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EDITORIAL COMMENT

Innovation at the Food and Drug Administration's Device Center*

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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 Food and Drug Administration (FDA) is committed to assuring that patients have timely access to important new technologies and next-generation medical devices without compromising safety. Recently, the FDA's Center for Devices and Radiological Health (CDRH) has taken a number of actions to encourage innovation, streamline regulatory and scientific device evaluation, and expedite the delivery of novel, important, safe, and effective medical devices to patients.

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In fact, CDRH has started implementing a new systematic approach to medical device oversight—one that not only continues to focus on *protecting* public health by assuring that devices are safe and effective, but also focuses on *promoting* public health by facilitating device innovation. This new approach requires that we move away from the traditional misperception that safety and innovation are incompatible. Rather than focus on more regulation or less regulation, we focus on smart regulation—how to effectively achieve both aspects of our mission as both a regulator and a facilitator. The FDA must help create a regulatory environment that allows innovation to thrive by eliminating undue regulatory obstacles and assuring consumer confidence that medical technology in the United States is safe and effective. Evidence-based assessments of safety and effectiveness and the facilitation of innovation are complementary, mutually supporting aspects of our mission to protect and promote public health.

In this issue of *JACC: Cardiovascular Interventions*, Krucoff et al. (1) make several suggestions for strengthening the medical device ecosystem to gain efficiencies in product evaluation and leverage the experience, expertise, and unique role of medical professional societies.

A changing paradigm. As medical devices become increasingly complex, we recognize that the responsibility of assuring the safety and effectiveness of devices resides, not only with the FDA, but also with industry, practitioners, and patients. Although the FDA has a world-class medical device scientific staff, it is unrealistic to expect us to have all the necessary expertise and experience, particularly in the review of emerging scientific fields and pioneering technologies.

For this reason, in October 2011, we began to pilot a new Network of Experts Program to serve as a resource for our staff in better understanding scientific fields with which our reviewers might not be immediately familiar. Collaboration agreements govern the relationship and exchange of ideas and information between CDRH staff and the several professional healthcare societies, including the American College of Cardiology (ACC), that constitute the Network of Experts pilot program. The Network provides the FDA with a fast and efficient mechanism to exchange knowledge with world-class scientific experts on an as-needed basis.

Start early and collaborate often. In addition to proactively collaborating more often and more efficiently with outside experts, we believe there are other changes we can make to speed the review of medical devices that address unmet public health needs. The CDRH's Innovation Pathway is a new way of doing business within our existing regulatory framework, one that could yield significant benefits to patients in the United States by giving them first-in-the-world access to innovative medical devices of public health importance.

The Innovation Pathway is an evolving system designed to help safe and effective, breakthrough medical products reach patients in a timely manner. The Pathway ultimately aims to shorten the overall time and cost it takes for the development, assessment, and review of medical devices, and to improve how CDRH staff and innovators work together.

By engaging with innovators much earlier, more collaboratively, and in new ways, we believe we can reduce the time and cost of the entire process of bringing safe and effective technologies to patients more quickly. In April of this year, the CDRH launched the second version of the Innovation Pathway, called "Innovation Pathway 2.0."

Innovation Pathway 2.0 offers new and modified tools and methods to deepen the collaboration between the CDRH and innovators early in the process, prior to premarket submission, with the goal of making the regulatory process more efficient and timely.

The Pathway also serves as a living laboratory to test new tools and methods for breakthrough devices that we may

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also apply to other technologies to enhance all of our device pre-market programs.

First in the world: it matters. Recently, the CDRH revised its mission and vision statements to explicitly reflect the importance of integrating innovation and safety as complementary parts of our public health mission. Patients remain—and will always remain—the core of our mission, which is to protect and promote the public health.

Our vision is ambitious—that patients in the United States have access to high-quality, safe, and effective medical devices of public health importance first in the world. This vision recognizes that delaying access to devices that bring important healthcare advances to patients has a public health cost—just as permitting the marketing of unsafe or ineffective products does. Assessing the benefits and risks of new technologies is the fundamental calculus that serves as the underpinning of good decision making.

Earlier this year, the CDRH released our first guidance on the principal factors considered in the assessment of benefit–risk—the foundation of our device approval decisions. These factors include, not only the type and magnitude of the clinical benefits and adverse events a patient may experience, but also explicit consideration of the severity of the underlying disease or condition, the availability of alternative treatments or diagnostics options, the novelty of the technology, and patients' tolerance for risk and perspective on benefit. We have also worked to create mechanisms for more efficient post-market surveillance of important new technologies so that the benefits and risks of novel device therapies can be better defined during real-world use. For example, the Transcatheter Valve Therapy (TVT) Registry, will serve as the data collection platform for the post-market study of the Edwards Lifescience Sapien Transcatheter Heart Valve, the first FDA-approved transcatheter aortic valve therapy as well as future transcatheter valve devices. The TVT Registry was formed through collaboration of the ACC (through the National Cardiovascular Data Registry), the Society of Thoracic Surgeons, the Centers for Medicare and Medicaid Services, and the FDA.

The CDRH has also announced new policies for facilitating the conduct of early feasibility studies, including first-in-human trials, for medical devices in the United States while maintaining appropriate patient protections. The policies are predicated on the idea that appropriately conducted early clinical experience with investigational medical devices can result in better-designed devices that reach patients sooner. These proposed approaches give investigators and the FDA device reviewers more flexibility to start investigational device human studies sooner, and once a study has begun, efficient ways to support iterative modifications to devices or study designs. Conducting safe, early feasibility studies in the United States means that clinicians get early experience with new technology, innovators have greater incentives to study their devices first in the United States, and patients may benefit more quickly.

Challenges and opportunities. Although the FDA has undertaken a number of activities to facilitate medical device innovation to help bring safe, effective, high-quality, transformative devices to patients more quickly, we recognize that there are additional opportunities. Pre-competitive collaborations, modernization of post-market surveillance, more efficient use of post-market and international device-related clinical data and electronic health information, and streamlining the conduct of clinical trials offer promise and will require broad device stakeholder input and collaboration to succeed. In the end, regulators, industry, patients, the clinical community, and the public at large all want the same thing—for patients to have timely access to high-quality, safe, effective important new technologies and next-generation medical devices.

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