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FDA Issues Preliminary Reports on the 510(k) Program and Use of Science in Decision Making for Medical Devices

On August 4, 2010, the U.S. Food and Drug Administration's ("FDA") Center for Devices and Radiological Health ("CDRH" or the "Center") released a two-volume set of documents entitled, "Center for Devices and Radiological Health Preliminary Internal Evaluations," which reflect the work of two different internal agency committees to improve the pre-market notification process, commonly referred as the "510(k) process." This is the primary vehicle by which medical devices are granted marketing authorization in the United States. The document encompasses two preliminary reports with proposals to reform the 510(k) program, one by the 510(k) Working Group and the other by the Task Force on the Utilization of Science in Regulatory Decision Making ("Task Force"). The reports were issued in response to concerns raised both within the agency and in the general community about weaknesses in the current 510(k) program and cover several recommendations that address FDA's public health objectives for medical devices.

FDA believes the recommendations will complement CDRH's recent efforts at collaborating with other governmental agencies, such as the Centers for Medicare & Medicaid Services, to streamline the process for bringing innovative medical technologies to patients and to facilitate medical device development to address unmet public health needs. However, FDA emphasizes that these reports are preliminary at this time and notes that the agency is still seeking to obtain public comment on these proposals through October 4, 2010, before it makes any final decision regarding which specific changes to pursue.

This article focuses on the ten specific recommendations in the preliminary reports, which were highlighted by the Center's Director. These recommendations address three of the agency's key objectives: (1) foster medical device innovation; (2) enhance regulatory predictability; and (3) improve patient safety. Other recommendations in the reports, not discussed here in detail, seek to address FDA's goals to increase consistency and clarity in the review standards, ensure well-informed decision making, support continuous quality assurance, enhance the Center's scientific knowledge base, and improve agency communications regarding current or evolving regulatory thinking.

Copies of both reports with all the recommendations proposed by the 510(k) Working Group and the Task Force are available here, on FDA's website.

Fostering Medical Device Innovation

- Reform of the De Novo Classification Process (or Automatic Class III Designation) - Although novel devices that lack a clear predicate device cannot be cleared through the 510(k) process, many such devices do not present risks warranting a pre-market approval (versus a 510(k) clearance) level of review. The de novo classification process is an alternative regulatory pathway, intended to apply to lower-risk devices that are classified into Class III through the 510(k) process. A 510(k) submitter who receives a Not Substantially Equivalent ("NSE") determination may request a de novo classification of the device into Class I or II. To reduce the extensive review timeframes currently associated with the de novo classification process and increase the transparency of the data requirements, the 510(k) Working Group recommends that CDRH encourage 510(k) applicants to engage in pre-submission discussions with review staff to discuss any devices eligible for de novo classification, instead of an exhaustive 510(k) review. In addition, CDRH is encouraged to explore the possibility of establishing a single generic set of controls that could serve as baseline special controls for devices classified into Class II, instead of the current practice of developing device-specific guidance to serve as special controls for each device, which is time-consuming for FDA reviewers.

- Increase Science-Based Professional Development of CDRH Staff – Both the 510(k) Working Group and the Task Force recommend that the agency enhance the professional development, collaboration, and training of CDRH staff to ensure reviewers have appropriate scientific and regulatory expertise and to support consistent, high-quality 510(k) reviews.

- Develop a Network of External Experts to Facilitate the Review of Cutting-Edge Technologies - In recognition of the agency's need to leverage external scientific expertise regarding scientific developments in newly emerging fields, current standards of care, and real-world practice, the Task Force recommends the development of a web-based network of external experts, using social media technology, to supplement in-house expertise on such matters. The agency would need to assess best practices and standard business processes to ensure appropriate use of these external experts by CDRH staff.

Enhancing Regulatory Predictability

- Clarify Evidentiary Expectations to Facilitate the Submission of Quality 510(k) Data – Because significant delays in the 510(k) process occur when review staff must request clinical information midway through a review, the 510(k) Work Group suggests that CDRH consider establishing a subset of Class II devices, called "class IIb" devices, for the limited number of devices for which clinical or manufacturing information may be necessary to support a "substantial equivalence" determination. In addition, CDRH is asked to consider a requirement that manufacturers provide periodic updates listing any incremental or so-called "minor" modifications to a device, along with the manufacturer's rationale for determining that the submission of a new 510(k) was not necessary for the change.

- Implement a "Notice to Industry" Tool for Communicating Changes to Pre-market Evidentiary Expectations – Currently, manufacturers are informed of changes in CDRH's pre-market evidentiary expectations for certain types of devices on a case-by-case, individual basis, often after the manufacturer has already prepared its pre-market submission. To improve the timely and broad sharing of information about changes in the agency's decision making process due to the emergence of new science, the Task Force recommends that CDRH use standardized "Notice to Industry" letters to convey any changes in regulatory expectations to the affected industry, as a precursor to developing more detailed guidance.

- Clarify the Statutory Definition of "Substantial Equivalence" in the 510(k) Review Process – To eliminate inconsistency in the agency's decision making and minimize unnecessary delays in the review process, the 510(k) Working Group proposes that CDRH provide further guidance on the "substantial equivalence" definition (*i.e.*, explain what constitutes the same versus a new "intended" use or when "different technological characteristics" may raise "different questions of safety and effectiveness"). Due to the wide range of devices subject to the review standard and the increasing variety, complexity, and risks related to such devices, CDRH needs to define these terms clearly in its guidance and training to review staff as well as the medical device industry.

- Establish a Center Science Council to Assure Quality and Consistency in Science-Based Decision Making – Both the 510(k) Working Group and the Task Force suggest that the agency establish a Center Science Council, which would be responsible for overseeing the Center's science-based decision making process, including the pre-market review process, and support greater consistency in the decision making process at CDRH. Under the direction of the newly-created Deputy Center Director for Science, the Council would also periodically audit decisions, assess program performance, and serve as a resource to CDRH staff on science issues.

Improving Patient Safety

- Require 510(k) Submissions to Include More Complete Safety and Effectiveness Information – The 510(k) Working Group suggests revising existing regulations to require that all 510(k) submissions include a summary of all scientific information known (or that should be reasonably known) regarding the safety and/or effectiveness of the device under review. Currently, pursuant to 21 C.F.R. § 807.87(f), 510(k) submissions are only required to provide "data to support the statement" of substantial equivalence. Because this allows for the omission of information that may be relevant to the agency's review, the modification to the regulatory requirements would facilitate the efficiency of review staff in the decision making process.

- Develop a Searchable Online Public Database to Increase Access to Medical Device Information – The 510(k) Working Group and the Task Force both recommend that FDA increase its use of web-based public resources to provide more detailed, up-to-date information to the medical device industry,

healthcare practitioners, and consumers. The current, online 510(k) database can be improved to be used as a searchable, one-step source for medical device information to educate the public, as well as to allow prospective 510(k) submitters to identify appropriate predicate devices. The agency could also build on the existing CDRH Transparency website, which contains pre- and postmarket information, to allow public access to the results of other studies that it is allowed to legally disclose. This information would provide greater insight into FDA's regulatory decisions and the scientific basis for such decisions, across a product's total life cycle.

- Clarify the Agency's Recission Authority and Provide Guidance on Devices that Cannot Be Used as a Predicate – Because any legally marketed device not subject to pre-market approval may be cited as a predicate, the 510(k) Working Group suggests that CDRH consider developing guidance to help the industry identify situations in which a device should not be used as a predicate due to safety and/or effectiveness concerns. In addition, the 510(k) Working Group encourages CDRH to consider issuing a regulation to define the scope, grounds, and proper procedures to rescind or modify the scope of a 510(k) clearance for a device and determine whether FDA requires additional legal authority for these actions.

It is important to recognize that these recommendations are preliminary and CDRH has not made any decision on specific changes to pursue. Consequently, interested persons may submit comments on the reports, including viewpoints regarding the feasibility of implementation and better alternatives.