performance of FDA's device program has significantly improved. FDA is on track to meet all of its MDUFA performance goals related to device review, and premarket performance measures of FDA's device program show marked improvement since the start of the current decade on several measures related to how quickly devices come to market in the United States.

FDA is making progress in bringing down total review times for 510(k) submissions, de novo requests, IDEs, and the higher-risk PMA applications. While data is not complete for the years 2013 and 2014 because some applications remain open, existing data show improvements on several important measures:[3]

- Time to decision on device submissions has decreased:
    - **510(k)s**: The vast percentage of device premarket submissions received by FDA in any given year are 510(k)s. In Fiscal Year (FY) 2010, it took 116 days for a total time to decision on a 510(k). By FY 2014, total time had dropped by 10

[2] FDA estimates that it has added at least 190 of the planned 240 staff authorized by MDUFA III, since the end of FY 2011. These additional staff members have contributed to FDA achieving the new performance goals under MDUFA III.

[3] Appendix A provides additional data showing the current performance of FDA's device program, including data over several years that show the course of improvement over the past five years.

percent to about 105 days (these figures compare review times when 75.8 percent of submissions are closed).

- **PMAs**: Original PMAs generally account for only about 1 percent of all device applications received by FDA. Average total time to decision in FY 2014 has decreased to 236 days from 320 days at its peak in FY 2009, or an improvement of 26 percent (these figures compare review times when 41 percent of applications are closed). Once all FY 2014 applications are closed, we project performance will meet or exceed FY 2012 levels, which would be at least a 32 percent improvement since 2009.
- **IDEs**: Median total time to full IDE approval decision has decreased from 442 days in FY 2011 to 101 days in FY 2014, reducing the time it takes to bring a new medical device to market by nearly a full year. The number of IDE studies requiring more than two cycles to full approval has been reduced by 34 percent.
- ***De novo***: The average total time to final decision for *de novo* requests (510(k) plus *de novo* review) submitted after a device was found to be not substantially equivalent through the 510(k) process has been reduced from 992 days in FY 2010 to 300 days in FY 2014.

- Another measure of the performance of the medical device program is that FDA is working with industry to ensure that submissions are complete and ready for review. As a result, the percentage of submissions that are cleared and approved has increased since 2010:
  - The percentage of 510(k)s cleared increased from 73 percent to 84 percent.
  - The percentage of PMAs approved increased from 59 percent to 86 percent.

- The number of pending submissions at the end of a year has significantly decreased since 2010:
    - The number of 510(k) submissions has been reduced by 30 percent.
    - The number of PMA submissions pending has been reduced by 43 percent.

Our experience also suggests that there is marked improvement in the medical device industry's perception of FDA. In 2014, CDRH made providing excellent customer service a strategic priority and launched an effort to improve customer service that included staff training, surveys to assess interactions with customers and measure customer satisfaction, and, based on feedback from customers, actions to improve the quality of CDRH actions and services. CDRH's 2014 results show 83 percent satisfaction. While customers include everyone who interacts with FDA's medical device program, CDRH's results generally appear to track our experience.

Framework for Device Oversight

The basic framework under which FDA oversees devices was put in place almost 40 years ago, when Congress enacted the Medical Device Amendments of 1976 (MDA). The MDA established a flexible framework for FDA's oversight of medical devices and required that FDA tailor its oversight of devices to the degree of risk presented. Although the framework established under the MDA recognizes that medical devices inherently carry risk, the MDA did not mandate that FDA eliminate risk. Rather, FDA applies only the level of oversight necessary to establish a reasonable assurance of safety and effectiveness for devices. Under this framework, only about half of all devices are subject to any premarket review by FDA, and, of the devices that are subject to premarket review, FDA reviews clinical data for fewer than 20

percent because there are other, less-burdensome means to determine that there is a reasonable assurance that a device is safe and effective.[4]

FDA oversight of devices is tailored to three risk-based classifications:

- **Class I, or low-risk devices**: FDA does not review any premarket information for Class I devices, with the exception of a small subset of Class I "reserved" devices. Class I makes up about 50 percent of all medical devices. An example of a Class I device is an elastic bandage.
- **Class II, or moderate-risk devices**: FDA generally reviews 510(k) submissions for these devices, which requires a demonstration of substantial equivalence to a legally marketed device. About 80% of all 510(k)s contain only non-clinical data. Examples of Class II devices include glucose test strips and infusion pumps.
- **Class III, or high-risk devices**: FDA generally reviews PMAs containing clinical and non-clinical data to determine whether there is a reasonable assurance of safety and effectiveness for these devices. FDA generally reviews about 40 PMAs a year. Examples of PMA devices include heart valve replacements and diagnostic tests used to select ovarian cancer patients for a drug regimen.

FDA's evidentiary standard for premarket review of devices is valid scientific evidence, a standard established by Congress in 1976 that still sets the benchmark for evidence to support premarket submissions. This benchmark ensures that the evidence is of sufficient quality that it can be relied on to determine whether or not a device should be approved or cleared. Although valid scientific evidence includes randomized-controlled clinical trials, the overwhelming majority of devices come to market based on non-clinical data, small clinical studies, or both. The valid scientific evidence standard encompasses many other forms of evidence, such as bench testing, journal articles, observational data, and foreign studies.

In vitro diagnostic (IVD) devices have been regulated by FDA under its risk-based device framework since the inception of the device program. Diagnostic tests can be used in the context of acute outbreaks, such as the recent Ebola outbreak, and in the diagnosis and treatment,

[4] The 20 percent includes *in vitro* diagnostics (IVD) devices, which typically contain test results based on human-derived samples. When IVDs are excluded, the number of submissions with clinical data drops to fewer than 10 percent.

including management, of chronic diseases like cancer and diabetes. Success in combatting these diseases depends on diagnostic tests that can accurately detect them and be used to select and manage treatments. A case in point is the widespread use of glucose meters and diabetes test strips. These devices can empower people with diabetes to manage their diseases independently, but only when the devices are accurate. In recent years, test reports of falsely high and low blood sugar levels have led to multiple recalls of these products over concerns that false readings could lead to incorrect treatment decisions; in particular, insulin administered in response to falsely high measures of blood sugar could lead to acute hypoglycemia, coma, and even death, if left untreated. The American Diabetes Association issued a statement of strong support of FDA oversight of these tests, stating:

> The American Diabetes Association strongly endorses [FDA] oversight of test strip manufacturers[]. The Association applauds the FDA's requirements that all test strips meet existing FDA standards for medical devices, since those standards are designed specifically to require the greatest accuracy in readings when an error would place a patient's health and life in danger. [5]

For IVD devices, a reasonable assurance of safety and effectiveness means that a test has analytical and clinical validity. "Analytical validity" assesses how well the test detects or measures certain markers in human specimens. "Clinical validity" assesses whether the marker has clinical significance, such as correlation with disease or the ability to predict a therapeutic response to a drug. As FDA's recent announcement – that it intends to exempt carrier screening

[5] *http://professional.diabetes.org/News_Display.aspx?CID=93129*

tests from premarket review – shows, the level of data FDA requires to show analytical and clinical validity for IVD devices depends largely on risks from the device.

The central features of FDA's device program – a risk-based framework that tailors oversight to device risk; a flexible review standard that requires a reasonable assurance of safety and effectiveness; and an adaptive but scientifically grounded evidentiary standard of valid scientific evidence – have served the public well. While there have been multiple amendments to FDA's original authority, providing new premarket pathways and enhancing FDA's post-market oversight, the framework put in place by the MDA continues to provide the tools to assure safety and effectiveness of therapeutic and diagnostic devices while allowing FDA to adapt its oversight to the demands of rapidly evolving medical technology.

Adapting FDA's Oversight Role to Current Challenges: 2010-2015

The new policies and programmatic changes FDA has implemented in the past five years respond to the needs of American patients to have timely access to high-quality, and safe and effective devices, and to challenges created by rapidly evolving fields of medical innovation. These initiatives have had far-ranging objectives, from providing FDA review staff with new tools to assess the benefits as well as the risks of a device to American patients to promoting regulatory certainty and empowering patients to manage their well-being. Among these initiatives are process improvements and policy changes to its oversight of clinical investigations of devices.

Streamlining Clinical Trials

In 2014, FDA established a Clinical Trials Program to coordinate its oversight of clinical studies of devices; provide interventions if a review of an application to conduct a clinical investigation of a device (Investigational Device Exemption or IDE) takes more than one cycle; offer more opportunities for interactions with sponsors; expand training for review staff; and establish new or modified policies in this area. For example, recognizing that devices that are studied in the United States in the early stages of clinical assessment are more likely to reach U.S. patients sooner in pivotal trials and as marketed devices, FDA implemented a pilot program in 2011 to encourage early feasibility studies, or early-stage clinical studies, of devices in the United States. In 2013, FDA issued final guidance on early feasibility studies;[6] under this program, FDA may accept a higher degree of uncertainty during the device development process to facilitate important early clinical evaluation of promising technologies. As a result, we are beginning to see an increase in companies submitting IDEs for early feasibility studies in the United States and more approvals of such IDEs. In the past two years, we have reduced the median time to approval for early feasibility studies by 70 percent, from 226 days in FY 2013 to 66 days in FY 2015.

Devices that are studied in the United States in the early stages of development are more likely to reach U.S. patients sooner in pivotal studies and as marketed devices. In the past 15 Fiscal Years, for those original PMAs whose approval was based on FDA-approved pivotal clinical studies, 94 percent (283 out of 300) of these approvals were based on a single pivotal clinical study. More recently, in the past five years, the number has increased to 98 percent (82 out of

[6] *Investigational Device Exemptions (IDEs) for Early Feasibility Medical Device Clinical Studies, Including Certain First in Human (FIH) Studies: Guidance for Industry and FDA Staff* (October 1, 2013), available at *http://www.fda.gov/downloads/medicaldevices/deviceregulationand%20guidance/guidancedocuments/ucm279103.pdf*.

84). Of the 82 FDA-approved original PMAs whose approval was supported by a single pivotal clinical study, 32 (39 percent) included studies enrolling subjects outside of the United States. For IVD devices, where clinical studies are typically conducted in at least three sites, sponsors generally choose to have one of those sites inside of the United States to address differences between the United States and other countries in how medicine is practiced, patient populations, and disease progression.

FDA is facilitating and encouraging the use of innovative clinical trial designs and statistical methods such as adaptive clinical trials and Bayesian statistics. By incorporating existing clinical information about devices into statistical analyses, adaptive clinical trials such as the Bayesian approach can support a marketing application for a device based on shorter and smaller clinical trials. In 2010, FDA published a guidance document on how Bayesian methods can be used to design and analyze data from medical device clinical trials.[7] FDA's efforts to promote the appropriate use of adaptive trial designs to support premarket device applications date to the late 1990s[8] and in recent years, many devices have come to market based on adaptive trial designs. For the period from 2007 to May of 2013, FDA received 250 submissions that were adaptive, most of which were pre-submissions and IDEs. About 30 percent of these used Bayesian methodologies. In addition, there were 17 PMAs and PMA Supplements that used adaptive clinical trials from 2007 to May of 2013, eight of which used Bayesian methodologies.

[7] *Guidance for the Use of Bayesian Statistics in Medical Device Clinical Trials* (February 5, 2010), available at *http://www.fda.gov/medicaldevices/deviceregulationandguidance/guidancedocuments/ucm071072.htm*

[8] Gregory Campbell (2011) Bayesian Statistics in Medical Devices: Innovation Sparked by the FDA, *Journal of Biopharmaceutical Statistics*, 21:5, 871-887, DOI: 10.1080/10543406.2011.589638. This article refers to 16 approved PMAs that relied on Bayesian analysis and one cleared 510(k); there have been several additional device approvals since 2011, but an exact number is not available.

These programmatic improvements and policy changes have already yielded results in significantly reduced time to approval of IDEs and increasing approval rates. While the full effect of these programmatic improvements on U.S. health care will not be known for several years, streamlined processes for initiating device studies in the United States and reductions in the time to approval for U.S. clinical studies are promising developments in the effort to ensure U.S. patients have timely access to medical devices of public health importance.

Flexible decision-making

In recent years, FDA has also implemented a series of new premarket policies that build on the risk-based framework established by the MDA. While these policies are relatively new, and the programmatic effects cannot yet be measured, many of the policies have affected important review decisions, impacting public health by speeding access to new safe and effective devices.

Benefit-Risk: FDA's standard for premarket review of high-risk devices has always required the Agency to weigh the benefits of a device against its risks. For the past three years, however, FDA has used a more flexible, patient-centric, and transparent benefit-risk framework to evaluate devices. Under this framework, developed with public feedback, reviewers weigh a number of factors to arrive at a decision of whether the benefits of a device outweigh its risks, including: the type, magnitude, and duration of a risk or benefit, the probability that a patient will experience the risk, patient tolerance for risk, availability of alternative treatments, and the value the patient places on treatment. Under this approach, devices that present a small but real likelihood of preventing serious disability or death could, with appropriate risk mitigation such as labeling, reach the market despite greater uncertainty about its risks. Also, in appropriate cases, FDA may defer some data otherwise collected premarket to the post-market setting to

promote timely access to the benefits of devices of public health importance, provided there is still a reasonable assurance of safety and effectiveness. FDA currently applies this benefit-risk framework to all reviews of high-risk and novel lower-risk devices.[9]

Patient Preferences Initiative: Increasingly, patients seek to be involved in decision-making about their own health. Recognizing the importance of considering patients' views in deciding how the probable risks and benefits of medical technology should be weighed, in 2013 FDA launched the Patient Preferences Initiative. The initiative seeks to incorporate valid scientific evidence of patient preferences on the benefit-risk tradeoffs of medical devices into premarket review and other decision-making by FDA's device program. For example, a team of FDA scientists published an article with leading behavioral economists, illustrating how patient preferences can inform medical device approval decisions.[10] The authors successfully tested a new method for capturing patient sentiment and translated it into a decision-making tool for incorporating patient preferences into clinical trial design for obesity treatments. They were able to estimate the tradeoffs in risks that obese patients are willing to accept in exchange for a certain amount of weight loss, and the minimum number of pounds they would have to lose to tolerate the risks of a weight-loss device. FDA used the results of this study to inform the product approval decision.

[9] *Factors to Consider When Making Benefit-Risk Determinations in Medical Device Premarket Approval and De Novo Classifications* (March 28, 2012), available at http://www.fda.gov/downloads/medicaldevices/deviceregulationandguidance/guidancedocuments/ucm296379.pdf.

[10] Marin P. Ho et al., Incorporating Patient-Preference Evidence into Regulatory Decision-Making, *Surgical Endoscopy* DOI 10.1007/s00464-014-4044-2 (2015).

Use of Patient Preferences to Approve a New Weight-Loss Device

In 2015, FDA approved a new weight-loss device – *the Maestro Rechargeable System*, a new therapeutic option for certain obese patients. The decision to approve the device was based in part on the patient preference data, which showed that a substantial portion of obese patients would accept the risks associated with a surgically implanted device if they lost a sufficient number of pounds. Maestro is the first FDA-approved obesity device since 2007.

Expedited Access Program: In 2014, FDA proposed a program for expedited patient access to devices that are of potential significant public health benefit because they are intended to treat or diagnose patients with life-threatening or irreversibly debilitating conditions whose medical needs are unmet by current technology – what some have called "breakthrough devices." Under this program, FDA would provide earlier and more interactive engagement with sponsors of such devices, including the involvement of senior management and a collaboratively developed plan for collecting the scientific and clinical data to support approval – features that, taken together, should provide patients with earlier access to safe and effective medical devices. The program would target devices with potentially high impact on patient health because, for example, they fulfill an unmet need by offering an important advantage over existing devices. To promote earlier patient access, some data collection for devices marketed under this pathway might be moved from pre- to post-market, provided there is still a reasonable assurance of safety and effectiveness concerning the device. FDA issued final guidance[11] in April 2015. The Expedited Access Pathway program went into effect on April 15, 2015.

[11] *http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM393978.pdf*

Regulatory Science: New Uses of Evidentiary and Analytical Tools

FDA has also invested in several new regulatory science programs over the past several years to reduce the time and cost but not the quality of data development for devices. These programs promote the development and use of tools, analytical methods, and data sources in premarket applications to bring safe and effective devices to market faster and at less cost.

Medical Device Development Tools (MDDTs)

An MDDT is a scientifically validated tool – a clinical outcome assessment (e.g., patient-reported or clinician-reported rating scales), a test used to detect or measure a biomarker, or a non-clinical assessment method or model (e.g., an *in vitro*, animal, or computational model) that aids device development and regulatory evaluation. In August, 2014, FDA announced a pilot program under which anyone can submit scientific information to FDA to "qualify" an MDDT. Once qualified, MDDTs can be used to support premarket applications. In practice, this can enable sponsors to support a PMA, *de novo* request, or a 510(k) using smaller and shorter clinical trials. The MDDT program builds on FDA's successes, developing computational models like the Virtual Family (VF), a set of highly detailed, anatomically correct, computational whole-body models, designed to mimic humans of both sexes at various stages of growth.

Regulatory Science – The Virtual Family (VF)

FDA collaborated with researchers and industry to create the VF, a set of four highly detailed, anatomically correct whole-body models of an adult male, an adult female, and two children. Currently, the VF models are used for electromagnetic, thermal, acoustic, and computational fluid dynamics (CFD) simulations—simulations that can supplement or replace data from clinical investigations of devices. At the end of 2014, the VF was used in more than 120 medical device submissions to FDA and was cited more than 180 times in peer-reviewed literature. Recently the Virtual Population 3.0 became available. The VF are available free of charge to researchers for use in device development.

Medical Device Innovation Consortium (MDIC)

In 2012, FDA and LifeScience Alley (a biomedical trade association) co-founded a new nonprofit partnership—the Medical Device Innovation Consortium—the first public-private partnership (PPP) whose mission is to advance medical device regulatory science. MDIC is a collaboration among Federal agencies, industry, nonprofit organizations, and patient advocacy organizations, and provides a venue for leveraging of resources, people, and intellectual capital to find solutions to common challenges in the precompetitive space. MDIC supports the development of non-clinical device development tools that can reduce the need for or size of clinical studies to support market approval as well as steps to reduce the time and cost of clinical trials. MDIC has several active project focus areas, including the following:

Patient-centered Benefit-Risk: This project focuses on developing scientifically robust ways to measure patient perspectives on the benefits and risks of medical devices, and a framework for incorporating patient perspectives into device development and regulatory decision-making.

Clinical Trials Innovation and Reform: MDIC is working with FDA, NIH, industry, academia, and patient groups to explore ways to improve the efficiency and cost-effectiveness of medical device clinical trials while maintaining data quality. The goal is to streamline the clinical trial process and restore the United States to the country of first choice to conduct clinical research for medical technology innovation. The project aims to innovate and reform the U.S. clinical trial process by defining and tackling top barriers to efficient design and conduct of medical device clinical trials.

Computer Modeling & Simulation: The goal of this project is to reduce the time and cost of bringing devices to market while improving patient safety by advancing the science around computer modeling and simulation for medical devices. These models, when of sufficient quality to be considered "regulatory grade," can be used to assess device performance, thus reducing or obviating the need for other more expensive or burdensome types of scientific evidence (such as human clinical studies).

MDIC's collaborations focus on advancing regulatory science to propel device development through the regulatory process and to market, resulting in smarter regulation and earlier patient access to safe, effective, and high-quality devices.

Real-world Data

In September 2012, FDA published a report, "Strengthening Our National System for Medical Device Postmarket Surveillance," which proposed a National Medical Device Surveillance System (MDS) for improving and addressing the limitations of our current system for monitoring medical device safety and effectiveness. This report recommended establishing a national infrastructure for gathering and analyzing real-world data, or data collected as part of routine clinical practice and patient experience. The purpose of such a national system is to identify potential safety signals in near real-time; better understand the benefit-risk profiles of medical devices on the market; and facilitate the clearance and approval of new devices, or new uses of existing devices.

In the past year, FDA has achieved tremendous progress laying the groundwork for the MDS. FDA has begun implementing the unique device identification (UDI) rule for the highest-risk

devices, including development of a Global UDI Database (GUDID) as the repository for information that unambiguously identifies devices through their distribution and use. By promoting incorporation of UDIs into electronic health information (such as electronic health records, or EHRs, and device registries), a vast quantity of untapped real-world data from clinical experience with devices housed in EHRs and other electronic information sources may become available for use in understanding the benefit-risk profiles of medical devices. In addition, FDA continues to build registry capabilities both domestically (such as the National Breast Implant Registry) and internationally (such as the International Consortium of Vascular Registries). FDA established a Medical Device Registry Task Force consisting of key registry stakeholders as part of the Medical Device Epidemiology Network (MDEpiNet) Program, a collaborative program that FDA co-founded to develop new and more efficient methods to study medical devices and to enhance FDA's ability to more fully understand the safety and effectiveness of medical devices after they are marketed. FDA commissioned the Engelberg Center for Health Care Reform at the Brookings Institution to convene and oversee deliberations of the Medical Device Postmarket Surveillance System Planning Board. In February 2015, the Planning Board issued a report, "Strengthening Patient Care: Building an Effective National Medical Device Surveillance System," outlining recommended steps toward the development, oversight, and effective use of medical devices, while supporting improvements in patient safety and health outcomes.

FDA's work in developing registries has relieved post-market burden by allowing device sponsors to submit data from registries instead of conducting their own new post-market studies. FDA is also pursuing strategies to use data from the most robust registries in the premarket

context, and has already relied on registry data to expand access to transcatheter aortic valve replacement devices.

Use of Real-World Evidence to Expand Use of Minimally Invasive Heart Valve Replacement

Before 2014, transcatheter aortic valve replacement, a minimally invasive alternative to open heart surgery, was indicated only for patients with aortic stenosis for whom open heart surgery was too risky, who were yet healthy enough to undergo certain placement procedures. At the same time, clinical experience indicated this device could offer good outcomes to inoperable patients with no other options. In 2014, FDA expanded approval for the Edwards Sapien® TranscatheterAortic Valve Replacement to patients deemed inoperable without requiring controlled clinical trials of the new use. FDA approved the expanded indication based on registry data from clinical use of the device.

Adapting to New Technology

FDA's device program aims to be adaptive in responding to new technologies. Recent policies have focused FDA oversight of health IT on medical devices that present greater risks, with the goal of permitting access to a range of products while ensuring the safety and effectiveness of medical devices the a subset of mobile medical apps that present a greater risk to patients if they do not work as intended such as those that provide or assist health care practitioners with treatment and diagnosis. FDA's device program is leading the development of clear, streamlined pathways for technologies that are pivotal to the success of precision medicine, such as companion diagnostics and Next-Generation Sequencing devices. The approach to oversight in these areas demonstrates the adaptability of the existing regulatory framework.

Mobile Medical Applications and Other Health IT:

As the number and functionality of mobile applications, or apps, exploded in recent years, in 2013, FDA announced a policy under which FDA intended to focus its regulatory oversight on those mobile medical apps that pose the greatest risk to consumers and exercise enforcement discretion for the majority of mobile apps as they pose minimal risk to consumers. FDA

followed this policy with a preliminary health IT report produced in collaboration with the Office of the National Coordinator and the Federal Communications Commission, as required by the Food and Drug Administration Safety and Innovation Act (FDASIA) of 2012;[12] this report outlines a series of recommendations and actions for the public and private sectors to take in this dynamic area of health IT to avoid duplicative regulation, while promoting innovation and protecting patient safety. The agencies accepted public comment on this report to inform its development. Recently, FDA has issued guidance under which FDA clarified that it intends to exercise enforcement discretion for medical device data systems,[13] a form of health IT that, while low risk, is widely used in the delivery of health care. With these actions, FDA helped to make clear the narrow arena of health IT where the Agency intends to continue its oversight—namely, the space occupied by the riskiest forms of medical software—while clearly stating its intention to not focus its oversight over a broad range of other medical device software products.

FDA recently proposed a similar policy for all low-risk devices used to promote health and well-being and to help individuals with chronic disease maintain wellness. The policy extends to products used to promote physical fitness, maintenance of a healthy weight, relaxation, and similar states of well-being, so long as the product does not present inherent risks to users. As with FDA's recent policies concerning health IT, FDA proposed this policy to provide greater certainty to product developers and users that FDA intends to focus its oversight in these emerging areas of product development on medical devices that present more than low risk.

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[12] See FDASIA Health IT Report (April 2014), available at *http://www.fda.gov/downloads/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/CDRH/CDRHReports/UCM391521.pdf*

[13] *Medical Device Data Systems, Medical Image Storage Devices, and Medical Image Communications Devices: Guidance for Industry and FDA Staff* (February 9, 2015), available at *http://www.fda.gov/downloads/medicaldevices/deviceregulationandguidance/guidancedocuments/ucm401996.pdf*

Companion Diagnostics:

Companion diagnostic tests play an important role in promptly determining which therapies are safe and effective for a particular patient and are a key component of precision medicine. FDA has approved 20 companion diagnostic tests, all of them within the PDUFA performance goals for the corresponding drug or biological product, ensuring the timely marketing authorization of both. In 2014, FDA issued guidance[14] describing a clear marketing pathway for developers of companion diagnostic tests and pharmaceutical manufacturers, receiving strong support from both pharmaceutical and conventional test manufacturers for providing regulatory clarity in this rapidly advancing area of medicine. Companion diagnostics approved by FDA in recent years include the BRACAnalysis CDx™ test, a laboratory-developed test that aids in determining which ovarian cancer patients are more likely to respond to the drug Lynparza™ (olaparib), based on certain BRCA variants; the THxID™ BRAF Kit, which detects certain mutations in melanoma tissue samples to aid in selecting patients for drug therapy with Tafinlar® (dabrafenib) or Mekinist™ (trametinib); and the *therascreen*® KRAS RGQ PCR Kit, a test that screens out colorectal cancer patients with genetic mutations known to predict a nontherapeutic response to the biological products Erbitux® (cetuximab) and Vectibix® (panitumumab).

Next-generation Sequencing:

Many newly developed genomic diagnostic tests rely on next-generation sequencing (NGS), an advanced technology, which is becoming a keystone of precision medicine. NGS tests can rapidly generate an unprecedented amount of genetic data for each patient. Most IVD devices are used to detect a single or a defined number of markers to diagnose a limited set of conditions;

[14] *In Vitro Companion Diagnostic Devices: Guidance for Industry and Food and Drug Administration Staff* (August 6, 2014), available at *http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM262327.pdf*.

in contrast, a single NGS test can identify thousands or millions of genetic variants that can be used to diagnose or predict the likelihood of an individual developing a variety of diseases. FDA has provided marketing authorization for an NGS test for cystic fibrosis using innovative approaches to establishing the test's effectiveness. As part of the President's Precision Medicine Initiative FDA will develop a new approach for evaluating Next Generation Sequencing technologies to facilitate the generation of knowledge about which genetic changes are important to patient care and foster innovation in genetic sequencing technology, while ensuring that the tests are accurate and reliable.

Next-generation Sequencing: Cystic Fibrosis (CF)

FDA authorized marketing for the Illumin MiSeqDx Cystic Fibrosis System *in vitro* diagnostic test, which detects 139 genetic mutations that are relevant to whether an individual will develop CF or transmit the CF genetic mutation to his or her children. FDA worked with the test developer to apply novel approaches to establishing clinical validity by using publicly available, quality-weighted human reference genomes (databases) that were created through collaboration between FDA and the National Institutes of Standards and Technology (NIST), and analytical validity by using data showing the test could accurately detect a representative sample of variants.

FDA recently published a white paper outlining a possible approach to review of this technology that would greatly reduce burden by leveraging data in existing high-quality curated genetic databases as an alternative to conducting new clinical trials and by reviewing analytical performance for only a subset of variants. FDA has received positive feedback from thought leaders in this area for identifying ways to adapt its review practices to this important new technology.[15]

[15] Lander, Eric S., Cutting the Gordian Helix – Regulating Genomic Testing in the Era of Precision Medicine, *NEJM* 2015, DOI: 10.1056 p150.

CONCLUSION

This is a time of remarkable advances in medical device technology, advances that can extend lives, and minimize suffering for American patients. New technologies hold out promise for empowering patients in their own health care decision-making and for delivering precision treatments that are truly targeted to individuals. At the same time, the promise of advances in medical technology will only be realized if the patients and providers who use them are confident that they are safe and can do what they are intended to do.

FDA's device program has evolved alongside changes in medical technology and in the global marketplace. FDA has implemented several new policies and programmatic improvements to ensure American patients have timely access to devices without compromising standards of safety and effectiveness. Devices are coming to market more quickly, and more devices that go through FDA's premarket program are being approved and cleared for marketing. In addition, FDA has made its review of investigational devices more efficient and expeditious, streamlining the pathway to conducting clinical investigations in the United States.

The improvements in FDA's device program have occurred under a long-standing framework that tailors FDA oversight to a device's risks and benefits. This framework provides flexibility to adapt to new technology and to consider a variety of different forms of evidence. At the same time, the framework establishes a standard for devices marketed to American patients: there must be a reasonable assurance of safety and effectiveness for devices, demonstrated by valid scientific evidence. We believe this framework serves the public well, allowing FDA to meet the

demands of rapid innovation and a changing global marketplace, while promoting public confidence in high-quality, safe, and effective devices.

Thank you for the opportunity to testify today about the steps FDA is taking to foster innovation. I am happy to answer questions you may have.

Appendix A. Medical Device Premarket Program Performance

MDUFA III

Performance Goals: Preliminary data for MDUFA performance goals through September 30, 2014, indicate that FDA is on track to meet all of its performance goals while maintaining a high workload. In FY 2014, FDA received over 6,000 submissions for PMAs, PMA supplements, 510(k)s, *de novos*, and HDEs.

The 4th quarter MDUFA III Performance Report presents preliminary performance for the FY 2013 and FY 2014 MDUFA III submissions. Further details can be found in the MDUFA III Quarterly Performance Reports available on FDA's MDUFA III website. (**Table 1**)

Table 1. FY 2014 MDUFA III performance for selected submission types, as of September 30, 2014.

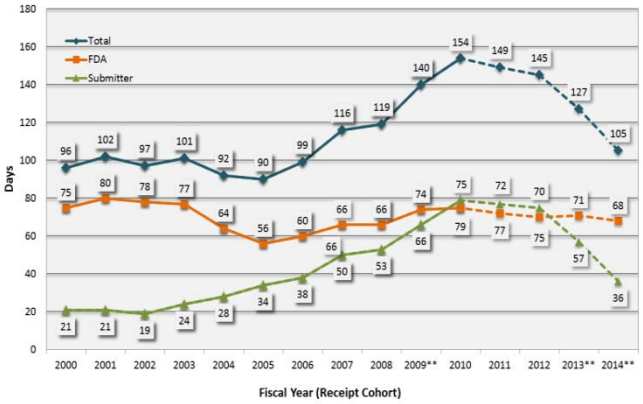
	Performance Goal	Current Performance[16]	Review Progress[17] (% complete)
PMA, Panel-Track PMA Supplements, and Premarket Reports			
Substantive Interaction	**75%**	**95%**	37 of 45 (82%)
Decision with no Advisory Committee input	**80%**	**100%**	7 of 43 (16%)
Decision with Advisory Committee input	**70%**	-	0 of 2
180-Day PMA Supplements			
Substantive Interaction	**75%**	**94%**	127 of 178 (71%)
Decision	**90%**	**100%**	78 of 178 (44%)
Real-Time PMA Supplements			
Decision	**90%**	**99%**	272 of 333 (82%)
510(k) Premarket Notifications			
Substantive Interaction	**75%**	**97%**	2,739 of 3,166 (87%)
Decision	**93%**	**99%**	1,811 of 3,133 (58%)
CLIA Waivers			
Substantive Interaction	**95%**	**100%**	14 of 14 (100%)
Decision for dual submissions ((510(k) and CLIA waiver)	**90%**	-	0 of 1 (0%)
Decision with no Advisory Committee input	**95%**	**100%**	8 of 14 (57%)
Decision with Advisory Committee input	**95%**	-	0 of 0

[16] **Current** Performance presents the percentage of actions that FDA completed within the review-time goal as of September 30, 2014.

[17] **Review Progress** presents the number of submissions that had actions taken in FY 2014, plus submissions pending but overdue as of September 30, 2014, whether or not they met the MDUFA goal date, out of all MDUFA cohort submissions.

Premarket Notification (510(k)) Program

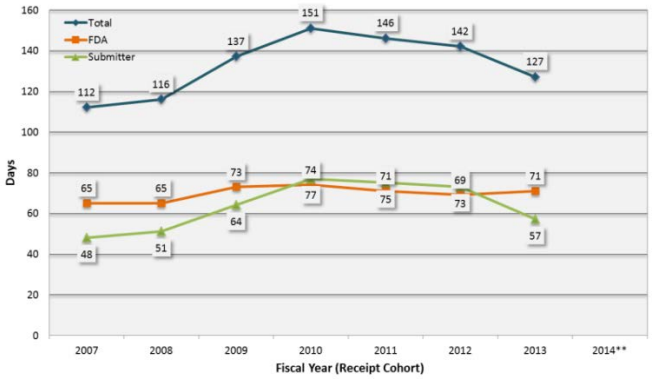
Average Time to Decision for 510(k)s: Total time to decision includes the time spent by FDA reviewing the application as well as the time spent by the submitter responding to questions from FDA. 510(k) average total time to decision has decreased since its peak in FY 2010.(**Chart 1**) FY 2013 and FY 2014 cohorts are not yet fully closed; as of December 31, 2014, the FY 2013 510(k) cohort was 99.2 percent closed and 2014 cohort was 75.8 percent closed. Comparison of receipts cohorts at the same closure[18] levels show a 16 percent decrease in total review time (**Chart 2**) between FY 2010 and FY 2013 and a 10 percent decrease in total review time between FY 2010 and FY 2014. (**Chart 3**) The FY 2013 cohort had the same average total time to decision as FY 2014 at the 75.8 percent level of closure.



***Cohorts still open; percentage of cohort closed: FY 2009 = 99.9%, FY 2013 = 99.2%, and FY 2014 = 75.8%—average times will increase.*

Chart 1. Average time to decision for 510(k) receipt cohorts as of December 31, 2014. Includes SE and NSE decisions only; times may not add to total due to rounding.

Organizationally, CDRH medical device premarket review offices are divided into review divisions, which are comprised of review branches. FDA is also closing the gap between the premarket review branches with the fastest and slowest review times. In 2003, the lowest performing branch reached 34 percent of its 510(k) MDUFA decisions within 90 FDA Days. In FY 2013 and 2014, most branches were reaching decisions within 90 FDA days 90 percent of the time or better.



***FY 2014 cohort is not yet 99.2% closed (as of December 31, 2014)*

Chart 2. Average time to decision for 510(k). Comparison of receipt cohorts when 99.2 percent closed. SE and NSE decisions only; times may not add to total due to rounding.

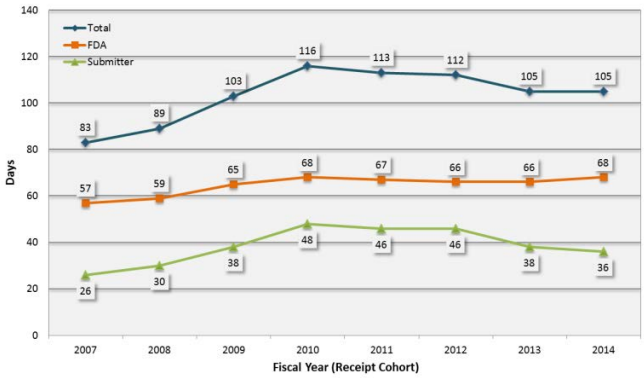
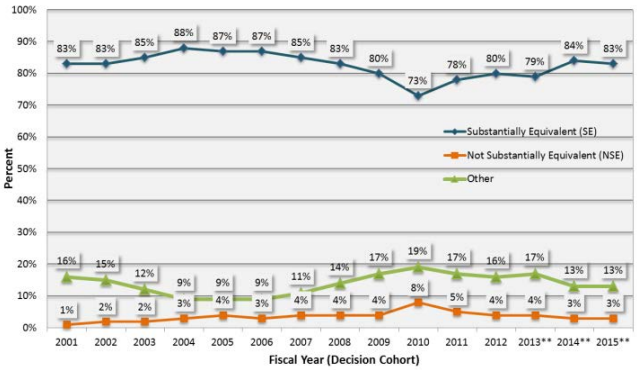


Chart 3. Average time to decision for 510(k). Comparison of receipt cohorts when 75.8 percent closed. SE and NSE decisions only; times may not add to total due to rounding.

[18] Use of closure level provides a means for fair "apples to apples" comparisons, as performance is compared using the same percentage of work completed in a given year.

Substantially Equivalent (SE) Determinations and Pending Submissions: Improvements to the 510(k) program have increased the number of submissions determined to be substantially equivalent (SE) since 2011 (decision cohort). The number of submissions determined to be SE in FY 2014 is 10 percent greater than in FY 2010. The impact of CDRH improvements is further observed in the number of pending 510 (k) submissions, which has been reduced by 30 percent from its highest level in FY 2010.

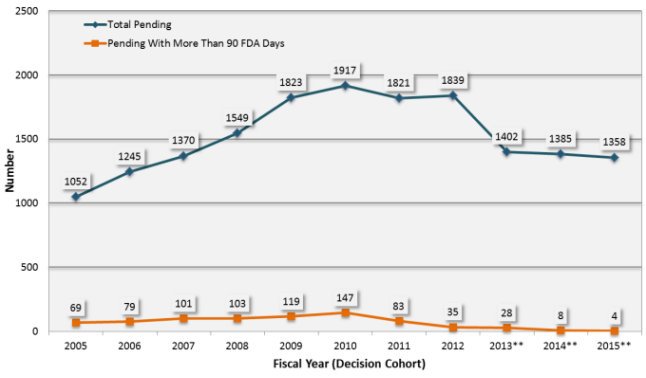


***Excludes final decisions made on FY 2013 - FY 2015 receipts that were not accepted for review as of December 31, 2014*

Chart 4. Percent of 510(k) determined to be Substantially Equivalent (SE). Percentages may not add to 100 percent due to rounding**.** FY 2015 includes only 3 months of data.

510(k) Refuse to Accept (RTA) Program: Under the RTA Program FDA conducts an early review against specific acceptance criteria to assess whether the submission meets a minimum threshold of acceptability and should be accepted for substantive review. The assessment of the completeness of the 510(k) occurs during the early acceptance review, while the assessment of the quality of the submitted information occurs during the substantive review. Since the initiation of the Refuse to Accept (RTA) program on January 1, 2013, the RTA rate has been decreasing from 58 percent during the second quarter of FY 2013 to 39 percent during the last quarter of FY 2014. (**Chart 6**)

Training and increased FDA and Industry experience regarding the RTA process have contributed to the decreased rate while improving the quality of 510(k) submissions. FDA is undertaking a process improvement exercise to further reduce the RTA rate and improve consistency of this program. Overall acceptance rate, when RTA 1st and 2nd cycles are combined, was 84 percent in FY 2013 and 90 percent in FY 2014.



***Excludes FY 2013 - FY 2015 receipts that were not accepted for review as of end of year.*

Chart 5. 510(k) submissions pending at end of the year. Includes 510(k) submissions under review or on hold. FY 2015 is as of December 31, 2014.

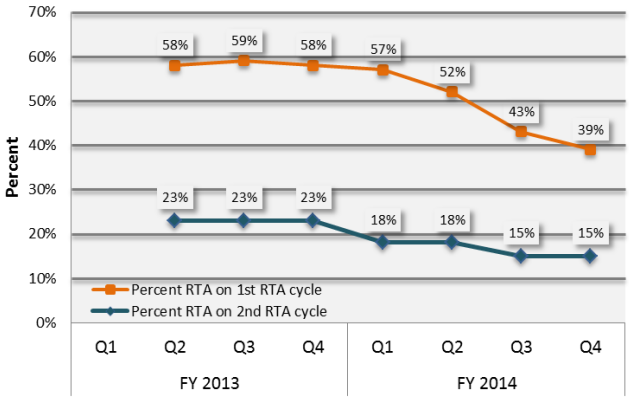
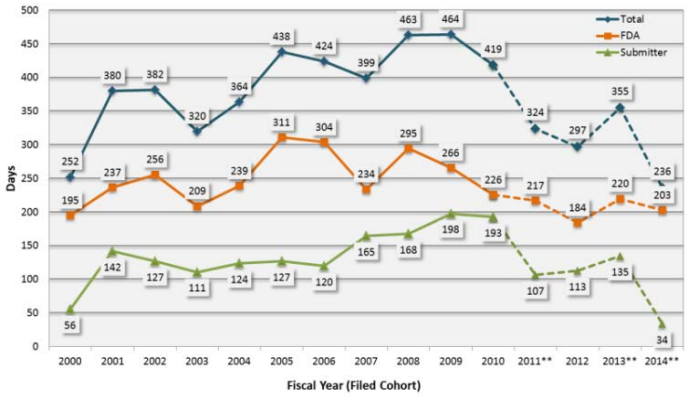


Chart 6. 510(k) Refuse to Accept (RTA) rate for first and second RTA cycles.

Premarket Approval Application (PMA) Program

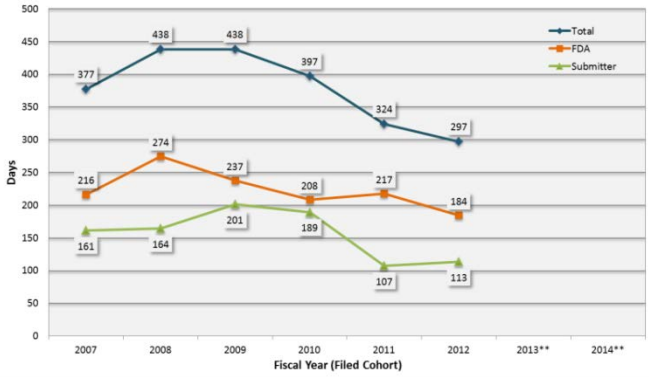
Average Time to Decision for PMAs: Average time to decision has decreased since its highest point in FY 2009. (**Chart 7**) As of December 31, 2014, the FY 2012 original PMA cohort was 98 percent closed, the FY 2013 cohort was 72 percent closed and the FY 2014 cohort was 41 percent closed. Comparison of receipt cohorts at the same closure levels show a 32 percent decrease in total review times (**Chart 8**) between FY 2009 and FY 2012 when the cohort is 98 percent closed, 3 percent decrease in total review times between FY 2009 and FY 2013 (**Chart 9**) when the cohort is 72 percent closed, and a 26 percent decrease in total review times between FY 2009 and FY 2014 (**Chart 10**) when the cohort is 41 percent closed. Examination of the applications included in these cohorts, detected a correlation between average total time to decision and panel meetings (see further explanation below).



***Cohorts are still open, average times will increase.*

Chart 7. Average time to MDUFA decision for PMAs, as of December 31, 2014. Includes original PMAs only; FY 2013-FY 2014 are receipt cohorts including PMAs filed as of December 31, 2014, prior cohorts are filed cohorts; times may not add to total due to rounding. Percent of cohort with MDUFA decision: FY 2011 = 98% (42/43); FY 2013 = 72% (21/29); FY 2014 = 41% (11/27).

FDA is also closing the gap between the divisions with the fastest and slowest review times. Performance has decreased significantly, from a difference in total average days to final decision between the highest and lowest performing divisions of 633 days in FY 2008 to 197 days in FY 2014.



*** FY 2013 and FY 2014 cohorts are not yet 98% closed (as of December 31, 2014).*

Chart 8. Average time to MDUFA decision for PMAs. Comparison of filed cohorts when approximately 98 percent closed. Includes original PMAs only; times may not add to total due to rounding. Proportion of cohort closed (MDUFA decision) in this comparison: FY 2007 = 34/35; FY 2008 = 29/30; FY 2009 = 31/32; FY 2010 = 42/43; FY 2011 = 42/43; FY 2012 = 24/24.

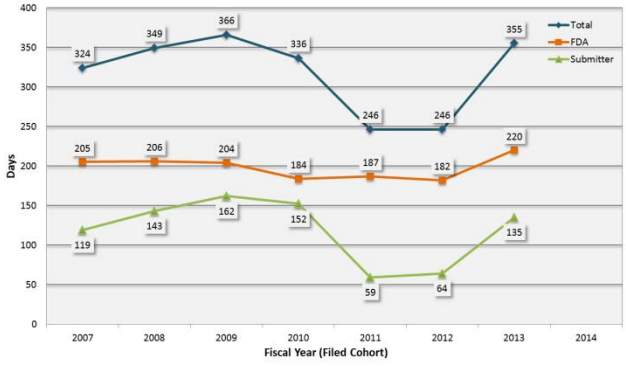


Chart 9. Average time to MDUFA decision for PMAs. Comparison of filed cohorts when approximately 72 percent closed. Includes original PMAs only; times may not add to total due to rounding. Proportion of cohort closed (MDUFA decision) in this comparison: FY 2007 = 25/35; FY 2008 = 22/30; FY 2009 = 23/32; FY 2010 = 31/43; FY 2011 = 31/43; FY 2012 = 17/24; FY 2013 = 21/29. As of December 31, 2014, FY 2014 cohort not yet 72% closed.

Effect of an Advisory Panel Meeting on Average Total time to Decision: As part of the review process, FDA may present a PMA to an expert advisory panel for its recommendations. Medical device advisory committees provide independent, professional expertise and technical assistance on the development, safety and effectiveness, and regulation of medical devices. PMAs that undergo an advisory panel review have different performance goals than PMAs that do not go to an advisory panel because holding an advisory panel meeting adds more time to a review. Examination of the FY 2013 cohort shows the highest percentage of PMAs undergoing an advisory panel review since 2007, which led to what appears to be an increase in review times. But when "apples-to-apples" comparisons are made, total review times continue to show a decrease.

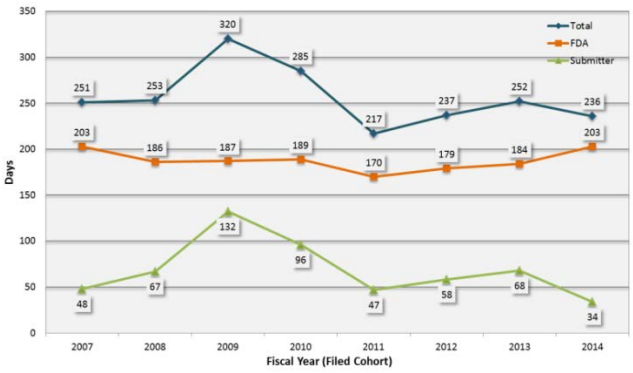


Chart 10. Average time to MDUFA decision for PMAs. Comparison of filed cohorts when approximately 41 percent closed. Includes original PMAs only; times may not add to total due to rounding. Proportion of cohort closed (MDUFA decision) in this comparison: FY 2007 = 14/35; FY 2008 = 12/30; FY 2009 = 13/32; FY 2010 = 18/43; FY 2011 = 18/43; FY 2012 = 10/24; FY 2013 = 12/29; FY 2014 = 11/27: FY 2011 = 98% (42/43); FY 2013 = 72% (21/29); FY 2014 = 41% (11/27)

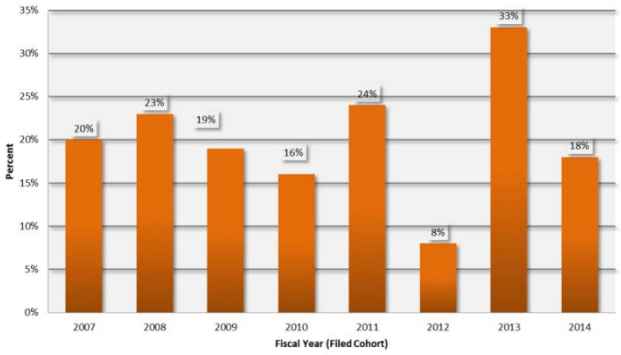


Chart 11. Percentage of PMAs with panel review, as of December 31, 2014, based on PMAs with a MDUFA decision

PMAs that undergo an advisory panel review typically take longer to reach a final decision, as accounted for in MDUFA III performance goals. Because the average total time includes both PMAs that go and do not go to an advisory panel meeting, the spike in review time for FY 2013 reflects the significantly higher percentage of applications with an advisory panel meeting (33 percent). (**Chart 11**) However, when comparing reviews times of PMAs with a panel meeting (**Chart 12**) across different years and PMAs without panel meetings across different years, we continued to see improved performance in FY 2013 for both categories of PMAs. In addition, the percent of PMAs that will undergo advisory panel review in FY 2014 is considerably less than FY 2013. A decrease in the percent of PMAs which will go to an advisory panel meeting in FY 2014 along with other program improvements lead us to expect lower average total review times in FY 2014.

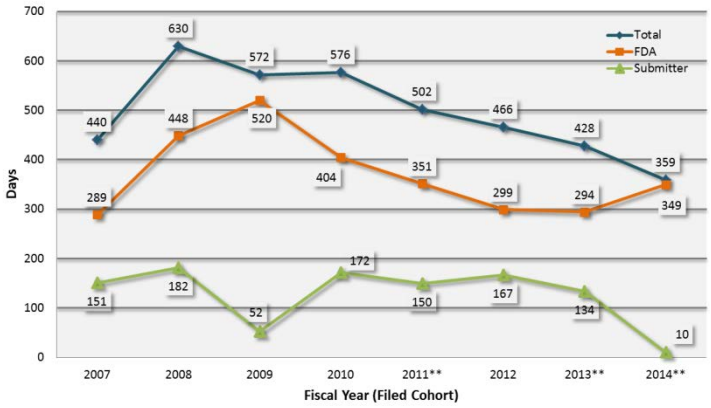


Chart 12. Average time to MDUFA decision for PMAs with Panel Review, as of December 31, 2014**.** Includes original PMAs only; FY13-FY14 are receipt cohorts including PMAs filed as of December 31, 2014, PMAs for prior cohorts are filed cohorts; times may not add to total due to rounding. Cohort still open, average times will increase; percent of cohort with MDUFA decision: FY11 = 91% (10/11); FY13 = 70% (7/10); FY14 = 67% (2/3)

Approved and Pending PMAs: Improvements to the PMA program have resulted in an increase in the number of applications approved since 2011 (decision cohort). The number of applications approved in FY 2014 was 27 percent greater than FY 2010. (**Chart 13**)

Note that the FY 2015 cohort only includes three months of data. The impact of CDRH improvements is further observed in the number of pending original PMAs, which has been reduced by 43 percent from its highest level in FY 2010. (**Chart 14**)

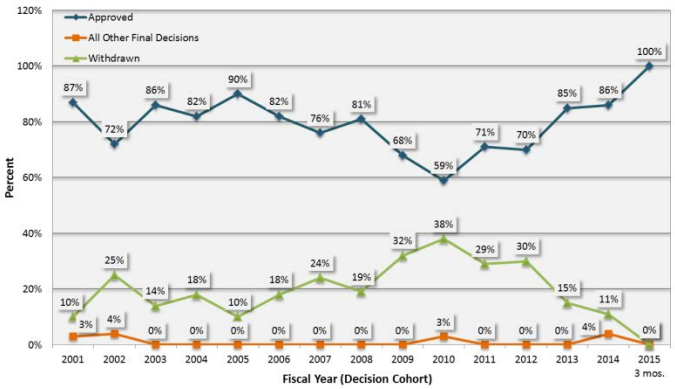
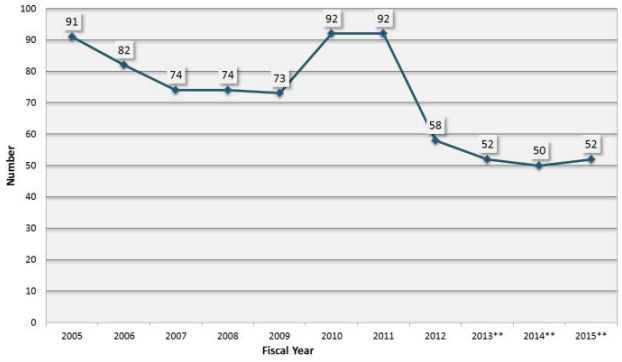


Chart 13. **Percentage of PMAs approved.** Based on original PMAs that were accepted for filing as of December 31, 2014; percentages may not add to 100 percent due to rounding.



***Excludes FY 2013 - FY 2015 receipts not accepted for review at year's end.*

Chart 14. **PMAs pending at the end of the fiscal year.** Includes original PMAs under review or on hold. FY 2015 is as of December, 31, 2014.

De Novo Program

Average Time to *De Novo* Granting:
Improvements to the de novo program have resulted in a 70 percent reduction in the average total time to decision for these submissions. Average total time to final de novo decision for devices with post-NSE de novo requests (includes FDA and Industry days for 510(k) NSE review and post-NSE de novo review) has been reduced from 992 days in FY 2010 to 300 days in FY 2014. Average total time to decision for direct de novo requests are even lower than for de novo requests using the post-NSE review pathway. (**Chart 15**) While time to decision has significantly decreased since FY 2010, the number of de novo requests received has almost doubled (25 de novo requests in FY 2010 versus 46 and 41 in FY 2013 and 2014, respectively).

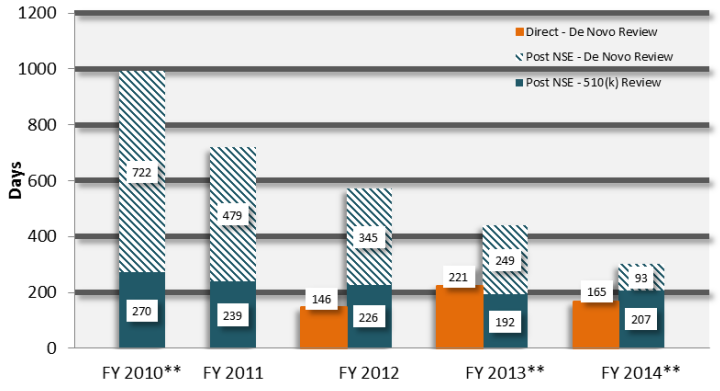


Chart 15. **Average total time to final *de novo*** decision for devices with post-NSE *de novo* request and devices with direct *de novo* request.

Investigational Device Exemption (IDE) Program

IDEs Approved within Two Cycles: Improvements to the IDE Program (e.g., establishing a formal Clinical Trials Program, process improvements, policy changes, extensive training for CDRH review staff and the device industry, and new guidance documents) have greatly shortened the time for an IDE to reach approval, so that a clinical trial can begin. The number of IDE studies that get fully approved within two cycles has increased significantly. The percentage of fully approved IDE studies within one cycle has increased nine-fold compared to FY 2011 and the percentage fully approved within two cycles has increased four-fold compared to FY 2011. (**Chart 16**) In FY 2014, 63 percent of IDEs submitted were approved within 2 cycles.

Median Days to IDE Full Approval: The median number days to full IDE approval has decreased from 442 in FY 2011 to only 101 in FY 2014, reducing the time it takes to bring a new medical device to market by nearly a full year. (**Chart 17**)

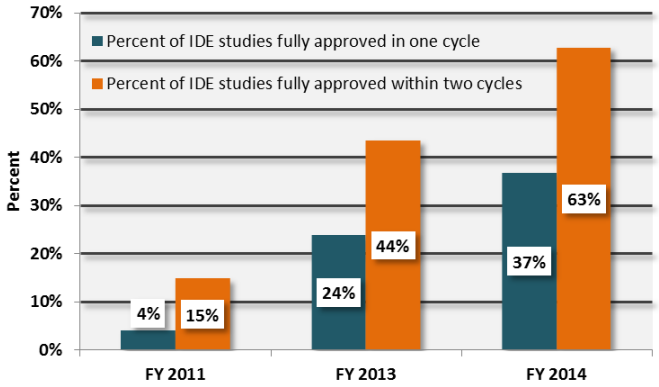


Chart 16. Percentage of IDE studies fully approved within one and two cycles.

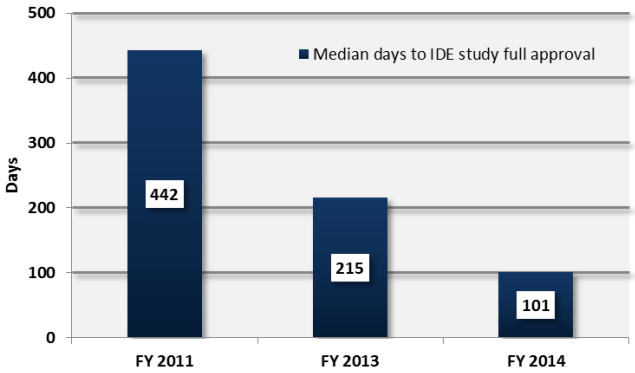


Chart 17. Median number of days to full IDE approval.

Clinical Studies: Devices that are studied in the US in the early stages of development are more likely to reach US patients sooner in pivotal studies and as marketed devices. In the past five fiscal years, 82 FDA approved original PMAs were supported by a single pivotal IDE study. Of those, 32 (39 percent) included studies enrolling subjects outside the U.S. For *in vitro* diagnostic devices (IVD), where clinical studies are typically conducted in at least three sites, sponsors generally choose to have one of those sites inside the US to address differences between the US and other countries in how medicine is practiced, patient populations, and disease progression.

FDA is facilitating and encouraging the use of innovative clinical trial designs and statistical methods such as adaptive clinical trials and Bayesian statistics. For the period from 2007 to May of 2013, FDA received 250 submissions that were adaptive, most of which were pre-submissions and IDEs. About 30 percent of these used Bayesian methodologies. In addition, there were 17 PMAs and PMA Supplements that used adaptive clinical trials from 2007 to May of 2013, eight of which used Bayesian methodologies.

Customer Satisfaction

Industry Customer Service Rating for Premarket Program:
Excellent customer service means understanding and addressing, as appropriate, stakeholders' and colleagues' needs through active listening, problem solving, seeking out the ideas of others, explaining the rationale for our decisions and requests for information, learning from our mistakes, and doing our best. Providing excellent customer service improves our interactions supports better regulatory outcomes, thereby improving patient health.

By providing excellent customer service, we do not alter our regulatory obligations. Customer service does not mean letting unsafe or ineffective devices on the market – rather it involves identifying and meeting our customers' needs, as appropriate, while achieving our mission and vision.

Chart 18. Premarket program 2014 customer satisfaction rating. The satisfaction score includes respondents who indicated they have interacted with CDRH's premarket offices.

The experience of receiving excellent customer service can encourage device makers to choose the US first when bringing their products to market; in turn, US health care providers gain access to the technologies that they need to administer quality health care to patients. In June 2014 CDRH began measuring customer satisfaction and established a goal of 70 percent satisfaction by the end of 2014. The Center's performance was 83 percent (95 percent confidence level and 2 percent margin of error). The performance of the premarket program was 86 percent satisfaction (95 percent confidence level and 3 percent margin of error). Among its industry stakeholders –industry, industry consultants, and industry trade associations— was even higher, 89 percent (95 percent confidence level and 4 percent margin of error). (**Chart 18**)