



November 8, 2011

The Honorable Brian Bilbray
U.S. House of Representatives
2410 Rayburn HOB
Washington, DC 20515

Dear Representative Bilbray:

The American Association for Clinical Chemistry (AACC) endorses your legislation, H.R.3203, the “Novel Device Regulatory Relief Act of 2011,” which would streamline the Food and Drug Administration’s (FDA’s) de novo process. We believe that reducing the regulatory burden on manufacturers may lead to greater utilization of this review mechanism, while increasing patient access to innovative assays.

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). AACC supports this approach.

Unfortunately, confusion over evidentiary requirements, along with the length of time associated with Agency review, has discouraged many IVD manufacturers from pursuing this route. In each of the past few years, the Office of Vitro Diagnostic (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, H.R.3203 would 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. We support your initiative and look forward to working with you in passing this important legislation.

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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".

Ann M. Gronowski, PhD
President, AACC