



April 2, 2010

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

Dear Sir/Madam:

The American Association for Clinical Chemistry (AACC) and its scientific academy, the National Academy of Clinical Biochemistry (NACB), welcomes the opportunity to provide input to the Food and Drug Administration (FDA) regarding its efforts to improve the clinical accuracy of blood glucose meters (BGM). We share the agency's dual objectives, namely to improve the accuracy, precision and overall quality of these measurements, while continuing to ensure patient and caregiver access to these cost-effective, life saving monitors. AACC and NACB applaud the FDA's decision to engage stakeholders in this process.

We recommend that the FDA establish a two-track approach to address this issue. We suggest that the agency develop or recognize separate standards for blood glucose monitors used in the home and those used in hospital settings--where one objective is the achievement of tight glycemic control. AACC and NACB believe the distinctive needs among users in each community warrant this dual approach.

In regards to home use monitors, AACC and NACB suggest FDA continue to work with the International Standards Organization (ISO) to improve ISO 15197, "In vitro diagnostic test systems – Requirements for blood-glucose monitoring systems for self-testing in managing diabetes mellitus." The consensus opinion at the two-day FDA forum indicated that a 15 percent total error rate is achievable for these devices. AACC and NACB recommend that FDA urge ISO to adopt a 15 percent target and revisit this issue again as technology improves.

Many participants at the forum also offered compelling arguments in support of FDA examining the total testing process in both settings, since many of the problems patients and health care personnel report are, in fact, errors by the user, not device malfunctions. Therefore, AACC and NACB recommend that the agency work with device manufacturers, clinical laboratories, other clinical provider groups and patient advocates to develop better training tools to reduce user errors. Improvements in the total testing process for these devices will significantly reduce errors and greatly enhance care in both the non-clinical and clinical environments.

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We also note that the Clinical Laboratory Standards Institute (CLSI) is currently developing a document, POCT12-A3, the “Point of Care Blood Glucose Testing in Acute and Chronic Care Facilities,” which is intended to address problems arising from the use of blood glucose monitors in hospital settings. AACC and NACB recommend that FDA await the publication of the CLSI guidance before taking action. Once released, the agency can assess whether the document fully meets its needs.

In the interim, AACC and NACB recommend that FDA gather evidence on the maximum acceptable margin of error tolerable in hospital settings. At this time, there does not seem to be a clear consensus on the threshold for defining the accuracy, precision and quality for blood glucose monitors in hospitals or its impact on patient outcomes. AACC and NACB suggest FDA fund a study to determine the optimal performance for hospital meters, either by collection of outcomes data or by extension of modeling studies or by both. Ultimately, we believe that any decision should be evidence-based with emphasis on optimizing important health-related outcomes and economic considerations. AACC and NACB look forward to working with the FDA and other agencies on these important issues.

By way of background, AACC is the principle 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 diagnostics industry worldwide. The AACC provides international leadership in advancing the practice and profession of clinical laboratory science and its application to health care.

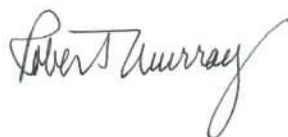
NACB is the Academy of the American Association for Clinical Chemistry and is dedicated to advancing the science and practice of clinical laboratory medicine through research, education, and professional development. The Academy is a leading advocate for scholarship through scientific research and it conducts educational programs to promote scientific discovery, application, and integration. It publishes Laboratory Medicine Practice Guidelines (LMPG) for the application of clinical biochemistry to medical diagnosis and therapy.

If you have any questions, please call Vince Stine, PhD, Director, Government Affairs, at (202) 835-8721.

Sincerely,



President, AACC



President, NACB