DEVICES AND RADIOLOGICAL HEALTH

(Dollars in Thousands)	FY 2016 Final	FY 2016 Actuals	FY 2017 Annualized CR	FY 2018 President's Budget	FY 2018 President's Budget +/- FY 2017 CR
Devices and Radiological Health	**450,221**	**447,605**	**440,988**	**489,696**	**48,708**
Budget Authority	***323,170***	***323,157***	***322,555***	***140,069***	***-182,486***
User Fees	***127,051***	***124,448***	***118,433***	***349,627***	***231,194***
Center	351,990	354,457	342,819	396,261	53,442
Budget Authority	240,750	240,740	240,292	73,842	-166,450
User Fees	111,240	113,717	102,527	322,419	219,892
Prescription Drug (PDUFA)				1,292	*1,292*
Medical Device (MDUFA)	*104,991*	*108,007*	96,150	*314,750*	*218,600*
Mammography Quality Standards Act (MQSA)	*6,249*	*5,710*	6,377	*6,377*	---
Field	98,231	93,148	98,169	93,435	-4,734
Budget Authority	82,420	82,417	82,263	66,227	-16,036
User Fees	15,811	10,731	15,906	27,208	11,302
Medical Device (MDUFA)	*2,199*	*409*	2,014	*13,316*	*11,302*
Mammography Quality Standards Act (MQSA)	*13,612*	*10,322*	13,892	*13,892*	---
International Courier	---	---	---	---	---
FTE	**2,243**	**2,243**	**2,289**	**2,352**	**63**

Authorizing Legislation: Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321-399); Radiation Control for Health & Safety Act (21 U.S.C. 360hh-360ss); Medical Device Amendments of 1976; Clinical Laboratory Improvement Amendments of 1988 (42 U.S.C. 201); Safe Medical Devices Act of 1990; Mammography Quality Standards Act of 1992 (42 U.S.C. 263b); Medical Device Amendments of 1992; Food and Drug Administration Modernization Act; Medical Device User Fee and Modernization Act of 2002; Project Bioshield Act of 2004 (21 U.S.C. 360bbb-3); Medical Device User Fee Stabilization Act of 2005; Food and Drug Administration Amendments Act of 2007 (FDAAA); Patient Protection and Affordable Care Act, 2010; FDA Safety and Innovation Act (FDASIA), 2012

Allocation Methods: Direct Federal/Intramural

PROGRAM DESCRIPTION AND ACCOMPLISHMENTS

The Devices and Radiological Health Program (the Devices Program) began in 1976, when President Gerald Ford signed the law that amended the Federal Food, Drug, and Cosmetic Act of 1938 to define medical devices and outline a risk-based classification system. The Devices Program operates with appropriations and user fees and is composed of the Center for Devices and Radiological Health and the Office of Regulatory Affairs.

The Devices Program is responsible for the national regulation of all medical devices, from simple articles such as tongue depressors to complex robotic equipment for surgery and cutting-edge products such as implantable defibrillators. To protect the public from unnecessary exposure to radiation, the Devices Program also regulates radiation-emitting products that include microwave ovens, X-ray equipment, and medical ultrasound and MRI machines. In addition, the Devices Program monitors mammography facilities to make sure the equipment is safe and properly run.

FDA assures that patients and providers have timely and continued access to safe, effective, and high-quality medical devices and safe radiation-emitting products. FDA provides consumers, patients, their caregivers, and providers with understandable and accessible science-based information about the products it oversees. FDA facilitates medical device innovation by

advancing regulatory science, providing industry with predictable, consistent, transparent, and efficient regulatory pathways, and by assuring consumer confidence in devices marketed in the U.S.

The vision of the Devices Program is to ensure that patients in the U.S. have access to high-quality, safe, and effective medical devices of public health importance – first in the world. The U.S. is the world's leader in regulatory science, medical device innovation and manufacturing, and radiation-emitting product safety. Surveillance quickly identifies poorly performing devices, accurately characterizes real-world performance, and facilitates device approval or clearance. Devices are legally marketed in the U.S. and remain safe, effective, and of high-quality.

The following strategic priorities describe the most important areas that the Devices Program will focus on to reach this vision. These priorities are to: [44]

- Establish a National Evaluation System for Medical Devices
- Incorporate Patient Input into Decision Making
- Promote a culture of quality and organizational excellence.

By addressing these priorities, the Devices Program aims to help medical device developers choose the U.S. as the country of first choice for their innovative new technologies – a key contributor to early patient access to high quality, safe and effective devices.

Recent accomplishments of the Devices Program include the following: [45]

- Average of 217 days during 2016 to arrive at a decision for high-risk innovative devices; down from 278 days in 2015.
- Reduced the median time to approve an Investigational Device Exemption (IDE) study to just 30 days in FY 2016.
- On September 28, 2016, FDA approved a first of its kind device that is intended to automatically monitor glucose (sugar) and provide appropriate basal insulin doses. This technology can provide people with type 1 diabetes greater freedom to live their lives without having to consistently and manually monitor baseline glucose levels and administer insulin.

The following selected accomplishments demonstrate the Devices Program's delivery of its regulatory and public health responsibilities within the context of current FDA strategic goals and priorities.

[44] For more information on guidance please visit http://www.fda.gov/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/CDRH/CDRHVisionandMission/default.htm
[45] For more information on guidance please visit http://www.fda.gov/downloads/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/CDRH/CDRHVisionandMission/UCM481590.pdf

Improve and Safeguard Access

The Devices Program is committed to flexible, smart regulation, and to working with industry and the clinical community to ensure that innovative new medical devices that demonstrate a reasonable assurance of safety and effectiveness are available for U.S. patients. Each year, the Devices Program evaluates the safety and effectiveness of new devices and approves or clears thousands of products for entry into the market. As a result, millions of U.S. patients benefit from innovative medical devices that reduce suffering, treat previously untreatable conditions, extend lives, and improve public health.

The Devices Program has evolved alongside changes in medical technology and the global marketplace. The Devices Program 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 introduced to the market more quickly, and more products that go through The Devices Program's premarket process are being approved and cleared for marketing.

Among the FDA strategic goals and priorities, the Devices Program supports FDA's Smart Regulation, Regulatory Science, and Safety and Quality priorities through efforts including the Clinical Trial Enterprise, Precision Medicine and Partner with Patients.

Guidance Documents

Below are selected guidance documents issued by the Devices Program during calendar year 2016. These guidance documents help address various issues. This list does not represent any degree of importance or priority ranking among the published guidances.[46]

Date	#	Title	Description
July 2016	FDA-2016-D-1270	Use of Standards in FDA Regulatory Oversight of Next Generation Sequencing (NGS)-Based In Vitro Diagnostics (IVDs) Used for Diagnosing Germline Diseases	This guidance provides recommendations for designing, developing, and validating NGS-based 119 tests for germline diseases.
Jun 2016	FDA-2015-D-137	Leveraging Existing Clinical Data for Extrapolation to Pediatric Uses of Medical Devices	This guidance explains the circumstances in which it may be appropriate to extrapolate existing medical device data to support pediatric device indications.
Feb 2016	FDA-2011-D-0469	Applying Human Factors and Usability Engineering to Medical Devices	This guidance will assist medical device developers in following appropriate human factors and usability engineering processes.
Jan 2016	FDA-2015-D-5105	Postmarket Management of Cybersecurity in Medical Devices	FDA is issuing this draft guidance to provide recommendations for managing postmarket cybersecurity vulnerabilities for marketed medical devices.

[46] For more information on guidance please visit http://www.fda.gov/RegulatoryInformation/Guidances/.

Regulatory Science Priorities

CDRH protects consumers by applying the best possible science to its regulatory activities, including premarket review of safety and effectiveness, postmarket product surveillance, and review of product quality. Rapid advances in innovative science have provided new technologies to discover, manufacture, and assess novel medical products and to improve device safety and quality. FDA must both keep pace with and utilize these new scientific advances in order to protect and promote public health.

One of CDRH's core functions is to advance regulatory science, which is the science of developing new tools, standards, and approaches to assess the safety, efficacy, quality, and performance of medical devices and radiation-emitting products. This includes laboratory research in the areas of physical, life, and engineering sciences as well as epidemiological research in postmarket device safety. CDRH conducts research in our own labs and through collaborations with academia, healthcare providers, other government agencies, and industry. CDRH relies upon this work to support innovation and regulatory decision-making in areas as varied as medical imaging, manufacturing, and clinical trials.

Regulatory Science Priorities include but are not limited to:

- Leverage "Big Data" for regulatory decision-making
- Modernize biocompatibility and biological risk evaluation of device materials
- Leverage real-world evidence and employ evidence synthesis across multiple domains in regulatory decision-making
- Advance tests and methods for predicting and monitoring medical device clinical performance.

These priorities help focus the Devices Program's attention on the most important regulatory science research needed, as well as promote alignment with external scientists and potential scientific research partners. These priorities will be reassessed and updated periodically to reflect current regulatory science needs.[47] In addition, the Devices Program makes public information on 43 active research programs that advance Regulatory Science.[48]

Expanded Access for Medical Devices

When a patient has a serious or life-threatening condition that is not addressed by current approved treatments, options may exist to use an investigational medical device—one that has not been approved or cleared by FDA—to treat the patient. Normally, investigational devices with significant risks may only be used on human subjects through an FDA-approved clinical trial for which an investigational device exemption (IDE) was approved by FDA to allow the investigational device to be used in a clinical study.

However, there are circumstances under which a health care provider may use an investigational device outside of a clinical study to save the life of a patient or to help a patient suffering from a serious disease or condition for which no alternative treatment exists. The use of an investigational device outside of a clinical trial for treatment of a patient is called "expanded access." If enrollment in an existing clinical trial protocol is not possible—either because a patient is not eligible for any ongoing clinical trials, or there are no ongoing clinical trials to

[47] CDRH's Regulatory Science Priorities are available at: http://www.fda.gov/MedicalDevices/ScienceandResearch/ucm467550.htm
[48] Available at http://www.fda.gov/MedicalDevices/ScienceandResearch/ResearchPrograms/default.htm

address the patient's condition—patients and physicians may be able to use an investigational device using one of three mechanisms.[49]

Early Feasibility Studies

Early Feasibility Studies (EFS) are small clinical studies designed to gain early insights into an innovative technology during the development process before starting a larger clinical trial. EFS often are a critical step in device innovation, but they are frequently conducted in other countries rather than in the United States. Device developers tend to conduct subsequent feasibility and pivotal clinical studies and then bring their products to market earlier in the countries where they conducted the EFS in order to leverage clinician experience with their technologies.

CDRH established a goal of increasing the number of EFS investigational applications (also known as investigational device exemption applications, or IDEs) submitted to each review division in the Center. Since 2013, the number of early feasibility studies approved has more than doubled—from 17 in FY 2013 to 40 in FY 2016. These results provide evidence that the EFS Program remains robust and permits efficient clinical trial progression in the U.S. while providing appropriate human subject protections.[50]

Parallel Review of Medical Devices

On October 24, 2016, FDA and the Centers for Medicare & Medicaid Services (CMS) informed the public that the Parallel Review of medical devices pilot program will be fully implemented and extended indefinitely. FDA and CMS are soliciting nominations from manufacturers of innovative medical devices to participate in this program. The Parallel Review program is a collaborative effort between FDA, CMS, and the device manufacturer that is intended to reduce the time between FDA marketing authorization and Medicare coverage decisions through the CMS National Coverage Determination (NCD) process. This program is intended to ensure prompt and efficient patient access to safe, effective, and appropriate medical devices for the Medicare population.

Precision Medicine

CDRH has a unique role in advancing precision medicine due to the products under our jurisdiction. Precision medicine generally means tailoring treatments to specific characteristics, such as a patient's genetic makeup or the genetic profile of a tumor. Targeting treatments based on genetic information can improve the success of the treatment and minimize exposure to adverse effects. To fully realize precision medicine, next generation sequencing (NGS) tests used for risk assessment, diagnosis, and treatment must be accurate and reliable. The Devices Program aims to ensure that NGS tests provide accurate, reproducible, and meaningful results relevant to a person's medical condition while continuing to foster innovation so that patients have access to the best available results possible.

The goal of the Precision Medicine Initiative (PMI) is to help translate scientific knowledge about genomics into clinical care. To help achieve that, FDA is drawing upon the latest computing and storage technologies to provide an open source, cloud-based environment where experts can share data, ideas, and methodologies. Today, the environment hosts more than 1,600

[49] More information about the medical device expanded access program is available at this website: http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/InvestigationalDeviceExemptionIDE/ucm051345.htm.

[50] More information about the EFS program is available in this guidance document: http://www.fda.gov/downloads/medicaldevices/deviceregulationand%20guidance/guidancedocuments/ucm279103.pdf

participants, including researchers, test developers, industry, academics, statisticians, and clinicians.

Partner with Patients

The Devices Program values patient perspectives and engagement with patients improves our understanding of the patient experience. By working directly with patients, rather than only on their behalf, we can better meet their needs and public health commitment to improve health and quality of life.

In FY 2016, the Device Program undertook efforts to promote a culture of meaningful patient engagement by facilitating interactions between patients and FDA staff, providing twenty on-site and offsite patient interaction opportunities. By November 30, 2016, 68 percent of Devices Program staff had at least one interaction with patients. These interactions enhance Devices Program staff understanding of the patient experience with medical devices.

The Devices Program is committed to working with partners to develop more patient-friendly information, promote more patient-centric clinical trials, advance benefit-risk assessments that are informed by patient perspectives, promote the use of patient-reported outcome data, and foster access to new devices that meet patients' needs.

Balancing Premarket & Postmarket Data Collection and the Expedited Access Pathway

When a device developer seeks U.S. marketing approval or clearance, the extent of premarket data that FDA requires—including data from clinical trials or engineering tests—impacts the amount of time needed to complete a premarket submission. Generally, the more data that is required, the longer it takes to acquire the data and make the submission. Consequently, FDA data requirements impact when U.S. patients have access to a device. Striking the right balance between premarket and postmarket data—including data from real-world use of a device that may be collected in an electronic health record or device registry—means balancing the potential benefits of earlier patient access to the device against the possible risks of patient harm from exposure to an unsafe or ineffective device. Balancing premarket and postmarket data collection reflects a predictive and evaluative approach to understanding the benefit-risk profile of medical devices.

On April 15, 2015, the Devices Program launched the Expedited Access Pathway (EAP) Program to speed patient access to qualifying devices. EAP is a voluntary program for certain medical devices that demonstrate the potential to address unmet medical needs for life threatening or irreversibly debilitating diseases or conditions that are subject to PMA or are eligible for *de novo* requests.[51]

[51] More information about the EAP program is available in this guidance document: http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM393978.pdf

Product Approvals

Below are examples of selected Devices Program product approvals during 2016. This list does not represent any degree of importance or priority ranking of products.[52]

Date	Product Name	Description
Jun 2016	cobas EGFR Mutation Test v2 Approval	This is the first FDA-approved, blood-based genetic test that can detect epidermal growth factor receptor (EGFR) gene mutations in non-small cell lung cancer patients.
Jun 2016	AspireAssist	A new obesity treatment device that causes weight loss by removing about 30 percent of food from the stomach before the calories are absorbed into the body.
Apr 2016	Medtronic Micra Transcatheter Pacemaker System	A first-of-a-kind self-contained pacemaker implanted in the right ventricle via the femoral vein, provides bipolar sensing and pacing, similar to transvenous single chamber pacemaker systems.

Enhance Oversight

Ensuring manufacturer compliance with laws and regulations helps assure the safety and efficacy of devices and protects consumer confidence in U.S. medical products worldwide. The Devices Program quickly identifies major violations and takes prompt, clear, and appropriate actions to resolve issues before they have widespread negative impacts on public health. The Devices Program monitors postmarket performance including adverse events, responds quickly to identify and limit potential public health problems, and collaborates with industry to improve the quality of medical devices for U.S. patients.

Among FDA strategic goals and priorities, the Devices Program supports Smart Regulation through efforts including the National Medical Device Evaluation System and Unique Device Identification. At the same time, Globalization is supported by The Medical Device Single Audit Program and Safety and Quality by efforts including the Case for Quality Initiative and the Mammography Quality Standards Act Program.

[52] For a complete list of product approvals, clearances, and designations, visit http://www.fda.gov/NewsEvents/ProductsApprovals/.

Guidance Documents

Below are other selected guidance documents issued by the FDA during calendar year 2016. These guidance documents help address various issues. This list does not represent any degree of importance or priority ranking among the published guidances.[53]

Date	#	Title	Description
Jul 2016	FDA-2014-N-1039	General Wellness: Policy for Low Risk Devices	This final guidance provides clarity to industry and FDA staff on the CDRH compliance policy for low risk products that promote a healthy lifestyle (general wellness products).
May 2016	FDA-2011-D-0514	Postmarket Surveillance Under Section 522 of the Federal Food, Drug, and Cosmetic Act	This guidance will assist device manufacturers on how to fulfill the section's obligations, and recommendations on the format, content, and review of postmarket surveillance plan submissions.
Mar 2016	FDA-2016-D-06361	Assessment of Radiofrequency-Induced Heating in the Magnetic Resonance Environment	This guidance provides an approach to reduce the number of possible device configurations to a manageable number.

National Evaluation System for health Technology

CDRH is leading the establishment of the National Evaluation System for health Technology (NEST), which will quickly identify safety concerns, better characterize real-world performance of medical devices, and facilitate premarket clearance or approval of new devices and new uses of currently marketed devices. NEST will link and synthesize data being collected as part of routine clinical care from different sources across the medical device landscape, including clinical registries, electronic health records (EHRs) and medical billing claims. It will also help improve the quality of real-world evidence that health care providers and patients can use to make better informed treatment decisions and strike the right balance between assuring safety and fostering device innovation and patient access.

In April 2016, the Duke-Margolis Center for Health Policy published "Better Evidence on Medical Devices: A Coordinating Center for a 21st Century National Medical Device Evaluation System." This document outlines the expectations, roles, and responsibilities of the NEST Coordinating Center. In September 2016, the Duke-Margolis Center for Health Policy published "The National Evaluation System for health Technology: Priorities for Effective Early Implementation", outlining the governance and oversight recommendations for the NEST Coordinating Center, as well as identifying priority areas and projects to support medical device evaluation and surveillance.[54]

Also in September 2016, the Medical Device Innovation Consortium (MDIC) was selected by FDA to establish the NEST Coordinating Center, whose initial focus will be creating governance and operations for the system. Establishing the NEST is one of FDA's 2016-2017 strategic

[53] For more information on guidance please visit http://www.fda.gov/RegulatoryInformation/Guidances/.
[54] Available at https://healthpolicy.duke.edu/files/2016/03/med-device-report-web.pdf

priorities and FDA established goals for increasing access to and use of real world evidence in our regulatory decisions.

Medical Device Innovation Consortium (MDIC)
Through the Medical Device Innovation Consortium (MDIC), FDA collaborates with patient organizations, nonprofit organizations, industry, and other federal agencies to find solutions for common medical device challenges. MDIC's focus is on advancing regulatory science to propel device development through the regulatory process, resulting in smarter regulation and earlier patient access to safe, effective, and high-quality devices. This includes providing a venue for leveraging resources, people, and intellectual capital to support 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.

For example, in 2016, MDIC issued a blueprint on early feasibility studies as a best practices guide for sponsors looking to conduct U.S.-based EFS and "The Framework for Simplification of Clinical Trials in Regulated Medical Devices" outlining a vision and roadmap for simplification of medical device clinical trials. The ultimate goal is to improve the clinical trial ecosystem to lead to new treatments and diagnostics being available in the U.S. market earlier.[55]

Cybersecurity
Many medical devices are "life critical systems," meaning they play a crucial role in monitoring and protecting human life. As more of these systems use technology to interconnect, we must take steps to secure them from hackers and cyber-attacks. The Devices Program works with hospitals, health care professionals, and patients to provide manufacturers with guidance for monitoring, identifying, and addressing cybersecurity vulnerabilities in their devices before and after they have entered the market.

FDA entered into a partnership with the National Health Information Sharing and Analysis Center (NH-ISAC) and the Medical Device Innovation, Safety, and Security Consortium (MDISS) to foster rapid sharing of medical device vulnerabilities, threats, and mitigations within the health care ecosystem. Doing so will help to proactively address cybersecurity threats and vulnerabilities that may impact patient safety.

Digital connections provide great power to innovate and security must keep pace with that innovation. Safeguarding patients includes first identifying, and then addressing previously unforeseen medical device cybersecurity vulnerabilities. Through a joint approach encompassing the public and several government agencies, FDA is working toward the necessary changes in culture within the medical device ecosystem, accompanied by progress in the management of medical device cybersecurity.

Digital Health Program
The widespread adoption and use of digital health technologies like smartphone apps is creating innovative ways to improve health and health care delivery. These products can help people manage their own health and wellness, promote healthy living, and gain access to useful information when and where they need it. FDA encourages the development of digital health technologies, and has clarified that when technologies meet the definition of a medical device

[55] Available at http://mdic.org/

but pose low risk to patients, we do not intend to enforce certain regulatory requirements for such technologies.

FDA's Devices Program has clarified that we are focusing oversight on a small subset of technologies that present a greater risk to patients because those technologies perform the same functions as traditional medical devices or impact the functionality or performance of traditional medical devices. FDA is also working towards a framework that better aligns regulation with the rapid innovation cycles that occur with digital health products. The framework relies more on quality management systems and postmarket safety controls coupled with real world evidence than review of premarket data. Taking into account the global nature of these technologies, CDRH is working with other countries to create an internationally harmonized regulatory framework for digital health products.

Unique Device Identification

FDA is in the process of implementing a unique device identification (UDI) system that will improve the quality of information in medical device adverse event reports, help FDA identify product problems more quickly, and better target recalls and improve patient safety. Further, by providing a standard and clear way to document device use, incorporating UDI in EHRs, clinical information systems, billing systems, and registries will enable NEST to perform enhanced analyses of devices on the market to better understand device performance in diverse populations.

When fully implemented, the label of most devices will include a unique device identifier (UDI) in human and machine readable form. Device labelers must also submit certain information about each device to the Global Unique Device Identification Database (GUDID). As of the end of the FY 2016, more than one million device identification records have been established in the GUDID.

The incorporation of UDI into electronic healthcare data sources, such as EHRs, will have many benefits for patients, the health care system, and the device industry. The UDI system improves the identification of medical devices by making it possible to rapidly and definitively identify a device through distribution and use. [56]

Culture of Quality and Organizational Excellence

CDRH's 2016-2017 strategic priority "Promote a Culture of Quality and Organizational Excellence" focuses on improving quality internally and externally. We are working with stakeholders—industry, health care providers, patients, payers, and investors—to foster a culture of quality in the medical device ecosystem. The objective is to assure technologies perform consistency, reliably, and are available to those who will benefit from them when they are most needed. This is achieved by identifying and promoting practices that result in high-quality devices and adapting FDA regulatory approaches to align with those practices. Ultimately, this provides stakeholders with understandable and objective data and analysis on medical device quality; focuses stakeholder interactions on device quality; and facilitates medical device innovation.

FDA launched the Case for Quality in 2011 following an in-depth review of device quality data and feedback from both FDA and industry stakeholders. FDA's analysis flagged manufacturing

[56] Available at: http://www.fda.gov/medicaldevices/deviceregulationandguidance/uniquedeviceidentification/default.htm

quality risks and showed that firms that manage those risks by driving quality organization-wide are more productive, with fewer complaints and investigations and often with lower quality-related costs than their competitors. In other words: investing in quality pays. More recently, efforts under CDRH's "Culture of Quality" strategic priority include developing metrics, standards, and tools, and identifying successful industry practices—beyond what's required by law or regulation—that lead to high-quality devices and device use. CDRH intends to pilot voluntary use of those metrics and tools and to propose a voluntary program to recognize independent evaluation of product and manufacturing quality.

CDRH is implementing a robust quality management program that includes many components and principles found in internationally recognized organizations, including the International Organization for Standardization (ISO) and the Baldrige Excellence Framework. The quality management program will facilitate consistency in plans, processes, measures, and actions, and will help us achieve our vision of patient access to medical devices through accountability to outcomes reflective of a quality-focused organization. Additionally, CDRH has an active customer service program to collect and act on feedback; we are implementing a more robust document control system; and we are developing an audit and performance evaluation program.

Next Generation Sequencing (NGS)

Next-Generation Sequencing (NGS) is a term used to describe a number of different modern sequencing technologies; sequencing means determining the order of the bases in a DNA segment. Sequencing can highlight changes in a gene that may be related to disease, creating opportunities for diagnostics and therapies. The Precision Medicine Initiative (PMI) directed FDA to develop a new regulatory approach for NGS that will advance precision medicine. FDA released white papers and draft guidances describing this new approach, which is based on the use of community-developed standards. FDA has also developed and released "precisionFDA," an open-source platform inviting the NGS community to advance innovation and help lower regulatory barriers for NGS test developers. FDA continues to develop plans to implement this approach. While there is not a deadline, FDA is moving rapidly because of NGS' rapid adoption in clinical settings.

Radiological Health Program

The Devices Program protects public safety by monitoring industry's compliance with regulatory performance standards to reduce the incidence and severity of radiation injury. The Devices Program reviews initial and period reports as well as inspects establishments that manufacture radiation emitting electronic products to determine compliance with the law. The Devices Program has initiated multiple efforts to improve the efficiency and effectiveness of these programs through manufacturer engagement, reliance on international standards, and proposals to reduce or eliminate unnecessary reporting.

As a regulatory agency, FDA also shares in the responsibility for strengthening radiation protection of patients and health workers with other national and international agencies, institutions, and organizations. That is why FDA collaborated with stakeholders, including the International Atomic Energy Agency (IAEA) and the World Health Organization (WHO), to develop a list of priorities for radiation protection in medicine for the next decade called the

Bonn Call for Action. The Bonn Call for Action is divided into ten principal actions, each of which is considered essential for strengthening radiation protection over the next decade.[57]

Mammography Quality Standards Act Program

The Mammography Quality Standards Act (MQSA) Program helps to ensure all women in the U.S. have access to quality mammography for the detection of breast cancer in its earliest, most treatable stages.

In FY 2016, FDA announced the approval of an alternative standard for using the Quality Assurance Program recommended by the American College of Radiology (ACR) Digital Mammography Quality Control Manual for full-field digital mammography systems, for systems without advanced imaging capabilities. The alternative standard allows for use by mammography facilities of the ACR Digital Mammography Control Manual as an alternative to the quality assurance program recommended by the image receptor manufacturer.[58]

As part of the MQSA Program, FDA and its state contract partners annually inspect more than 8,700 certified mammography facilities in the U.S. to ensure compliance with national quality standards for mammography. In FY 2016, more than 99 percent of mammography facilities had no serious violations of the law, and less than 1 percent of facilities were cited with the most serious violations. These MQSA-certified facilities provide nearly 39 million mammography procedures annually in the U.S.[59]

Use of Symbols

In June 2016, FDA issued the "Use of Symbols in Labeling" final rule, which describes the circumstances in which manufacturers may use a standalone symbol in device labeling without any adjacent explanatory text. For example, if certain requirements are met under the final rule, manufacturers of sterile syringes could opt to use the symbol for "do not reuse" on a syringe package without adding the actual words "do not reuse" to the package.

The final rule, which went into effect on September 13, 2016, does not mandate the use of standalone symbols in device labeling. Under the final rule, device manufacturers have three options. They can choose to:

- not use symbols
- use symbols with adjacent explanatory text, or
- use standalone symbols that have been established in a standard if certain requirements are met, including providing an explanation of the symbols in a symbols glossary that is included in the labeling for the device.

Adding the option of standalone symbols is expected to reduce design costs for manufacturers because it is more consistent with how devices are currently labeled in Europe and other foreign

[57] Available at: http://www.fda.gov/downloads/Radiation-EmittingProducts/RadiationSafety/RadiationDoseReduction/UCM439602.pdf
[58] Available at: http://www.fda.gov/Radiation-EmittingProducts/MammographyQualityStandardsActandProgram/Regulations/ucm489348.htm
[59] More information about FDA's mammography activities is available at: http://www.fda.gov/mammography

markets. Replacing small and difficult-to-read text with a symbol will also help make some labeling more user-friendly and understandable, which is critical in medical device labeling, where space may be limited. The use of standalone symbols on a global scale may help promote better understanding to people who speak different languages through consistent labeling across products distributed in the U.S. and foreign markets.

FUNDING HISTORY

Fiscal Year	Program Level	Budget Authority	User Fees
FY 2014 Actual	$417,583,000	$320,815,000	$96,768,000
FY 2015 Actual	$442,689,000	$320,793,000	$121,896,000
FY 2016 Actuals	$447,605,000	$323,157,000	$124,448,000
FY 2017 Annualized CR	$440,988,000	$322,555,000	$118,433,000
FY 2018 President's Budget	$489,696,000	$140,069,000	$349,627,000

BUDGET REQUEST

The FY 2018 President’s Budget is $489,696,000, of which $140,069,000 is budget authority and $349,627,000 is user fees. This level provides a net increase of $48,708,000. Budget authority decreases by $182,486,000 compared to the FY 2017 Annualized CR level and user fees increase by $231,194,000. The Center for Devices and Radiological Health (CDRH) amount in this request is $ 396,261,000. The Office of Regulatory Affairs amount is $93,435,000.

The FY 2018 budget allows the Devices Program to continue to ensure the safety and effectiveness of medical devices that U.S. patients rely on every day, while facilitating scientific innovations that extend and improve lives. Each year, millions of American patients benefit from innovative medical devices that reduce suffering, treat previously untreatable conditions, extend lives, and improve public health. The FY 2018 budget enables the Devices Program to continue to meet its core mission to protect and promote public health, including:

- assuring patients and providers have timely and continued access to safe, effective, and high-quality medical devices and safe radiation-emitting products
- providing consumers, patients, their caregivers, and providers with understandable and accessible science-based information about products
- facilitating medical device innovation by advancing regulatory science, providing industry with predictable, consistent, transparent, and efficient regulatory pathways
- assuring consumer confidence in devices marketed in the U.S.

Devices are coming to market more quickly, and more devices that go through the premarket program are being approved and cleared for marketing.

BUDGET AUTHORITY

Reductions (-$10.9 million)

Center: -$5.8 million (Medical Product Safety & Availability)
Proposed budget reductions will require FDA to reprioritize and reevaluate CDRH activities related to post-market device surveillance and device adverse event reports. While some categories of adverse event reports will have longer review times, FDA will work to address the most serious and highest priority adverse event reports to mitigate potential negative impacts. The goal of FDA is to minimize the impact of these reductions on FDA's core mission activities.

Field: -$5.1 million (Medical Product Safety & Availability)
ORA will apply strategic reductions to its programs in order to preserve the highest priority activities and operations in support of protecting public health. ORA will reduce existing workforce levels through attrition.

In order to continue operations under the FY 2018 request levels, ORA will apply the necessary program reductions to areas such as training, IT and lab equipment, and across all program office operating budgets while protecting resources for inspections and compliance activities.

Medical Product Budget Authority Recalibration (-$171.6 million)

Center: -$160.7 million / Field: -$10.9 million (Medical Product Safety & Availability)
The FY 2018 President's Budget recalibrates FDA funding for medical product review and approval processes from budget authority to user fees.

USER FEES

Medical Product User Fee Recalibration and Regulatory Efficiencies (+$231.2 million)

Center: +$219.9 million / Field: +$11.3 million (Medical Product Safety & Availability)
The FY 2018 President's Budget recalibrates FDA funding for medical product review and approval processes from budget authority to user fees. The budget also includes a package of administrative actions designed to achieve greater regulatory efficiency and speed the availability of innovative, safe, and effective medical products in the market. These actions include the improvements are described in the PDUFA VI and MDUFA IV commitment letters submitted to Congress in January 2017.

In FY 2018, CDRH will take actions to achieve regulatory efficiency and speed the development of safe and effective medical devices. CDRH will reaffirm its commitment to its least burdensome requirements by having all employees involved in the premarket review of devices receive training on the least burdensome approach, developing and applying decision support tools to assure FDA data requests are least burdensome, and all 510(k) and PMA deficiency letters will provide a justification for every deficiency as well as supervisory review and concurrence. CDRH's premarket review processes will be standardized and more predictable; such as by eliminating unnecessary variance in communications with companies and reducing the number of unique document categories. CDRH will further reduce regulatory uncertainty in medical product development by implementing new performance goals for, and providing, earlier advice to inform pre-submission meetings. CDRH will reduce average total review times for PMA and 510(k) devices so that patients are able to more quickly benefit from FDA approved medical products.

PERFORMANCE

The Devices Program's performance measures focus on premarket device review, postmarket safety, compliance, regulatory science, and Mammography Quality Standards activities which assure the safety and effectiveness of medical devices and radiological products marketed in the United States, as detailed in the following table.

Measure	Year and Most Recent Result / Target for Recent Result (Summary of Result)	FY 2017 Target	FY 2018 Target	FY 2018 +/- FY 2017
253203: Percentage of received Original Premarket Approval (PMA), Panel-track PMA Supplement, and Premarket Report Submissions reviewed and decided upon. *(Outcome)*	FY 2015: 94% in 180 days Target: 80% in 180 days (Target Exceeded)	90% in 180 days	90% in 180 days	Maintain
253204: Percentage of 180 day PMA supplements reviewed and decided upon within 180 days. *(Outcome)*	FY 2015: 99% in 180 days Target: 90% in 180 days (Target Exceeded)	95% in 180 days	95% in 180 days	Maintain
253205: Percentage of 510(k)s (Premarket Notifications) reviewed and decided upon within 90 days. *(Outcome)*	FY 2015: 96% in 90 days Target: 95% in 90 days (Target Exceeded)	95% in 90 days	95% in 90 days	Maintain
253208: Percentage of De Novo requests (petitions to classify novel devices of low to moderate risk) reviewed and classified within 150 days. *(Output)*	FY 2015: 42% in 150 days (Historical Actual)	NA	50% in 150 days	New Goal
253211: Percentage of planned Medical Device Bioresearch Monitoring (BIMO) inspections (approximately 300 in total). *(Output)*	FY 2016: 309 Target: 300 (Target Exceeded)	91%	91%	Maintain
252203: Percent of total received Code Blue MDRs reviewed within 72 hours during the year. *(Output)*	FY 2015: 91% Target: 90% (Target Exceeded)	90%	90%	Maintain
254202: Percentage of time CDRH meets the targeted deadline of 60 working days to review GMP information and issue Device Warning Letters. *(Output)*	FY 2016: 45% Target: 50% (Target Not Met)	50%	50%	Maintain

254203: Percentage of time CDRH meets the targeted deadlines for on-time recall classification (*Output)*	FY 2016: 86% Target: 85% (Target Exceeded)	85%	85%	Maintain
254211: Percentage of planned domestic and foreign Class II and Class III device inspections (approximately 1,600 in total). *(Output)*	FY 2016: 2,075 Target: 1,600 (Target Exceeded)	57%	57%	Maintain
252101: Number of technical analyses of postmarket device problems and performance. *(Output)*	FY 2015: 51 Target: 50 (Target Exceeded)	50	50	Maintain
253207: Number of technical reviews of new applications and data supporting requests for premarket approvals. *(Output)*	FY 2015: 2,480 Target: 2,000 (Target Exceeded)	2,000	2,000	Maintain
254101: Percentage of an estimated 8,700 domestic mammography facilities that meet inspection standards, with less than 3% with Level I (serious) problems. *(Outcome)*	FY 2016: 99.2% Target: 97% (Target Exceeded)	97%	97%	Maintain

The following selected items highlight notable results and trends detailed in the performance table.

Premarket Device Review

FDA is committed to protecting and promoting public health by providing timely access to safe and effective medical devices. In FY 2015, FDA exceeded all of its MDUFA III performance goals.

De Novo Classification process

The De Novo classification process is an important new tool in the medical device review process. This process allows industry an alternate path to get novel devices of low to moderate risk to market without submitting a PMA.

Code Blue Medical Device Reports

Code Blue Medical Device Reports (MDRs) are defined as high priority MDR reports based on criteria including but not limited to: pediatric deaths, multiple deaths and serious injuries, device explosions, and electrocutions. Timely review of code blue MDRs can minimize widespread failure of the device, thereby limiting the loss of life due to similar events as the one submitted.

Warning Letters

Warning Letters are issued to achieve voluntary compliance and to establish prior notice. The use of Warning Letters and the prior notice policy are based on the expectation that most

individuals and firms will voluntarily comply with the law. A Warning Letter is the agency's principal means for prompt voluntary compliance with the Federal Food, Drug, and Cosmetic Act (the Act) and is issued for violations of regulatory significance. Recent shifts in workload, organizational restructuring, and decreases in staff levels have resulted in the inability to meet internal targets for the timely review of GMP information and issuance of Device Warning Letters. Due to the staffing uncertainties, targets will decrease.

PROGRAM ACTIVITY DATA TABLES

Devices and Radiological Health Program Activity Data (PAD)

CDRH Workload and Outputs	FY 2016 Actual	FY 2017 Annualized CR	FY 2018 President's Budget
Original PMAs and Panel-Track Supplements (without Advisory Committee input)			
Workload [1]	72	72	72
Total Decisions [2]	69	69	69
Approved [3]	55	55	55
Original PMAs and Panel-Track Supplements (with Advisory Committee input)			
Workload	1	1	1
Total Decisions [2]	6	6	6
Approved	2	2	2
Modular PMAs			
Workload	72	72	72
Actions [4]	106	106	106
180-day PMA Supplements			
Workload	210	210	210
Total Decisions [5]	206	206	206
Approved	94	94	94
Real Time PMA Supplements			
Workload	329	329	329
Total Decisions [6]	328	328	328
Approved	311	311	311
510(k) Premarket Notifications			
Workload	3,677	3,844	3,844
Total Decisions [7] (SE & NSE)	3,078	3,185	3,185
Cleared [9] (SE)	2,962	3,081	3,081
Humanitarian Device Exemptions (HDE)			
Workload	4	4	4
Total Decisions [2]	4	4	4
Approved	3	3	3
Investigational Device Exemptions (IDE)			
Workload	284	290	290
Total Decisions [8]	306	309	309
Approved	188	198	198
Investigational Device Exemption Supplements			
Workload	2,051	2,051	2,051
Closures [10]	2,066	2,066	2,066
Pre-Submissions			
Workload	2,368	2,405	2,405
Closures [11]	2,324	2,335	2,335
De Novo			
Workload	54	70	70
Total Decisions [14]	49	64	64
Granted	25	32	32
Standards			
Total Standards Recognized for Application Review	1,209	1,250	1275
Medical Device Reports (MDRs) [12]			
Reports Received	1,335,278	2,672,800	2,672,800
Analysis Consults [13]	737	1,678	1,678

[1] Workload' includes applications received and filed. (Receipt Cohort)

[2] Total Decisions' include approval, approvable, approvable pending GMP inspection, not approvable, withdrawal, and denial - regardless of the fiscal year received. (Decision Cohort)

[3] Approved' includes applications approved regardless of the fiscal year received. (Decision Cohort)

[4] Actions' include accepting the module, request for additional information, receipt of the PMA, and withdrawal of the module. (Decision Cohort)

[5] Total Decisions' include approval, approvable, approvable pending GMP inspection, and not approvable. (Decision Cohort)

[6] Total Decisions' include approval, approvable, and not approvable. (Decision Cohort)

[7] Total Decisions' include substantially equivalent (SE) or not substantially equivalent (NSE). (Decision Cohort)

[8] Total Decisions' include approval, approval with conditions, disapproved, acknowledge, incomplete, withdrawal, or other. (Decision Cohort)

[9] Cleared' includes substantially equivalent decisions (SE). (Decision Cohort)

[10] Closures' include approval, approval with conditions, disapproved, acknowledge, incomplete, no response necessary, withdrawal, or other. (Decision Cohort)

[11] Closures' include a meeting with Industry, deficiency, or other. (Decision Cohort)

[12] MDRs' include individual and summary Medical Device Reports.

[13] Analysis Consults' include analysis of individual and summary Medical Device Reports (analyzing trends and signals in MDR data).

[14] Total Decisions include granted, declined, and withdrawal – regardless of the fiscal year received. (Decision Cohort)

Field Devices and Radiological Health Program Activity Data (PAD)

Field Devices and Radiological Health Program Workload and Outputs	FY 2016 Actual	FY 2017 Annualized CR	FY 2018 President's Budget
FDA WORK			
DOMESTIC INSPECTIONS			
UNIQUE COUNT OF FDA DOMESTIC DEVICES ESTABLISHMENT INSPECTIONS	***2,499***	***2,492***	***2,492***
Bioresearch Monitoring Program Inspections	272	300	300
Pre-Market Inspections	61	60	60
Post-Market Audit Inspections	69	60	60
GMP Inspections	1,420	1,400	1,400
Inspections (MQSA) FDA Domestic (non-VHA)	704	700	700
Inspections (MQSA) FDA Domestic (VHA)	54	50	50
Domestic Radiological Health Inspections	47	50	50
Domestic Field Exams/Tests	15	100	100
Domestic Laboratory Samples Analyzed	255	170	170
FOREIGN INSPECTIONS			
UNIQUE COUNT OF FDA FOREIGN DEVICES ESTABLISHMENT INSPECTIONS	***603***	***595***	***595***
Foreign Bioresearch Monitoring Inspections	15	14	14
Foreign Pre-Market Inspections	26	30	30
Foreign Post-Market Audit Inspections	30	20	20
Foreign GMP Inspections	728	550	550
Foreign MQSA Inspections	13	14	14
Foreign Radiological Health Inspections	78	50	50
TOTAL UNIQUE COUNT OF FDA DEVICE ESTABLISHMENT INSPECTIONS	***3,102***	***3,087***	***3,087***
IMPORTS			
Import Field Exams/Tests	29,992	19,800	19,800
Import Laboratory Samples Analyzed	577	670	670
Import Physical Exam Subtotal	**30,569**	**20,470**	**20,470**
Import Line Decisions	18,757,725	20,070,766	21,475,719
Percent of Import Lines Physically Examined	0.16%	0.10%	0.10%
STATE WORK			
UNIQUE COUNT OF STATE CONTRACT DEVICES ESTABLISHMENT INSPECTIONS	***7,803***	***7,880***	***7,880***
UNIQUE COUNT OF STATE PARTNERSHIPS DEVICE ESTABLISHMENT INSPECTIONS[1]	***0***	***0***	***0***
Inspections (MQSA) by State Contract	6,716	6,800	6,800
Inspections (MQSA) by State non-Contract	1,044	1,060	1,060
GMP Inspections by State Contract	43	20	20
State Partnership GMP Inspections	0	0	0
State Contract Devices Funding	$267,249	$275,266	$283,524
State Contract Mammography Funding	$9,720,997	$9,957,944	$10,157,103
Total State Funding	**$9,988,246**	**$10,233,210**	**$10,440,627**
GRAND TOTAL DEVICES ESTABLISHMENT INSPECTIONS	***10,905***	***10,967***	***10,967***

[1] The FY 2016 actual unique count of foreign inspections includes 12 OIP inspections (8 for China and 4 for India).

[2] The State inspections that are funded by the FDA are now being obligated via formal contract funding vehicles.