



September 6, 2011

Division of Dockets Management (HFA-305)
Food and Drug Administration
5630 Fishers Lane, rm. 1061
Rockville, Maryland 20852

Docket # FDA-2011-N-0556

Dear Sir/Madam:

The American Association for Clinical Chemistry (AACC) welcomes the opportunity to provide input to the Food and Drug Administration (FDA) regarding the Institute of Medicine's (IOM's) report entitled: "Medical Devices and the Public's Health, the FDA 510(k) Clearance Process at 35 Years," which makes a series of recommendations for improving the medical device review process. Our recommendations follow:

510(K) Review Process

The IOM recommends that the FDA design a "new medical-device regulatory framework for Class II devices so that the current 510(k) process...can be replaced with an integrated premarket and post market regulatory framework." Although AACC shares the IOM's concerns regarding the use of pre-1976 instruments as predicates for newer, technologically advanced devices, we do not believe the agency should eliminate the current process.

Instead, AACC supports an approach suggested by the FDA Working Group, which recommended that CDRH develop a system for providing "greater assurance that any comparison of a new device to a predicate is valid and well-reasoned." We agree that not all predicate devices are the same. Many are of high quality, but some may be substandard, while others may not be in use anymore. We urge the FDA to develop and implement a process that ensures that a predicate both meets the agency's safety and effectiveness criteria, as well as serves as a valid comparison. Any changes to the review process, however, must balance the evidentiary requirements with patient access to medical technologies.

De Novo Process

The IOM study recognizes that the current de novo process "is time-consuming and difficult for the FDA and manufacturers to navigate" and is in need of reform. The research group recommends that the agency "investigate the viability of a modified de novo process as a mechanism for evaluating the safety and effectiveness of Class II devices" in the hope that one day a revised de novo mechanism could replace the 510(k) process.

The FDA 510(k) Working Group also identified the de novo process as needing reform. The group stated that “although there exists an alternative regulatory pathway for devices that lack a clear predicate but whose risks do not warrant class III controls...this pathway, as currently implemented, is inefficient and has not been utilized optimally across the Center.” On the basis of this finding, the Group recommended that the FDA “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.”

AACC strongly agrees that the de novo process needs revisions. We support the IOM’s request for studies to identify methods for improving the de novo process. However, AACC does not foresee de novo replacing 510(k), but rather serving as a viable alternate review mechanism. We generally support the agency’s approach to further refine and integrate de novo into the existing review process.

Post-marketing Surveillance and Authority

The IOM recommends the FDA “develop and implement a comprehensive strategy to collect, analyze, and act on medical-device post-market performance information.” We agree with this suggestion. Over the past few years, the agency has initiated efforts, such as the Medical Product Safety Network (MedSun) and LabNet to gather such data. Unfortunately, due to budgetary constraints, these programs are limited to 350 sites. We urge FDA to expand these programs and to identify new means of disseminating their findings.

IOM also recommends that FDA identify limitations to its use of post-market regulatory authority and “determine how the limitations can be addressed.” AACC supports this approach. The FDA should have clear, established authority to remove a device from the market if it endangers public safety. If needed, the agency should seek congressional authorization to obtain the needed powers. This authority must be clearly delineated, however, to ensure that manufacturers understand what circumstances that trigger an agency action and what options are available for appeal.

Software

The IOM recommends that “the FDA should develop a better understanding of the roles that software plays in medical devices, analyze their potential effects on the safety and effectiveness of the devices, and insist on evidence-based features that ensure devices safety and effectiveness. The committee believes that the FDA should review and update its guidance on software validation.” AACC supports this approach.

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By way of background, AACC is the principal association of professional laboratory scientists--including MDs, PhDs and medical technologists. AACC's members develop and use chemical concepts, procedures, techniques and instrumentation in health-related investigations and work in hospitals, independent laboratories and the diagnostics industry worldwide. The AACC provides international leadership in advancing the practice and profession of clinical laboratory science and its application to health care. If you have any questions, please call me at (314) 362-0194, or Vince Stine, PhD, Director, Government Affairs, at (202) 835-8721.

Sincerely,

A handwritten signature in cursive script that reads "Ann M. Gronowski". The signature is written in black ink and is positioned above the typed name and title.

Ann M. Gronowski, PhD
President, AACC