FDA Recommends Actions to Improve Oversight of Medical Devices

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On Wednesday, August 4, 2010, the Food and Drug Administration's (FDA) Center for Devices and Radiological Health (CDRH) released for public comment two preliminary reports recommending steps to: (1) foster medical device innovation; (2) enhance regulatory predictability; and (3) improve patient safety. According to CDRH Director Jeffrey Shuren, MD, JD, the actions proposed in the reports represent "a blueprint for smarter medical device oversight" and are intended to advance CDRH's responsibility to both protect and promote public health. The reports were prepared by two separate internal groups within CDRH, both convened in September 2009.

The first report, entitled *CDRH Preliminary Internal Evaluations − Volume I*, was prepared by the 510(k) Working Group, while the second report, entitled *CDRH Preliminary Internal Evaluations − Volume II*, was prepared by the Task Force on the Utilization of Science in Regulatory Decision Making. Both preliminary reports, as well as introductory and summary materials, are available on FDA's website and were officially announced in the Federal Register on August 5.

CDRH commissioned the 510(k) Working Group to evaluate the 510(k) premarket notification review program for potential improvements, focusing on actions that could be taken in the short term under FDA's existing statutory authority. As an initial step to inform its report, the 510(k) Working Group solicited stakeholder input at a well-attended public meeting in February. At that meeting, numerous public commenters indicated the need for a clear, predictable 510(k) regulatory pathway to stimulate innovation, but also noted that a major overhaul to the 510(k) framework was unnecessary. A summary of the public meeting is included in the preliminary report released yesterday and more information about the meeting, including a transcript, can be found on FDA's website. Additionally, FDA has asked the Institute of Medicine (IOM) to conduct its own, independent assessment of the 510(k) process, though that report is not expected until mid-2011.

Concurrently, CDRH commissioned the Task Force on the Utilization of Science in Regulatory Decision Making to identify steps CDRH should take to ensure regulatory predictability yet adapt to emerging science. The recommendations from this Task Force may feed into a larger collaboration between FDA and the National Institutes of Health (NIH) announced earlier this year by FDA Commissioner Hamburg and NIH Director Collins to enhance "regulatory science." FDA also recently signed an information-sharing Memorandum of Understanding with the

Centers for Medicare & Medicaid Services (CMS), which will allow the two agencies to better coordinate their efforts. The CDRH Task Force suggestions could help with implementation of that initiative as well.

Recommendations of the 510(k) Working Group

1. CDRH should clarify the meaning of the statutory terms "substantial equivalence" and "different questions of safety and effectiveness" through guidance and training for reviewers, managers, and industry. Clarification would address industry's concern that small changes in a device's labeled "indications for use" could be considered a change in "intended use." Additionally, CDRH should explore the possibility of pursuing a statutory amendment that would provide the agency with express authority to consider an off-label use when determining the "intended use" of a device under review through the 510(k) process.
2. CDRH should provide greater assurance that any comparison of a new device to a predicate is valid and well-reasoned. This includes guidance and rulemaking regarding: (1) factors in deciding when a device should no longer be available for use as a predicate; (2) scope, grounds, and procedure for rescission of a 510(k) clearance; and (3) the use of "multiple predicates" and the possible disallowance of "split predicates."
3. CDRH should reform its implementation of the *de novo* classification process to provide a practical, risk-based option that affords an appropriate level of review and regulatory control for eligible devices. CDRH should encourage pre-submission communication potentially in lieu of an exhaustive 510(k) review, and consider establishing a generic set of baseline controls for class II *de novo* devices.
4. CDRH should take steps through guidance and regulation to facilitate the efficient submission of high-quality 510(k) device information. CDRH should improve the clarity of submissions by: (1) establishing which modifications do not warrant submission of a new 510(k), and considering regular manufacturer reports on modifications; (2) considering an "assurance case" formal framework for 510(k) submissions; and (3) accepting both photographs and schematics for device review, and including these in the 510(k) public database.
5. CDRH should develop guidance defining a subset of class II devices, called "class IIb" devices, for which clinical information, manufacturing information, or, potentially, additional evaluation in the postmarket setting, would typically be necessary to support a substantial equivalence determination. This would only be an administrative distinction. Potential candidates for class IIb may include some implantable, life-sustaining devices, and/or life-supporting devices, which present greater risks than other class II device types.
6. CDRH should take steps to enhance its internal and public information systems and databases to provide easier access to more complete information about 510(k) devices and previous clearance

decisions. For example, CDRH should develop guidance on the development and assignment of product codes as well as an improved public database with information on cleared devices.

7. CDRH should enhance training, professional development, and knowledge-sharing among reviewers by establishing a Center Science Council, composed of experienced reviewers and managers, to serve as a cross-cutting oversight body that can facilitate knowledge-sharing across CDRH. CDRH should also regularly evaluate the list of device types eligible for third-party review and use the information to add or remove devices types as appropriate.

Recommendations of the Task Force on the Utilization of Science in Regulatory Decision Making

1. CDRH should take steps to improve its ability to readily access high-quality information about regulated products. These steps include additional guidance on clinical trial design, the use of ad hoc committees to temporarily assist with time-critical work in a particular area, and the development of advanced postmarket analysis tools.
2. CDRH should improve its mechanisms for leveraging external scientific expertise, including collaborative relationships with other science-led organizations.
3. CDRH should establish and adhere to as predictable an approach as practical for determining what action, if any, is warranted with respect to a particular product or group of products on the basis of new scientific information. To support this approach, CDRH should establish a Center Science Council, composed of experienced employees and managers, to provide oversight and help assure consistency across CDRH.
4. CDRH should make use of more rapid communication tools to convey its current thinking and expectations. CDRH should also encourage industry and other constituencies to submit proposed guidance documents in order to help CDRH staff develop agency guidance more quickly. CDRH should send periodic “Notices to Industry” to all manufacturers of a particular group of devices for which CDRH has changed its regulatory expectations.
5. CDRH should provide additional information to its external constituencies about its process for determining an appropriate response to new science and the bases for its actions.

Future Outlook

FDA is now soliciting public input on the recommendations discussed in these reports, including the feasibility of implementation and potential alternatives. Comments are due by October 4, 2010, and may be submitted online to Docket No. FDA-2010-N-0348. Once its assessment of public input and other necessary reviews are completed, FDA will announce which improvements will be implemented as well as projected timelines for implementation. In addition, when the final IOM report on the 510(k) process is released in 2011, CDRH may propose changes in its own

preliminary 510(k) report and may refer such changes to the IOM for additional review. Finally, these reports will be certain to inform any legislative proposals to amend FDA's medical device authorities, including potential provisions attached to the upcoming reauthorization of medical device user fees by September 2012.