FOREWORD: A MESSAGE FROM THE CENTER DIRECTOR

Today, FDA's Center for Devices and Radiological Health (CDRH or the Center) is releasing for public comment two preliminary reports recommending concrete steps we could take to advance three key objectives of a balanced public health approach: fostering medical device innovation, enhancing regulatory predictability, and improving patient safety.

These reports address issues of great importance to the Center, the industry we regulate, and the public we serve. Together, they represent a blueprint for smarter medical device oversight, with the tools CDRH needs to drive innovation and help bring the best technologies to patients.

CDRH's responsibility is two-fold: to protect and promote the public health. We use our oversight to keep patients from harm, and we foster the development of safe and effective new products. The recommendations in today's reports represent significant opportunities to increase our effectiveness in carrying out both parts of our mission. By increasing the predictability, reliability, and efficiency of our regulatory pathways, we can help provide better treatments and diagnostics to patients more quickly, stimulate investment in and development of promising new technologies to meet critical public health needs, and increase the global market position of U.S. medical devices.

The actions proposed in these reports would complement two major steps CDRH is already taking, in collaboration with others in the federal government, to foster medical device innovation. We have established a new interagency Council on Medical Device Innovation, whose aim is to identify unmet public health needs and facilitate the development or redesign of devices to address those needs.[1] In addition, FDA recently signed an information-sharing Memorandum of Understanding with the Centers for Medicare and Medicaid Services (CMS), which will allow us to better coordinate the work of our two agencies.[2] These efforts have the potential to dramatically streamline the process of bringing new safe and effective medical technologies to patients.

The reports were developed by two internal committees I established in September 2009: the 510(k) Working Group and the Task Force on the Utilization of Science in Regulatory Decision Making. I convened these groups to address critical challenges facing the Center and our external constituencies.

The premarket notification (510(k)) medical device review program is intended to meet two important goals: making available to consumers devices that are safe and effective, and fostering innovation in the medical device industry. In recent years, however, concerns have been raised both within and outside of FDA about whether the current 510(k) program optimally achieves these goals. Some have argued that the 510(k) process allows devices to enter the market without sufficient evidence of safety and effectiveness. Others have argued that a lack of predictability, consistency, and transparency in the process is hindering device development. I charged the 510(k) Working Group to evaluate the 510(k) program and explore actions CDRH could take to enhance our 510(k) decision making.

[1] *See* "Identifying Unmet Public Health Needs and Facilitating Innovation in Medical Device Development; Notice of Public Workshop; Request for Comments," 75 Federal Register 101 (26 May 2010), pp. 29560-29561. Available at http://edocket.access.gpo.gov/2010/2010-12588.htm.

[2] *See* "Memorandum of Understanding Between United States Food and Drug Administration and Centers for Medicare & Medicaid Services." Available at http://www.fda.gov/AboutFDA/PartnershipsCollaborations/MemorandaofUnderstandingMOUs/DomesticMOUs/ucm217585.htm.

One factor that complicates our science-based decision making, in the 510(k) context and more broadly, is that we operate within an ever-changing scientific landscape. As new scientific information emerges about the risks and benefits of a given device type, we must be prepared to modify our treatment of that device type accordingly. At the same time, to facilitate innovation, we seek to maintain predictability in our regulatory pathways. I charged the Task Force on the Utilization of Science in Regulatory Decision Making to assess the way CDRH uses science in our decision making and identify steps we could take to strike a better balance between these two critical aims.

These are challenging issues, and the way we address them has the potential to significantly impact medical device development, the competitiveness of the American economy, and, most fundamentally, the health and well-being of the public. We have heard a range of perspectives on these topics at public meetings and town halls over the past several months. While there has not always been agreement on the best approach for CDRH to take moving forward, there is widespread recognition that there is significant room for improvement in the way we operate.

The preliminary reports we are releasing today reflect the input of many within and outside of CDRH. They cover a substantial amount of material in careful detail — a testament to the thoughtful and thorough assessment each committee has undertaken over the past several months. Together, these reports propose several actions to foster medical device innovation, enhance regulatory predictability, and improve patient safety. I would like to highlight 10 recommendations in particular.

I. Fostering Medical Device Innovation

1. *Streamline the premarket pathway for lower-risk novel devices.*

   The process for Evaluation of Automatic Class III Designation (also known as the de novo classification process) is meant to serve as a regulatory pathway for novel devices that cannot be cleared through the 510(k) process because they lack a clear predicate, but whose risks do not warrant a premarket approval (PMA) level of review. As currently implemented, the de novo classification process tends to be associated with lengthy review timeframes and nontransparent data requirements, making it an impractical path to market for many device developers. The 510(k) Working Group recommends that CDRH make major reforms in our implementation of the de novo process, including steps to streamline the process and clarify the Center's evidentiary expectations for de novo requests.

2. *Enhance science-based professional development for CDRH staff.*

   To accommodate the development of novel technologies, within the 510(k) context and beyond, CDRH must be able to readily tap into relevant scientific expertise in the course of our decision making. Both the 510(k) Working Group and the Task Force on the Utilization of Science in Regulatory Decision Making recommend that CDRH enhance training, professional development, and knowledge-sharing among Center staff, to assure that appropriate scientific expertise and regulatory experience are brought to bear in decision making. Both groups recommend that these efforts include providing greater opportunities for staff to stay abreast of recent scientific developments and current clinical practice.

3. *Establish a network of external experts to better inform the review of cutting-edge technologies.*

   Because it is not feasible for CDRH experts to be up-to-date on all scientific developments, particularly in newly emerging fields, it is sometimes necessary for us to supplement our in-house expertise with that of external parties. The Task Force on the Utilization of Science in Regulatory Decision Making recommends that the Center continue ongoing efforts, in keeping with the Center's FY 2010 Strategic Priorities, to develop a network of external experts using web-based social media technology. Such a network would allow Center staff to more efficiently and effectively leverage outside knowledge in order to answer important scientific questions, but would not serve in an advisory capacity.

II. Enhancing Regulatory Predictability

4. *Increase the predictability of 510(k) data needs by establishing a new "class IIb."*

   Within the 510(k) context, most instances where concerns have been raised by industry and Center staff generally have involved the small subset of devices for which staff requested clinical information midway through a review but where the submitter had no advance notice that such information would be needed as part of its 510(k), leading to avoidable delays. The 510(k) Working Group therefore recommends that CDRH develop guidance to define, at least as a heuristic, a subset of class II devices called "class IIb" devices, for which clinical or manufacturing information would typically be necessary to support a substantial equivalence determination. The development of a "class IIb" guidance document would help clarify, up front, what information submitters should include in their 510(k)s, so that they can plan accordingly. In so doing, it would help our review staff obtain, in a more efficient and predictable manner, the type and level of evidence they need to make reliable, well-supported decisions.

5. *Create a new "Notice to Industry" tool to more rapidly communicate changes in premarket expectations.*

   With respect to 510(k) review and also more broadly, we as a Center may need to modify our premarket evidentiary expectations for certain types of devices over time, as science evolves and new information emerges about the risks and benefits of a given device type. Under current law, our traditional guidance development process can be cumbersome, and it has not allowed us to communicate such changes in a rapid manner. Instead, manufacturers typically learn of these changes through individual engagement with the Center, often not until after they have prepared their premarket submissions. The Task Force on the Utilization of Science in Regulatory Decision Making therefore recommends that CDRH begin to use standardized "Notice to Industry" letters to quickly communicate to an affected sector of industry when we have changed in our regulatory expectations with respect to a particular group of devices, the general nature of the change, and the rationale for the change, generally as a precursor to more detailed guidance. These letters would help provide greater clarity to manufacturers, in a timelier manner, about our evolving expectations.

6. *Clarify the meaning of key terms in the 510(k) "substantial equivalence" review standard to improve the consistency, transparency, and timeliness of the review process.*

   Insufficient clarity with respect to critical terms in the statutory definition of "substantial equivalence" has, in some cases, contributed to inconsistency in CDRH's 510(k) decision making,

internal and external debates, and delays in review. As the 510(k) standard has been applied to a wider range of devices over time, including increasingly varied, complex, and potentially higher-risk technologies, the need for greater clarity has become even more pressing. The 510(k) Working Group recommends that CDRH more clearly define these terms in guidance and training for review staff and industry.

7. *Establish a Center Science Council as a new governance model to assure quality and consistency in CDRH's science-based decision making.*

   Regulatory predictability also depends on effective and expert internal oversight. To better assure quality and consistency in CDRH's science-based decision making, both the 510(k) Working Group and the Task Force on the Utilization of Science in Regulatory Decision Making recommend that CDRH establish a Center Science Council, comprised of experienced managers and employees and under the direction of the newly created Deputy Center Director for Science position. Consistent with the President's memorandum on scientific integrity,[3] this standing body would be responsible for overseeing science-based decision making across the Center, including premarket review; periodically auditing decisions and assessing program performance; and acting as a resource for staff on scientific questions, to support greater consistency in decision making and the treatment of cross-cutting issues.

III. Improving Patient Safety

8. *Require the up-front submission of more complete safety and effectiveness information to support the review of 510(k) devices.*

   In order to support robust and well-informed decision making within the 510(k) process, the 510(k) Working Group recommends that CDRH consider revising existing regulations to explicitly require 510(k) submitters to provide in their 510(k)s a summary of all scientific information known or that should be reasonably known to the submitter regarding the safety and/or effectiveness of the device under review. Current regulations do not expressly require submitters to provide such a summary. As a result, important relevant information may not be included in a 510(k) upon initial submission, even when that information is readily available to the submitter. Requiring this type of summary would allow review staff to more efficiently make well-supported 510(k) decisions that consider all relevant safety and effectiveness information. Including such a summary should not present a significant additional burden for submitters, many of whom typically collect this type of information in their own product development processes.

9. *Create a searchable online public database to provide more detailed, up-to-date medical device information to industry, the health care community, and patients.*

   Both committees recommend that CDRH enhance our web-based public resources to provide industry, practitioners, and patients with ready access to meaningful, up-to-date device information that will help support informed clinical decision making and safe device use. The 510(k) Working Group recommends that CDRH make major improvements to our current online 510(k) database, so that it can serve as a searchable one-stop source for detailed information

[3] Obama B, Memorandum for the Heads of Executive Departments and Agencies (March 9, 2009). Available at: http://www.whitehouse.gov/the_press_office/memorandum-for-the-heads-of-executive-departments-and-agencies-3-9-09/.

about cleared devices, including photographs and design schematics, summaries of FDA review decisions, and up-to-date device labeling. Such a database would allow prospective 510(k) submitters to more readily identify appropriate predicate devices and would provide practitioners and patients with more comprehensive and current information to support the safe use of cleared devices. Similarly, the Task Force on the Utilization of Science in Regulatory Decision Making recommends that CDRH continue to build upon our existing Transparency website to provide external parties with more information about our regulatory decisions and the science that grounds those decisions, across the total product life cycle.

10. *Clarify CDRH's 510(k) rescission authority and the circumstances under which a device should not be used as a predicate.*

    Concerns have been raised that current FDA regulations and practice may allow for some types of predicate comparisons that are insufficient to consistently provide reasonable assurance that a device under review, subject to general and applicable special controls, is safe and effective for its intended use. The 510(k) Working Group recommends that CDRH explore the development of guidance to identify situations in which a device should not be used as a predicate, such as when the device has been removed from the market because of safety concerns. In addition, to clarify the circumstances under which CDRH would exercise our authority to rescind a 510(k) clearance to remove an unsafe device from the market and preclude its use as a predicate, the 510(k) Working Group recommends that CDRH consider issuing a rescission regulation.

The two volumes that follow contain the findings and recommendations of both committees in full. Volume I provides the report of the 510(k) Working Group. Volume II provides the report of the Task Force on the Utilization of Science in Regulatory Decision Making. Where the reports overlap, they reference one another.

The recommendations contained in these reports are preliminary. CDRH has not made any decisions on specific changes to pursue. We invite interested individuals to submit comments on these reports and the recommendations they propose, including the feasibility of implementation and potential alternatives. Once our assessment of public input and other necessary reviews are completed, we will announce which improvements we intend to implement, as well as projected timelines for implementation.

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