U.S. Food and Drug Administration

2016-2017 Strategic Priorities

Center for Devices and Radiological Health

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Center for Devices and Radiological Heath

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.

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. postmarket 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.

Shared Values

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.

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.

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

Introduction

Success in realizing our Center for Devices and Radiological Health (CDRH) mission—to promote and protect public health—depends on achieving all parts of our vision. Our vision starts with patients because they are at the heart of what we do. We want patients to have access to high-quality, safe, and effective medical devices of public health importance first in the world. Under our vision, we also seek to assure the U.S. is the world's leader in medical device regulatory science, innovation, and manufacturing; establish a robust postmarket surveillance system; assure that devices on the market remain safe, effective, and high quality; and assure consumers, patients, caregivers, and providers have access to the information they need to make well-informed decisions.

As we release the CDRH 2016-2017 Strategic Priorities, we begin by highlighting the significant amount of work our staff accomplished over the past two years in support of our CDRH 2014-2015 Strategic Priorities. For example:

- We established a clinical trials program, developed clinical trials education for staff and industry, developed new policies and processes, and established and publicly reported Investigational Device Exemption (IDE) performance metrics in support of our strengthen the clinical trial enterprise priority, including reducing the median time to full approval by over one year.
- We conducted a retrospective review of all 210 high-risk device product codes, which required over 275 postmarket analyses, resulting in a reduction in premarket data requirements and/or a recommendation to downclassify a technology for about 30 percent of the product codes. We also established a regulatory pathway for breakthrough devices that, where appropriate, allows for shifting appropriate premarket data needs to the postmarket setting in support of our priority to strike the right balance between premarket and postmarket data collection.
- We established customer service standards of excellence, trained all of our staff on customer service, launched a customer service survey, issued our quality management framework, and made our customer service rating publicly available in support of our provide excellent customer service priority. These actions resulted in improved customer service.
- We completed fourteen premarket process improvement projects, which resulted in the implementation of all eleven recommendations stemming from the MDUFA III assessment of the premarket review process. Among the many actions undertaken under this effort were issuance of revised eCopy and RTA guidance documents, improved procedures for premarket review file management, adoption of the Kirkpatrick methodology for training evaluation, a plan for incorporating quality management into premarket review activities, adoption of review tools that promote consistency of reviews, and the establishment of FEEDBACK✓CDRH for the collection and management of suggestions for improvement and quality issues.

To achieve our priorities staff went above and beyond their already demanding workload - a remarkable achievement.

CDRH 2016-2017 Strategic Priorities continue and build on the success of our CDRH 2014-2015 Strategic Priorities. These important areas are critical next steps to reaching our vision:

- Establish a National Evaluation System for medical devices;
- Partner with patients; and
- Promote a culture of quality and organizational excellence.

Consistent with our vision, to successfully generate robust real-world data in an efficient manner to quickly identify new safety problems for devices on the market and optimally and appropriately rely on postmarket data collection to support product approvals or in lieu of some premarket evidence generation, the U.S. must have the necessary infrastructure – a national evaluation system – in place. Through our priority *Establish a National Evaluation System for Medical Devices* we take a significant step to create a national safety net to protect patients and incentivize innovators to study their technologies in and ultimately bring their products to patients in the U.S. first.

The role of patients has evolved over time– from passive recipients of practitioner advice to healthcare advocates; from consumers of information to shared decision makers. Now it's time to interact with patients as partners in advancing healthcare. Our priority to *Partner with Patients* reflects and builds on our strong commitment to patients as our most important customer. CDRH will establish a foundation to facilitate the development of 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.

Quality and organizational excellence are about a culture that understands how its actions can improve product, service, performance, and decision-making quality and how its decisions affect the quality of life of U.S. patients. *Promote a Culture of Quality and Organizational Excellence* strives to improve medical device manufacturers' ability to design and make high-quality, safe and effective devices and CDRH's ability to provide the necessary oversight to give U.S. patients timely access to life-enhancing innovative medical devices while assuring that devices on the market are of high-quality, safe and effective.

To achieve our 2016-2017 Strategic Priorities we are holding ourselves accountable for achieving measurable, publicly reported outcomes. As in the past, our efforts to achieve these outcomes will complement rather than take away from other important actions, such as implementation of our user fee agreement. And as in the past, we cannot achieve these ambitious goals without adequate resources, collaboration and support.

We encourage all interested parties to work with us to achieve the objectives of these Strategic Priorities and, ultimately, our vision.

Establish a National Evaluation System for Medical Devices

To successfully harness from the diverse set of real-world evidence in an efficient manner, the U.S. must develop the necessary infrastructure – a National Evaluation System for medical devices.

As we discussed in our 2014-2015 Strategic Priorities, we need to provide the right mix of safeguards and incentives to achieve our vision. This mix should reduce the time and cost of evidence generation while assuring the development and use of sound science and the implementation of adequate patient protections for patient-centered regulatory decision making. Over the past two years, CDRH has made significant strides to advance these objectives. However, to successfully harness from the diverse set of real-world evidence ("evidence from clinical experience") in an efficient manner, the U.S. must develop the necessary infrastructure – a National Evaluation System for medical devices. That system is not yet in place today.

The high costs and inefficiencies of data generation in clinical trials have created disincentives for innovators to study their technologies in the U.S. and ultimately bring their products to this country. Limitations of current postmarket surveillance tools, such as passive reporting, also constrain CDRH's ability to rapidly address safety concerns. A national medical device evaluation system that leverages real-world evidence can help us more efficiently strike the right balance between premarket and postmarket data collection to facilitate patient device access and more quickly identify safety signals by assuring timely and robust postmarket data collection.

The national medical device evaluation system will build upon and leverage the vast amount of information and knowledge created every day as a part of routine health care or generated at home, such as patients using monitoring devices – what we call "real-world evidence." Access to the large amounts of electronic clinical data being generated and collected today can be used to identify safety signals and support risk-benefit analyses when data quality is ensured and advanced analytics are applied. Real-world evidence in the future will be able to support regulatory decision making across the pre- and postmarket continuum. To make that vision a reality, we must develop systems to ensure that data quality is appropriate and sufficient for regulatory decision making, that data flows seamlessly between systems, and that unique device identifiers (UDI) are routinely incorporated into electronic health information.

In 2012 and 2013 CDRH set out a strategy and next steps for creating a national evaluation system for medical devices. In 2015 two multi-stakeholder groups issued reports (Strengthening Patient Care:

Building an Effective National Medical Device Surveillance System and Recommendations for a National Medical Device Evaluation System: Strategically Coordinated Registry Networks to Bridge the Clinical Care and Research) that endorsed the CDRH vision and made recommendations providing further direction for establishing this system. The National Evaluation System would utilize real-world evidence comprised of electronic health information (EHI) such as electronic health records (EHRs), registries, and medical billing claims in which device identifiers (such as UDI) have been incorporated. The system would leverage and integrate national resources such as PCORnet (EHRs), Sentinel (currently claims data), and national and international registries. It would be developed through strategic alliances between disparate data sources and advancing the UDI adoption in EHI, data quality standards, interoperability, and methods development. The National Evaluation System would be operated by a public-private partnership and governed by a board with representatives from the various stakeholder communities in the medical device ecosystem, including government.

Through this collaborative undertaking, we can build on our accomplishments under our CDRH 2014-2015 Strategic Priorities to move another step closer to achieving our vision.

GOAL: INCREASE ACCESS TO REAL-WORLD EVIDENCE TO SUPPORT REGULATORY DECISION MAKING

- By December 31, 2016, gain access to 25 million electronic patient records (from national and international clinical registries, claims data, and EHRs) with device identification.
- By December 31, 2017, gain access to 100 million electronic patient records with device identification.

GOAL: INCREASE THE USE OF REAL-WORLD EVIDENCE TO SUPPORT REGULATORY DECISION MAKING

- By December 31, 2016, increase by 40 percent the number of premarket and postmarket regulatory decisions that leverage real-world evidence. (compared to FY2015 baseline)
- By December 31, 2017, increase by 100 percent the number of premarket and postmarket regulatory decisions that leverage real-world evidence. (compared to FY2015 baseline)

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

- Resources permitting, establish an organizational structure and development of infrastructure for the National Evaluation System as envisioned in the report of the Engelberg Center for Health Care Reform Medical Device Postmarket Surveillance System Planning Board (February 2015) and the Medical Device Registry Task Force Report (August 2015).
- Develop a framework for the incorporation of real-world evidence into regulatory decision making.
- Develop real-world evidence education and training for CDRH staff and industry.
- Develop metrics to track progress on building a national medical device evaluation system.

Partner with Patients

We believe that if CDRH is to successfully achieve a mission and vision in the service of patients, we must interact with patients as partners and work together to advance the development and evaluation of innovative devices, and monitor the performance of marketed devices.

It's no coincidence that our vision begins with "patients." Patients are at the heart of everything we do. Patients are no longer passive bystanders in their health. They actively seek information and engage in disease management and shared decision-making with their health care practitioners. We value their perspectives and our engagement with them improves our understanding of the patient experience. However, we can and should do more. We believe that if CDRH is to successfully achieve a mission and vision in the service of patients, we must interact with patients as partners and work together to advance the development and evaluation of innovative devices, and monitor the performance of marketed devices. We also understand that many patients such as children have family caregivers who are also our customers and we are committed to engaging them to achieve this mission. This priority reflects and builds on our strong commitment to patients as our most important customers. The time to take this critical step forward is now.

Patient groups have evolved from patient support, advocacy and basic disease research funding organizations, to being more active in medical product development and assessment. Patients are committed to contributing their views, data, and resources to increase patient-centric medical product innovation, assessment, and regulatory decision-making, and we are committed to assuring that our decisions and actions are informed by patient perspectives. The advent of groups such as the Patient-Centered Outcomes Research Institute (PCORI) has increased visibility and funding of research geared towards patient-centricity, and there is substantial government, industry, and academic activity and investment in the patient-centricity realm which we should leverage. The patient data donation movement is gaining momentum and participant engagement is a focus for the White House Precision Medicine Initiative.

Patient representatives have long served on CDRH advisory committees. Over the past few years we have increased our efforts to engage with patients and patient groups to better understand their needs and to seek their input in the work we do. In addition, patient input as evidence is on the rise. CDRH has seen a substantial increase in the number of patient-reported outcome (PRO) measures used as primary and secondary endpoints in clinical studies, from about 20 before 2009 to more than 120 in 2014. Under our 2012 Benefit-Risk Framework for PMA approvals and *de novo* classifications, we identified patient perspectives on benefits and tolerance for risks as an important factor in our premarket approval decisions. From that we launched our Patient Preference Initiative to advance the development and use

of robust scientific methods to assess benefit-risk tradeoffs patients are willing to make such that we can rely on that information in our decision-making. Under this Initiative, CDRH sponsored a patient preference study in obese patients the results of which informed our decision to approve the first device treatment for obesity since 2007. We also issued a patient preference draft guidance, and participated in the Medical Device Innovation Consortium (MDIC) development of the Patient-Centered Benefit-Risk Framework and catalog of assessment methods.

By partnering with patients, CDRH can build on our earlier accomplishments and do much more. We can develop more patient-friendly information about safe and effective device use, promote more patient-centric clinical trials that measure what is most important to patients and are designed to facilitate patient participation, advance benefit-risk assessments that are informed by patient perspectives, and foster earlier access to beneficial new devices that meet patients' needs.

By working with patients, rather than only on their behalf, we can better meet their needs and our public health commitment to improve their health and quality of life.

GOAL: PROMOTE A CULTURE OF MEANINGFUL PATIENT ENGAGEMENT BY FACILITATING CDRH INTERACTION WITH PATIENTS

- By December 31, 2016, establish one or more new mechanisms for CDRH employees to obtain patient input on key pre- and postmarket issues facing CDRH and foster participation of 10 patient groups to participate.
- By December 31, 2017, foster participation of 20 patient groups to participate in these mechanisms.
- By December 31, 2016, 50 percent of CDRH employees will interact with patients as part of their job duties.
- By December 31, 2017, 90 percent of CDRH employees will interact with patients as part of their job duties.

GOAL: INCREASE USE AND TRANSPARENCY OF PATIENT INPUT AS EVIDENCE IN OUR DECISION MAKING

- By September 30, 2016, 50 percent of PMA, *de novo* and HDE decisions will include a public summary of available and relevant patient perspective data considered.
- By September 30, 2017, 100 percent of PMA, *de novo* and HDE decisions will include a public summary of available and relevant patient perspective data considered.
- By September 30, 2017, increase the number of patient perspective studies (e.g., evaluating patient reported outcomes or patient preferences) used in support of premarket and postmarket regulatory decisions. (compared to FY 2015 baseline)
- By September 30, 2017, increase the number of Expedited Access Pathway data development plans or regulatory submissions that consider patient perspectives. (Compared to FY 2015 baseline)

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

- Resources permitting, establish in CDRH a patient-focused program responsible for the strategic development and coordination of CDRH's initiatives to advance patient engagement and the science of patient input throughout the total product lifecycle.
- Convene the Patient Engagement Advisory Committee to discuss high priority topics regarding patient input in the total product lifecycle.
- Identify/define the various pre- and postmarket regulatory uses of patient reported outcome measures (PROMs) and issue a report summarizing current PROM regulatory usage patterns and gaps.
- Work with members of the medical device ecosystem to develop a framework for patient input to inform clinical study design and conduct, with a goal of reducing barriers to patient participation and facilitating recruitment and retention.
- Develop education and training for CDRH staff and industry on the development and use of the science of measuring and communicating patient input throughout the total product lifecycle.

Promote a Culture of Quality and Organizational Excellence

A manufacturer's ability to design and make high-quality, safe and effective devices and CDRH's ability to provide the necessary oversight to assure devices on the market are high-quality, safe and effective will increase as manufacturers and CDRH embrace a culture of quality and excellence throughout our respective organizations.

Our vision seeks to provide patients with devices that are not only safe and effective but also of high quality. It is widely recognized that a quality management system (QMS) is important to defining an organization's policies, procedures and practices. This is why, in 2013, CDRH developed and then began implementing our Quality Management Framework. However, while a QMS provides some level of confidence about its products and services, a culture focused on quality and customer service is needed to truly achieve organizational excellence. Throughout our organization, quality must be a driving principle in everything we do. We strive to create an environment where our individual commitments to quality are evident, we consistently take quality-focused actions, and where quality is always part of the conversation. We intend to fully implement our CDRH Quality Management Framework, to the extent that resources permit, and achieve the measurable outcomes reflective of a quality-focused organization.

For CDRH, our customers are the members of the medical device ecosystem—including patients, industry, and health care professionals—and our colleagues. As such, organizational excellence is about a culture that understands how its actions will improve product, service, performance, and decision-making quality and how its decisions affect the quality of life of U.S. patients. It is about continually striving for high quality and excellence in everything we do, and to work within the medical device ecosystem to champion adoption of the same culture. A manufacturer's ability to design and make high-quality, safe and effective devices and CDRH's ability to provide the necessary oversight to assure devices on the market are high-quality, safe and effective will increase as manufacturers and CDRH embrace a culture of quality and excellence throughout our respective organizations.

In 2011, we, along with FDA's Office of Regulatory Affairs, launched the Case for Quality, an initiative undertaken in collaboration with other members of the device ecosystem, to identify those practices that can promote a culture of quality and the implementation of a quality management approach that fosters continuous product quality. CDRH envisions a future state where the medical device ecosystem is inherently focused on device features and manufacturing practices that have the greatest impact on product quality and patient safety. Internally, this requires a shift in our traditional regulatory approach, toward a model that is preventive of problems before they occur, that adapts to changes in science and

technology, and that rapidly addresses events that impact safety. Externally, this requires partnerships and shared responsibility among FDA, industry, practitioners, and patients to continually evaluate and adjust based on experiences across the full life cycle of a device.

Through the Case for Quality and complementary efforts, such as the Voluntary Compliance Improvement Program, and the Medical Device Single Audit Program, CDRH has been working alongside members of the medical device ecosystem to identify key factors affecting medical device quality and develop innovative ways to afford patient access to high-quality medical devices. Over the coming two years CDRH will seek innovative ways to implement quality practices within CDRH, with ORA as part of our Program Alignment effort, and in our interactions with industry. Our objective is to assure technologies perform consistently, reliably, and are available to those who will benefit from them when they are most needed– improving the health and the quality of life of every American.

GOAL: STRENGTHEN FDA'S CULTURE OF QUALITY WITHIN THE CENTER FOR DEVICES AND RADIOLOGICAL HEALTH

- By September 30, 2016, increase by 10 percent the number of CDRH staff with quality and process improvement credentials to improve organizational excellence (compared to FY 2015 baseline)
- By September 30, 2017, increase by 25 percent the number of CDRH staff with quality and process improvement credentials to improve organizational excellence (compared to FY 2015 baseline)
- By September 30, 2017, have systems and procedures in place to be eligible for ISO 9001 certification.
- By December 31, 2017, submit to an Alliance for Performance Excellence member organization a formal application to assess our progress towards adopting the Baldrige Performance Excellence Criteria and achieving organizational excellence.

GOAL: STRENGTHEN PRODUCT AND MANUFACTURING QUALITY WITHIN THE MEDICAL DEVICE ECOSYSTEM

- By September 30, 2016, develop metrics, successful industry practices, standards, and tools that manufacturers can use to evaluate product and manufacturing quality beyond compliance with regulatory requirements.
- By December 31, 2016, pilot voluntary use of product and manufacturing quality metrics and evaluation tools.
- By December 31, 2017, propose a voluntary program to recognize independent evaluation of product and manufacturing quality.

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

- Resources permitting, continue to implement the CDRH Quality Management Framework.
- Develop education and training for CDRH staff to facilitate adoption of practices characteristic of a culture of quality and organizational excellence.

- Conduct a Baldrige Performance Excellence Criteria self-assessment to measure progress towards achieving organizational excellence.

- As part of the Case for Quality, collaborate with members of the medical device ecosystem to identify, develop, and pilot metrics, successful practices, standards, and evaluation tools that will be specific to the medical device industry and focus on assuring product and manufacturing quality.
- Identify external partnerships and mechanisms to support a sustainable, voluntary third party program that will utilize quality metrics, practices, standards, and evaluation tools to assess and promote medical device product and manufacturing quality within industry beyond compliance with regulatory requirements.
- Identify FDA policies and practices that will encourage adoption of metrics, practices, standards and evaluation tools that promote medical device product and manufacturing quality, and recognize efforts to exceed baseline expectations of compliance with regulatory requirements.