



May 16, 2012

The Honorable John Boehner
Office of the Speaker of the House of Representatives
H-232 Capitol Building
Washington, DC 20515-5117

Dear Speaker Boehner:

The House Energy and Commerce Committee recently approved legislation, the “Food and Drug Administration Reform Act of 2012,” which extends the current user fee programs for medical devices and other health areas. Included within this comprehensive bill is a provision that would streamline the FDA de novo process. AACC strongly backs this legislative change.

Congress authorized the de novo process in the FDA Modernization Act of 1997. This mechanism permits the agency to reclassify low risk devices that would automatically be designated as Class III devices, because there is no predicate device, as Class I or II. This means that manufacturers, in certain instances, are able to seek clearance through the less burdensome 510(k) process, rather than the more costly and onerous pre-market approval (PMA).

Unfortunately, confusion over evidentiary requirements, along with the length of time associated with Agency review, has discouraged many In Vitro Diagnostic (IVD) manufacturers from pursuing this route. In each of the past few years, the Office of In Vitro Diagnostics (OIVD) has received only one IVD de novo submission. Since 2005, the length of time for each review has averaged 311 days—50 days longer than the baseline year.

Fortunately, the FDA Reform Act may reduce this timeframe by eliminating the requirement that a manufacturer first obtain a Not-Substantially-Equivalent (NSE) finding prior to submitting a de novo petition. AACC believes this regulatory change may lead to an increase in the number of de novo applications, while also freeing up additional FDA resources.

AACC also supports Section 203(f) of the House measure, which gives the HHS Secretary the authority to waive medical device user fees in the interest of public health. The FDA has already stated that, if enacted,

“it intends to exercise that authority to ensure that no additional LDTs or laboratories would be subject to user fees under MDUFA III due to implementation of the regulatory framework under consideration or due to other changes in policy on LDTs.”

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We support the FDA's decision. Subjecting laboratory developed tests to this agreement could result in some laboratories no longer offering these vital tests, while diverting critical agency resources from the real purpose of this agreement—to reduce the time needed to review medical device submissions. AACC looks forward to working with you on these important provisions.

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 (804) 828-0375, or Vince Stine, PhD, Director, Government Affairs, at (202) 835-8721.

Sincerely,

A handwritten signature in blue ink, appearing to read "G Miller", enclosed in a thin black rectangular border.

Greg Miller, PhD
President, AACC