



August 17, 2018

The Honorable Diana DeGette  
2111 Rayburn House Office Building  
Washington, D.C. 20515

The Honorable Orrin Hatch  
104 Hart Office Building  
Washington, D.C. 20510

The Honorable Larry Buschon, M.D.  
1005 Longworth House Office Building  
Washington, D.C. 20515

The Honorable Michael Bennet  
261 Russell Senate Office Building  
Washington, D.C. 20510

Dear Representatives DeGette and Bucshon, and Senators Hatch and Bennet:

The Association of Public Health Laboratories (APHL) represents state and local governmental health laboratories that monitor and detect public health threats. We appreciate the opportunity to comment on the Food and Drug Agency's Technical Assistance (FDA TA) on the Diagnostic Accuracy and Innovation Act (DAIA) as part of a continued conversation regarding laboratory developed tests (LDTs).

Governmental public health laboratories form the backbone of a national laboratory network that monitors and detects infectious and foodborne diseases, emerging drug resistance, environmental contaminants, terrorist agents, genetic disorders in newborns and other health threats. They provide critical testing services not replicated by diagnostic manufacturers, private, commercial or clinical laboratories. Public health laboratories develop and use LDTs to provide laboratory testing data that inform broader public health actions. APHL is deeply concerned that the FDA TA and the original bill have the potential to unintentionally disrupt, delay or even eliminate critical testing conducted by public health laboratories because of the administrative and financial resources required to comply with proposed premarket review or precertification requirements.

APHL understands the rationale for considering alternatives to FDA's current enforcement discretion. The LDT landscape has changed, including offering LDTs beyond local populations, manufacturing LDTs in high volumes, the evolving business models of laboratories, and using LDTs for common instead of rare diseases. These are not characteristics of public health laboratories. Public health laboratories do not mass manufacture LDTs and instead continue to use and develop LDTs to inform public health needs in their local, tribal or state jurisdictions. Public health laboratories do not profit from developing LDTs, or any aspect of their operations.

One public health laboratory estimates utilizing nearly 200 LDTs on a regular basis, while others numbers range from 34-96 LDTs. The majority of these LDTs are used for newborn screening or

for infectious disease testing. All are validated according to the Clinical Laboratory Improvement Amendments' (CLIA) guidelines and regulations, and only put to use after review and approval by the laboratory director. In addition, it is the laboratory director's responsibility to determine the suitability of the test before it is developed and validated. A redundant and inefficient review or precertification process, disproportionate to any risk, cannot be allowed to delay the critical services offered by public health laboratories.

Based on differences between the FDA's 2014 draft guidance and the recent TA on DAIA, the FDA has clearly considered the comment of some stakeholders. However, the proposed regulatory oversight still does not adequately differentiate public health laboratories from commercial diagnostic manufactures or adequately consider rare diseases. For example, often LDTs have a dual purpose of informing surveillance programs and providing clinical information to providers. Several national surveillance systems such as weekly virologic surveillance for influenza, PulseNet, and the National Antimicrobial Resistance Monitoring System rely on many of the same LDTs that can be used for clinical diagnosis. As surveillance tests that also provide clinical information are not exempt from the extra regulatory burden, the proposed framework may well limit if not halt critical surveillance activities.

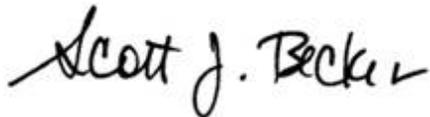
Another concerning example is the threat to one of the most important activities of a public health laboratory, accurately screening newborn children for rare diseases that are potentially fatal if not caught at birth. The FDA TA's proposed exemption for rare diseases utilizes a definition of rare diseases that is much narrower than the standard US definition used by the FDA's Center for Drug Evaluation and Research's (CDER) Rare Disease Program and FDA's Office of Orphan Product Development. The FDA TA uses a definition based on national test usage, a measure almost impossible for laboratories to track. It also sets a very low rate of <8000 tests performed in the nation annually, where newborn screens are run on millions of US born babies every year. The rare disease definition established by the Orphaned Drug Act of 1983 (Public Law 97-414) is "any disease or condition which affects less than 200,000 persons in the United States". If any proposed regulation were to adopt this recommended definition, it would not only standardize FDA's approach to rare diseases and set the same precedent for diagnostics as it does for treatments, it would also avoid the potentially insurmountable task of a local lab having to track national device usage.

While the FDA TA is lacking in many specifics, the current language raises serious concerns over public health laboratories' ability to continue their work effectively. APHL encourages that any regulatory or legislative oversight of LDTs acknowledge that governmental public health laboratories provide fundamentally different services from private, commercial, and clinical laboratories and diagnostic manufacturers, and therefore need to maintain their flexibility to ensure continued public health testing activities. Public health surveillance activities need preserved by explicitly outlining that assays with the intended use of surveillance, including those with a secondary use for clinical purposes, will not be under the purview of additional regulation. Newborn screening laboratories need explicit flexibility to provide uninterrupted

and timely testing services as the Recommended Uniform Screening Panel adds new disorders. As this discussion continues, we ask that all stakeholders in the laboratory community, not just a non-representative subset, be given more opportunity to provide input and feedback on the regulatory and legislative oversight of LDTs.

APHL appreciates your attention to this issue and your desire to ensure access to accurate and quality laboratory testing. We look forward to discussion of further modifications to the proposed regulatory framework. If we can be of any assistance, please contact Kuki Hansen, APHL's Manager of Regulatory and Public Policy at [kuki.hansen@aphl.org](mailto:kuki.hansen@aphl.org) or 240 485 2746.

Sincerely,

A handwritten signature in black ink that reads "Scott J. Becker". The signature is written in a cursive, slightly slanted style.

Scott J. Becker, MS

Executive Director

Association of Public Health Laboratories

*APHL works to strengthen laboratory systems serving the public's health in the US and globally. APHL's member laboratories protect the public's health by monitoring and detecting infectious and foodborne diseases, environmental contaminants, terrorist agents, genetic disorders in newborns and other diverse health threats.*