2. STRENGTHEN THE U.S. RESEARCH INFRASTRUCTURE AND PROMOTE HIGH-QUALITY REGULATORY SCIENCE

Innovative medical device development is facilitated by a solid research infrastructure that provides the scientific community with the tools and mechanisms to perform foundational research, develop new research methodologies, and enhance research collaboration and communication between different disciplines. Strengthening regulatory science – the science of developing new tools, standards and approaches to assess the safety, efficacy, quality and performance of FDA-regulated products – would serve to foster innovation, reduce the time and cost to meet regulatory evidentiary requirements, and improve the efficiency and quality of device manufacturing. In addition, having institutions and investigators skilled in good clinical practices can help assure proper clinical trial conduct, thereby also assuring patient protection and data integrity. A weak research infrastructure and underdeveloped regulatory science impedes the development of innovative devices because the tools necessary to efficiently evaluate their potential may not exist or the data collected from a clinical trial may be of insufficient quality.

The actions CDRH proposes to take to strengthen the U.S. device research infrastructure and promote regulatory science are as follows:

2.1 Establish a Voluntary Third-Party Certification Program for U.S. Medical Device Test Centers

Certifying medical device clinical trial centers would strengthen the U.S. research infrastructure by helping sponsors to more easily identify high quality test centers for medical device development and assessment while providing greater assurance of patient safety. Certified test centers would bring together the key scientific expertise required to more efficiently and safely develop and test innovative medical devices consistent with the iterative nature of device design, testing, and redesign. Sponsors, clinical investigators and Institutional Review Boards (IRBs) must continue to comply with all applicable FDA regulatory requirements.[8] CDRH expects these test centers would be able to identify and correct device shortcomings quickly, thereby minimizing patient exposure to significant and unnecessary safety risks. In addition, because of their expertise and established safety records, CDRH would consider permitting these certified test centers to conduct first-in-human studies at earlier stages in the development process. In some cases, test centers may be able to acquire a "Center of Excellence" distinction related to expertise in specific areas (such as diabetes, wireless technologies, etc.). CDRH would consider using a third-party certification approach and implement such a program to the extent resources permit.

Test centers that believe they meet the certification criteria may volunteer for third-party certification at their own discretion. A clinical trial test center would be considered worthy of third-party certification if it met certain criteria, such as the following (some criteria overlap with mandatory FDA regulatory requirements):

[8] *See*, e.g.; 21 CFR parts 50, 56 and 812.

1. The center has access to necessary device development expertise through a formal relationship with a medical device design and engineering "academic" (i.e. non-industry) center;
2. The center has a robust clinical program and diverse expertise to anticipate and manage medical issues that may arise during the course of clinical studies, particularly for those sites participating in early clinical trials and/or studying implanted devices;
3. The center has a robust safety monitoring system, such as timely and effective reporting of adverse events, for significant risk studies; and
4. The center demonstrates expertise in clinical trial design and conduct as well as human subject protection and data integrity training, expertise, and oversight consistent with Good Clinical Practices.

CDRH recognizes that currently there may be a limited number of institutions that are able to meet all of the criteria listed above, and that there may also be value to providing certification for institutions that conduct high quality clinical studies that assure data integrity and human subject protection. Therefore, CDRH would consider creating a two-tiered certification program. The first tier would include test centers that meet all the above-listed criteria (i.e., centers with both in-house device development and clinical assessment expertise); the second tier would include test centers that meet criteria 2 – 4 (i.e., centers with in-house clinical assessment expertise only). This two-tiered approach would be more resource-intensive, as more test centers would meet the eligibility criteria. CDRH is seeking public comment on the two-tiered versus single-tiered approach as well as establishing a voluntary certification program generally.

2.2 Create a Publicly-Available Core Curriculum for Medical Device Development and Assessment

Currently there are few institutions that possess all the necessary expertise to design, test and clinically evaluate devices, identify the root causes of adverse events and device malfunctions, develop iterative device designs, and navigate the regulatory process; even fewer offer curricula in these disciplines. To facilitate the widespread availability of educational programs in device development and assessment to train the next generation of innovators and help keep the U.S. the leader in medical device innovation, CDRH would work with academia, industry, and the health care community to develop a publicly-available core curriculum covering the areas of device design and engineering, pre-clinical testing, clinical evaluation, regulatory processes and post-market monitoring.

2.3 Leverage Device Experience and Data Collected Outside the United States

CDRH recognizes that a significant portion of medical device research occurs outside the United States, and CDRH accepts foreign clinical data that complies with FDA regulatory criteria.[9]

Historically, the applicability of data developed outside the United States has been limited due to key deficiencies, namely, insufficient study quality and/or data integrity, or lack of sufficient demographic and clinical information to determine applicability to the U.S. population. As part

[9] *See* 21 CFR 814.15.

of its Innovation Initiative, CDRH would develop a guidance document describing the Center's recommendations for the criteria and circumstances under which foreign test centers should develop data to be used in support of U.S. device marketing applications. In addition, CDRH would explore the possibility of extending its voluntary third-party certification program for clinical testing sites outside the United States, resources permitting, from which CDRH would routinely accept clinical data.

2.4 Develop New Science

CDRH has been and continues to be actively engaged in regulatory science research. In particular, scientists in CDRH's Office of Science and Engineering Laboratories (OSEL) pursue a broad portfolio of research and training activities, including:

- Product testing;
- Development of test methods for CDRH, industry, and academic use;
- Scientific investigations on emerging technologies;
- Participation in national and international standards development;
- Scientific and technical training of CDRH staff members; and
- Maintenance of laboratory collaborations and relationships with scientific researchers in academia and other Federal laboratories.

OSEL is also working on a number of projects to strengthen regulatory science, including:

- Novel imaging techniques to produce real-time, high-resolution cross-sectional medical images of tissue with a resolution of only a few microns. This technique is commonly used in ophthalmology, but is being studied for dental and dermatological use;
- Light therapy for neurostimulation, which will avoid the malfunction of electrodes that commonly occurs with long-term electrical stimulation; and
- High intensity focused ultrasound, which is a minimally invasive therapy to stop internal bleeding and ablate pathologic tissue.

In the coming months, the Center intends to issue a report highlighting recent achievements in the area of regulatory science and outlining future regulatory science projects and their applicability to medical device development and public health.

In addition, the Center plans to take the following actions to improve regulatory science for medical devices: (1) establish a formal process for CDRH-wide prioritization of scientific research that will include public input; (2) explore establishing public-private partnerships, including at least one new such partnership in 2011 – as we committed to do under our 2011 Strategic Priorities;[10] (3) collaborate with other government agencies – for example, we recently executed a Memorandum of Understanding with DARPA allowing us, among other things, to collaborate on developing new tests to quickly and accurately assess the safety and effectiveness of devices; and (4) hold public workshops promoting the advancement of regulatory science – in

[10] *See* "CDRH 2011 Strategic Priorities". Available at http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHVisionandMission/ucm240117.htm.

2011, CDRH plans to hold at least one public workshop focused on promoting advances in medical device computational modeling and simulation.

As part of the public comment period on CDRH's Innovation Initiative, we are interested in receiving comments about other programs that could support innovation in medical device development by strengthening the research infrastructure in the U.S. and advancing regulatory science.

3. PREPARE FOR AND RESPOND TO TRANSFORMATIVE INNOVATIVE TECHNOLOGIES AND SCIENTIFIC BREAKTHROUGHS

CDRH aims to maintain cutting-edge expertise and experience in-house, but some technologies emerge so rapidly that it is challenging for the Center to be fully prepared in advance for all devices it reviews, and, as a result, delays in review, particularly of the most innovative technologies, can occur. CDRH works to identify and predict developing technologies, and to identify sources of scientific expertise to adequately evaluate those technologies. Under the Innovation Initiative, CDRH would promote the following two programs to enhance our preparedness:

3.1 Horizon Scanning

Medical device technologies emerge and develop rapidly. For example, over the past decade CDRH has experienced significant growth in the need for expertise related to genomics, nanotechnology, biomaterials, and software. Rather than identify and seek out needed expertise when submissions have already been received, CDRH has strategically evaluated its needs through formal horizon scanning and hired or contracted with appropriate experts in advance of receiving device submissions in these areas.

During 2007-2008, CDRH developed a 10-year forecast for medical device technologies designed to help the Center and medical device stakeholders prepare for pioneering products and emerging medical device technologies that will pose new scientific and regulatory challenges.[11] The purpose of this forecast was to identify key scientific issues and novel technologies, and to set regulatory, scientific, and administrative strategies that adequately prepare the Center for these developments. Identified emerging areas included specific device technologies (computerized, wireless, robotic), scientific fields (genomic, proteomic, metabolomic, and epigenomic) and use characteristics (geriatric, home use).

CDRH seeks to enhance its horizon scanning methodology, an approach that reviews important scientific literature and accounts for public health needs as well as considers technologies funded by other government agencies, input from manufacturers and other stakeholders with knowledge of the medical device industry, and information from various other sources. Additionally, interval horizon scanning with public reporting of its findings would help CDRH anticipate and prepare for emerging device technologies by focusing our hiring and contracting, staff education, and research efforts in these areas.

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11 See "Medical Device Technology Forecast 2008: Future Trends in Medical Device Technologies". Available at http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHReports/ucm234726.htm.

3.2 CDRH Network of Experts

Given the need for additional expertise in certain areas to complement the Center's in-house knowledge and experience, CDRH announced its intention to develop a Network (or Networks) of Experts to serve as a resource to assist in better understanding emerging technologies in fields with which our reviewers might not be immediately familiar.[12] These Networks will function differently than the Advisory Panels that CDRH currently utilizes for review of certain device submissions. CDRH intends to consult members of the Network on an individual basis for their views on discrete scientific issues and does not intend to seek consensus opinions from more than one Network member as it would do with an advisory committee.[13] If the Center finds that it is necessary to disclose proprietary or other privileged information when consulting a Network member, the Center would ensure that any such proprietary or other privileged information is protected in accordance with applicable statutes and regulations. CDRH plans to post an SOP to FDA's website on how the Center will utilize these Networks of Experts by September 15, 2011.[14] With the assistance of scientific experts outside the Center, our reviewers can obtain additional perspectives, gain knowledge, and ultimately make better informed decisions, provide clearer expectations for data requirements, and more easily address other scientific issues that arise during the regulatory review process. In addition, engagement with external experts supports a culture of continuous scientific learning, promotes professional staff development, and provides the flexibility needed to review innovative devices in a timely manner.

CONCLUSION

CDRH is committed to assuring that American patients have safe, timely access to important new technologies and next-generation products. CDRH's Innovation Initiative is designed to strengthen the U.S. medical device research infrastructure, promote regulatory science, streamline the conduct of clinical trials, improve the quality and integrity of clinical trial data, identify and prepare for important emerging device technologies, and accelerate the regulatory review of these pioneering products. This program would help CDRH achieve its goal of advancing public health by facilitating innovation to help bring transformative devices to patients and make medical devices safer and more effective.

[12] *See* Footnote 1.
[13] CDRH does not intend to utilize the network as an advisory committee within the meaning of the Federal Advisory Committee Act, 5 U.S.C. App. 2.
[14] *See* Footnote 1. CDRH plans to address screening of network members for potential conflicts of interest in the SOPs.

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SEPTEMBER 2014

FDA Strategic Priorities

2014-2018

U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES
U.S. FOOD AND DRUG ADMINISTRATION

MESSAGE FROM THE COMMISSIONER

The world in which FDA operates today is one of growing complexity, new challenges, and increased risks. And thanks to revolutionary advances in science, medicine, and technology, we have enormous opportunities that we can leverage in order to overcome many of these challenges for the benefit of public health.

As a regulatory agency that makes its decisions based on the best available science, while maintaining its far-reaching mission to protect and promote the public health, FDA is uniquely prepared and positioned to anticipate and successfully meet these challenges.

FDA's responsibilities continue to escalate as we work to fulfill the mandates of groundbreaking legislation passed in recent years, including the Family Smoking Prevention and Tobacco Control Act of 2009, the Patient Protection and Affordable Care Act of 2010, the FDA Food Safety Modernization Act of 2011, the FDA Safety and Innovation Act of 2012, and the Drug Quality and Security Act of 2013. Further, with so many FDA-regulated products coming from overseas, FDA is keenly focused on the complexities of regulating in a global marketplace.

This Strategic Priorities document articulates the goals and priorities that guide our Agency. It creates a framework that will allow us to integrate and achieve our five strategic priorities – regulatory science, globalization, safety and quality, smart regulation, and stewardship.

While the priorities are individually important, they are also interconnected and cannot be addressed in isolation. Thus, for example, regulatory science is at the core of everything FDA does and therefore it influences and in turn is affected by any actions taken involving the other priorities. The cross-cutting nature of this plan will help FDA achieve the greatest benefits.

This document also sets forth FDA's core mission goals and objectives, such as improving and safeguarding access to – and making better informed decisions about – the products FDA regulates. It describes in detail key strategies to help the Agency fulfill its public health mission.

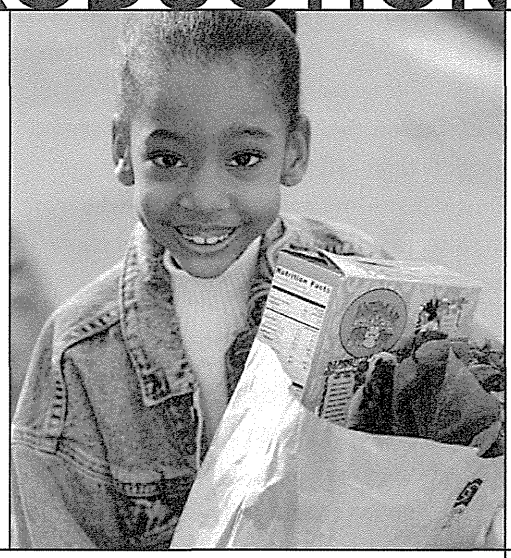
The many new responsibilities Congress has given FDA serve as an important backdrop for this plan, which includes a focus on advancing ways the Agency can continue to efficiently manage and build upon these new authorities. This will allow us to maintain our responsive and responsible stewardship of the public health for the 21st century.

The Strategic Priorities document is the result of an extraordinary and talented team of dedicated public servants who contribute each day to our mission to protect the health and safety of the American public, and who strengthen FDA's preeminent global reputation. These steadfast employees understand that the work we are engaged in and the challenges we face have extraordinary consequences for real people. It is through their commitment that we are able to meet this challenge and fulfill the potential and promise offered by science today.

Margaret A. Hamburg, M.D.
Commissioner of Food and Drugs

FDA STRATEGIC PRIORITIES 2014-2018

INTRODUCTION



The U.S. Food and Drug Administration (FDA) is the Agency within the U.S. Department of Health and Human Services (HHS) responsible for ensuring the safety, effectiveness, and quality of products that account for about 20 cents of every dollar spent by Americans each year. These products include human and animal drugs, 80 percent of the food supply, biological products, medical devices, cosmetics, and radiation-emitting products. FDA also regulates tobacco products using a population health standard.

This document provides an overarching Agency-level view of how FDA is addressing the public health challenges we face.

HHS Mission

The HHS mission is to enhance the health and well-being of Americans by providing effective health and human services and by fostering sound, sustained advances in the sciences underlying medicine, public health, and social services.

FDA Mission

FDA is charged with protecting the public health by ensuring the safety, effectiveness, and security of human and veterinary drugs, biological products, and medical devices; ensuring the safety of foods, cosmetics, and radiation-emitting products; and regulating tobacco products.

Specifically, FDA is responsible for advancing the public health by:

- Helping to speed innovations that make foods safer and make medicines and devices safer and more effective
- Ensuring the public has accurate, science-based information they need to use medicines, devices, and foods to improve their health
- Regulating the manufacture, marketing, and distribution of tobacco products and reducing tobacco use by minors and
- Addressing the nation's counterterrorism capability and ensuring the security of the supply of foods and medical products

Vision

FDA is dedicated to world-class excellence as a science-based regulatory agency with a public health mission. We aim to provide effective and innovative leadership — domestically and internationally — to protect health, prevent illness, prolong life, and promote wellness.

Organization

Ensuring a safe and secure nutritious food and feed supply, overseeing the manufacturing, marketing and distribution of tobacco products, and improving access to safe,