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AAB and NILA Urge the FDA and CMS to Take A New Approach Toward Overseeing Laboratory Developed Tests to Protect Patient Health and Access to Innovative Tests

Washington D.C. – The American Association of Bioanalysts (AAB), an administrator of one of the nation's full-service proficiency testing programs and the National Independent Laboratory Association (NILA), representing community and regional clinical laboratories across the country, believe a process must be in place to ensure that laboratory developed tests (LDTs) are accurate, reliable and reproducible and that this can be achieved by modernizing the current CLIA program and ensuring the FDA has a guided role in the oversight of tests deemed to be high risk.

The FDA issued guidance documents in October 2014 allowing for public comment by February 2015, asserting broad authority to regulate all LDTs as medical devices, defining a new risk classification to define LDTs as high, moderate, or low risk to patient health. The broad laboratory community disagrees with the agency's assertion that they have the statutory authority to regulate LDTs. The agency has never before enforced such authority, exercising what they call "enforcement discretion" over LDTs.

"The advancement in LDTs does not merit a complete overhaul by the FDA of the current process in place to oversee these tests," states Dr. Mark Birenbaum, administrator of AAB/NILA in comments delivered this week to the FDA. "FDA must first recognize that an oversight process already exists, both through CLIA and state government agencies in addition to private sector accreditation programs. We need to modernize current programs and consider where new oversight may be needed to address the gaps. We must ensure that any new process does not result in barriers to having laboratories develop LDTs to meet clinical needs, support vulnerable patient populations, or address public health emergencies."

AAB's and NILA's position on the regulation of LDTs outlined in comments filed to the FDA and at the FDA Stakeholder Meeting held on January 8-9, 2015 focus on the following tenants:

- Any new regulation of LDTs must be done through notice and comment rulemaking, not guidance documents and must include an economic impact analysis.
- LDTs should not be regulated as medical devices and a separate regulatory pathway is required both within the FDA for a limited number of tests and through CLIA for all other tests.
- The oversight of LDTs should be through a risk-based approach that ensures the analytic and clinical validity of the tests. The FDA should not be the sole decision maker in determining risk classification and a formal stakeholder process is needed to define risk levels for tests.
- CLIA should be modernized to support the oversight LDTs and a modified proficiency testing program should be developed to test the accuracy of laboratory developed tests.

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"To assume LDTs appropriately fit into the FDA's current regulatory oversight and clearance process for medical devices is flawed thinking," says Birenbaum. "AAB/NILA respectfully request that the FDA withdraw the guidances as outlined and work with the laboratory stakeholder community, Congress, and CMS on a fair process to assess the quality and safety of LDTs while allowing for continued innovation for patients."

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The National Independent Laboratory Association (NILA) is a national trade association of regional and community clinical laboratories that focuses on business/management issues facing regional and community laboratories, including reimbursement from Medicare and private insurers, contracting with managed care companies, competing with big, publicly traded laboratories, and acting on legislative and regulatory issues facing regional and community laboratories.

The American Association of Bioanalysts (AAB), founded in 1956, is a professional association representing bioanalysts (clinical laboratory directors, owners, managers and supervisors), medical technologists and medical laboratory technicians. AAB is committed to the pursuit of excellence in clinical laboratory management and testing by enhancing the professional skills of each of its members and promoting more efficient and productive operations. AAB's Proficiency Testing Service is approved under the federal CLIA regulations and is one of the largest proficiency testing providers in the United States.