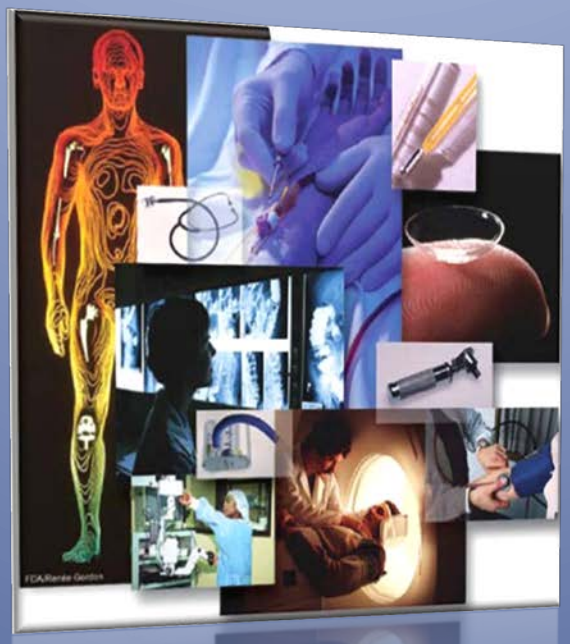

2014 - 2015 Strategic Priorities

Center for Devices and Radiological Health

U.S. Food and Drug Administration

U.S. Department of Health and Human Services

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Introduction

Patients are at the heart of what we do.

It's no coincidence that our vision starts with patients: "Patients in the U.S. have access to high-quality, safe, and effective medical devices of public health importance first in the world." We want our actions to improve the health, and enhance the quality of life of patients. If a device is safe and effective, we want patients to have access to it as quickly as possible.

But our success in achieving our mission—to promote and protect public health—depends on achieving all parts of our vision, not only better patient access. Our vision also sees us as the world's leader in regulatory science, medical device innovation, and manufacturing; establishing a robust postmarket surveillance system; assuring that devices on the market remain safe, effective, and high quality; and providing consumers, patients, caregivers, and providers the information they need to make well-informed decisions.

The Center for Devices and Radiological Health's (CDRH) 2014-2015 Strategic Priorities describe the most important areas that we will focus on because they are critical to reaching our vision. These priorities are:

- Strengthen the clinical trials enterprise;
- Strike the right balance between premarket and postmarket data collection; and
- Provide excellent customer service.

By addressing these priorities over the next two years, we hope to help medical device developers choose the U.S. as the country of first choice for their technologies. The country of first choice is a key contributor to early patient access to high-quality, safe and effective devices.

We also hope that providing excellent customer service will improve our interactions with stakeholders and colleagues, both internal and external, support better regulatory outcomes, and improve patient health.

You may notice that the 2014-2015 Strategic Priorities are different than our priorities from other years. We have taken a different approach to this year's strategic priorities by holding ourselves accountable for achieving measurable outcomes rather than for taking select actions in three areas that complement other important actions coming up in the next two years, such as implementation of our latest user fee agreement (MDUFA III) and other provisions of recent federal law (the Food and Drug Administration Safety and Improvement Act).

Mission

The mission of the Center for Devices and Radiological Health (CDRH) is to protect and promote the public health. We assure that patients and providers have timely and continued access to safe, effective, and high-quality medical devices and safe radiation-emitting products. We provide consumers, patients, their caregivers, and providers with understandable and accessible science-based information about the products we oversee. We facilitate medical device innovation by advancing regulatory science, providing industry with predictable, consistent, transparent, and efficient regulatory pathways, and assuring consumer confidence in devices marketed in the U.S.

Vision

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. U.S. post-market 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. Consumers, patients, their caregivers, and providers have access to understandable science-based information about medical devices and use this information to make health care decisions.

Public Health Focus• We focus on activities and outcomes that protect and promote public health.

Our People• Our staff is our most critical resource. We value individual excellence, teamwork, and personal and professional diversity.

Science-Based Decisions• We make decisions based on sound science using the best available data, methods, information, and tools. We value and take into account differing internal and external perspectives.

Innovation• We challenge the status quo and ourselves to foster positive change. We harness the creativity of our staff and stakeholders. We rapidly test and adopt new approaches to more effectively and efficiently accomplish our mission.

Transparency• We foster public trust and predictability by providing meaningful and timely information about the products we regulate and the decisions we make.

Honesty and Integrity• We maintain the public trust by acting with integrity and honesty. Our actions adhere to the highest ethical standards and the law.

Accountability• We hold ourselves accountable for the actions we do and do not take. We acknowledge our errors and learn from them.

Strengthen the Clinical Trial Enterprise

A key determinant of early U.S. patient access to high-quality, safe, and effective devices is whether and when a device developer chooses to study the product in this country, and a key factor in this decision is the time and cost of demonstrating that the developer's product meets our standard for marketing authorization. CDRH is committed to improving U.S. patient access to new devices by strengthening and streamlining the clinical trial enterprise so that medical device clinical trials are conducted in the U.S. in an efficient and cost-effective manner, while maintaining appropriate patient protections.

We recognize the value of encouraging medical device innovation, particularly when alternative treatments or assessments are unavailable, ineffective, or associated with substantial risks to patient safety.

CDRH has already taken a number of actions to expedite the safe initiation of clinical trials in the U.S., and we hope that these policies will result in conducting clinical studies in the U.S. earlier in the device development process than has historically occurred.

We issued guidance and started a pilot program to facilitate the early clinical evaluation of novel device technologies in the U.S., using risk-mitigation strategies that appropriately protect human subjects.

In addition, we implemented process changes to our Investigational Device Exemption (IDE) program, consistent with FDASIA. Our 2013 draft guidance on FDA Decisions for Investigational Device Exemption Clinical Investigations proposed additional program modifications to allow earlier and more efficient clinical study enrollment. These efforts are an extension of our 2012 guidance that describes the explicit factors we consider in making certain types of premarket benefit-risk determinations, including patient preferences on the benefit-risk tradeoffs of potential treatments.

We have already seen substantial impact. For example, the percentage of IDE submissions that received an approval decision authorizing study initiation (i.e. an IDE conditional approval or full approval decision) within two IDE cycles increased from 46 percent in FY 2011 to 77 percent in FY 2013, while the median time to full study approval was reduced from 435 days to 174 days.

In addition, we continue to improve the clinical trial ecosystem in the U.S. through collaborative efforts, such as the Medical Device Innovation Consortium's Clinical Trial Innovation and Reform Project, which have the potential to improve the efficiency of the clinical study process leading to earlier access in the U.S. to beneficial innovative technologies for patients.

We have identified as a priority achieving the following goals:

Goal: Improve the efficiency, consistency, and predictability of the IDE process to reduce the time and number of cycles needed to reach appropriate IDE full approval for medical devices, in general, and for devices of public health importance, in particular.

Targets:

IDE Cycles

- By September 30, 2014, reduce the number of IDEs requiring more than two cycles to an appropriate full approval decision by 25 percent compared to FY 2013 performance.*
- By September 30, 2014, for disapproved IDEs, offer all sponsors a teleconference or in-person meeting to occur within 10 business days of the IDE decision.
- By June 30, 2015, reduce the number of IDEs requiring more than two cycles to an appropriate full approval decision by 50 percent compared to FY 2013 performance.*

Time to IDE Approval

- By September 30, 2014, reduce the overall median time to appropriate full IDE approval by 25 percent compared to FY 2013 performance.*
- By June 30, 2015, reduce the overall median time to full appropriate IDE approval to 30 days.

Goal: Increase the number of early feasibility/first-in-human IDE studies submitted to FDA and conducted in the U.S.

Target:

Early Feasibility/First-in-Human IDE Studies

- By June 30, 2015, increase the number of early feasibility/first-in-human IDE studies submitted to each premarket Division compared to FY 2013 performance.

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* In FY 2013 (as of 12/11/2013), 45% of IDEs received a full approval decision within 2 cycles and median time to full IDE approval was 174 days.

To accomplish these goals, CDRH will take several steps including the following:

- Establish in the Office of Device Evaluation a premarket clinical trials program responsible for the oversight and performance of the IDE Program and the development and implementation of policies that contribute to the timely initiation and successful execution of medical device clinical trials.
- Formalize the incorporation of our benefit-risk framework, including patient-specific factors such as tolerance for risk and perspective on benefit, into the IDE process.
- Establish a process to efficiently and objectively resolve application-specific IDE issues to reduce the number of multi-cycle IDEs.
- Develop a clinical trials education and training program for CDRH review staff, managers, and industry.
- Develop real-time metrics to track CDRH and industry IDE and clinical trial performance.

Strike the Right Balance Between Premarket and Postmarket Data Collection

A second key determinant of early U.S. patient access to high-quality, safe, and effective devices is how much premarket data device developers must provide to the FDA.

Once a device developer decides to seek U.S. marketing approval or clearance, the extent of premarket data that we require impacts the length of time needed to complete a premarket submission—the more data required, the longer it takes to acquire the data and make the submission. Consequently, our data requirements impact when U.S. patients have access to a device.

This makes it critical that we strike the right balance between premarket and postmarket data collection. If we can shift—when appropriate—some premarket data needs to the postmarket setting, we can directly impact patient access to high-quality, safe, and effective medical devices of public health importance. However, we could undermine patient safety if we shift some data needs from the premarket to the postmarket setting without adequate assurances that necessary and timely data collection will occur. We could also undermine patient safety if we aren't able to quickly remove from the market a device for which postmarket data does not support reasonable assurances of safety and effectiveness, or is not provided in a reasonable timeframe.

Striking the right balance between premarket and postmarket data collection reflects a total life cycle approach to understanding the benefit-risk profile of medical devices. Balancing the need for premarket data and postmarket collection is part of what we consider when we look at the benefit-risk profile of devices—it's laid out in our 2012 guidance on that topic and also described in our 2002 guidance on the Least Burdensome provisions of federal law (Federal Food, Drug & Cosmetic Act, or FD&C Act).

According to the FD&C Act,

"[i]n making a determination of a reasonable assurance of the effectiveness of a device for which an application under section 515 (Premarket Approval Application or PMA) has been submitted, the Secretary shall consider whether the extent of data that otherwise would be required for approval of the application with respect to effectiveness can be reduced through reliance on postmarket controls."

One of the factors that we consider in determining whether or not to approve a device subject to a PMA is whether and to what extent we would accept a greater degree of uncertainty regarding the probable benefits or risks of the device by shifting some premarket data needs to postmarket data collection. In making that determination, we consider the likely benefits and risks of that decision. Specifically, striking the right balance between premarket and postmarket data means balancing the possible benefits of earlier patient access to the device especially when the alternatives are either absent or of limited use and the possible risks of patient harm from exposure to an unsafe or ineffective device.

This proper balance can be further supported by our efforts to establish and strengthen a National Medical Device Postmarket Surveillance System, which can quickly identify new safety concerns and better characterize real-world performance of medical devices. Likewise, our Case for Quality Initiative reduces the risk of patient harm by helping manufacturers to identify and deploy quality-related design and production practices. More broadly, our knowledge that postmarket studies will be properly developed and conducted, that devices will be properly labeled and promoted, and that device makers will reliably produce high-quality devices bolsters confidence in a premarket system that appropriately affords earlier patient access.

Efforts to advance international harmonization and convergence, such as through the International Medical Device Regulators Forum, can also play an important role in accomplishing this Strategic Priority. Efforts to enhance postmarket surveillance through internationally-harmonized data collection and to assure the manufacture of high-quality devices through the Medical Device Single Audit Program and related actions can support shifting premarket data requirements to postmarket studies, and reduce differences between the U.S. and other countries in the time and cost of device development.

We have identified as a priority achieving the following goal:

Goal: Assure the appropriate balance between premarket and postmarket data requirements to facilitate and expedite the development and review of medical devices, in particular high-risk devices of public health importance.

Targets:

Device Types Subject to PMA

- By December 31, 2014, review 50 percent of device types subject to a PMA that have been on the market to determine whether or not to shift some premarket data requirements to the postmarket setting or to pursue down classification, and communicate those decisions to the public.
- By June 30, 2015, review 75 percent of device types subject to a PMA that have been on the market to determine whether or not to shift some premarket data requirements to the postmarket setting or to pursue down classification, and communicate those decisions to the public.
- By December 31, 2015, review 100 percent of device types subject to a PMA that have been on the market to determine whether or not to shift some premarket data requirements to the postmarket setting or to pursue down classification, and communicate those decisions to the public.

To accomplish this goal, CDRH will take several actions including the following:

- Develop and seek public comment on a framework for when it is appropriate to shift premarket data collection to the postmarket setting.
- Conduct a retrospective review of all PMA device types to determine whether or not to shift some premarket data requirements to the postmarket setting or to down classify device types in light of our current understanding of the technology.
- Implement a mechanism to prospectively assure the appropriate balance of premarket and postmarket data requirements for new devices subject to a PMA.
- Using existing authorities, develop and seek public comment on a new pathway to market for devices subject to a PMA that address an unmet public health need by shifting appropriate premarket data needs to the postmarket setting and incorporating features of the Innovation Pathway pilots.

Provide Excellent Customer Service

A third key determinant of early U.S. patient access to high-quality, safe and effective devices is the quality of the customer service we provide to our stakeholders, including patients, industry, and health care professionals. Our ability to successfully fulfill our public health mission and vision depends on how we reach decisions, take actions, and interact with our stakeholders and colleagues. We have the greatest impact when we understand and try to address their needs.

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 with stakeholders and colleagues and 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 requires identifying and meeting our customers' needs, as appropriate, while achieving our mission and vision.

The experience of receiving excellent customer service can encourage device makers to choose the U.S. first when bringing their products to market; in turn, U.S. health care providers gain access to the technologies that they need to administer quality health care to patients. Providing excellent customer service to our colleagues, such as thorough timely and well-informed expert consults, can help them better succeed on the job. All of our stakeholders benefit as a result.

We have identified as a priority achieving the following goal:

Goal: Provide excellent customer service.

Targets:

Customer Satisfaction

- By December 31, 2014, achieve at least 70 percent customer satisfaction.
- By June 30, 2015, achieve at least 80 percent customer satisfaction.
- By December 31, 2015, achieve at least 90 percent customer satisfaction.

To accomplish this goal, CDRH will take several actions including the following:

- Implement Customer Service Standards to promote excellent customer service.
- Assess customer satisfaction using a standardized survey tool embedded in emails and available on our website.
- Establish a CDRH program to monitor and address feedback on CDRH processes and services and improve quality and performance that includes corrective action and preventative action (CAPA) processes.
- Implement the principles and practices outlined in the CDRH Quality Management Framework to improve the quality and performance of CDRH processes and services.