March 16, 2015

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

Docket No. FDA-2014-N-2214

Dear Sir/Madam:

The American Association for Clinical Chemistry (AACC) appreciates the opportunity to provide input to the Food and Drug Administration (FDA) regarding its preliminary discussion paper *"Optimizing FDA's Regulatory Oversight of Next Generation Sequencing Diagnostic Tests."* We agree that next generation sequencing (NGS) tests offer great opportunities for advancing laboratory medicine and improving patient care. AACC appreciates FDA's efforts to engage the health care community in a broad discussion of this topic prior to developing new policy in this area.

AACC is a global scientific and medical professional organization dedicated to clinical laboratory science and its application to healthcare. AACC brings together more than 50,000 clinical laboratory professionals, physicians, research scientists, and business leaders from around the world focused on clinical chemistry, molecular diagnostics, mass spectrometry, translational medicine, lab management, and other areas of breaking laboratory science. Since 1948, AACC has worked to advance the common interests of the field, providing programs that advance scientific collaboration, knowledge, expertise, and innovation.

Current Oversight Structure

AACC believes that NGS is an innovative and potentially invaluable technology for improving the abilities of health care providers to diagnose patients and improve patient outcomes. Although high throughput NGS is a relatively new type of laboratory developed test (LDT), CLIA-regulated laboratories conducting NGS testing are experienced in developing, verifying, and performing LDTs. Furthermore, professional organizations provide laboratories with guidance on how to perform, ensure the quality, and verify the accuracy of NGS tests.

A number of accrediting, professional, and standards setting organizations, such as the College of American Pathologists (CAP), American College of Medical Genetics and Genomics, and Clinical and Laboratory Standards Institute have already developed best practice documents to meet the clinical needs of laboratories performing NGS. For example, CAP created a specific checklist for inspecting laboratories performing clinical NGS tests and initiated a proficiency testing program to ensure the accuracy of the testing. CAP has pledged to update

these areas on an ongoing basis. AACC believes that CLIA-recognized accrediting bodies and professional societies should continue to take the lead in providing oversight and guidance for NGS testing in the absence of specific, identified problems.

Use of Electronic Databases

AACC supports the greater accumulation and sharing of genetic data. We believe electronic databases can serve as an invaluable resource for professional laboratory scientists, clinicians, genetic counselors and researchers seeking greater information about variants associated with differing disease conditions and interpretations. We would caution the FDA, however, in placing too much reliance on these data repositories to the exclusion of expert judgment. There are a number of limitations associated with archived data, including the age of the information, limited accumulated data, and varying interpretations. Electronic databases are effective tools to assist health care professionals in interpreting genetic test results, but they are not a replacement for professional judgment.

Stakeholder Group

AACC appreciates the FDA's efforts to initiate a dialogue among the various organizations and professionals involved in NGS and those affected by such testing. We suggest that the agency periodically convene a stakeholder panel of interested parties, such as clinical laboratories, medical device manufacturers, physicians, payers, federal and state agencies, private accrediting, proficiency testing, and standards organizations to discuss the complex technical, health, ethical and communication issues surrounding NGS. We believe this dialogue, in conjunction with ongoing government and private sector efforts, will help to address any perceived gaps in oversight.

We look forward to the FDA's continued engagement of the stakeholder communities in this process. If you have any questions, please contact me at ddkoch@emory.edu, or Vince Stine, PhD, AACC Director of Government Affairs, at vstine@aacc.org.

Sincerely,

David D. Koch

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President, AACC