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CLINICAL LABS INDUSTRY FILES PETITION AGAINST POTENTIAL FDA REGULATION OF LABORATORYDEVELOPED TESTS

Washington, D.C. — The American Clinical Laboratory Association (ACLA) filed today a citizen petition under the Federal Food, Drug, and Cosmetic Act (FDCA) challenging Food and Drug Administration (FDA) authority to regulate laboratory developed tests (LDTs) in response to statements that the agency intends to regulate LDTs as "devices" under the FDCA.

As detailed in ACLA's petition, LDTs are in vitro assays that clinical laboratories develop as testing services according to their own procedures. These tests are often created in response to unmet clinical needs, and are commonly used for early and precise diagnosis, monitoring, and guiding patient treatment. LDTs are also used to diagnose and assessdiseases and disorders for which no FDA-authorized test kit currently exists, such as rare diseases, or those with small patient populations. Indeed, in some cases, LDTs represent the standard of care. Theability of laboratories to develop custom diagnostic tests has been critical to the growth of personalized medicine and keeping pace with the changing face of disease.

Since 1988, the laboratories performing LDTs have been highly regulated by a "comprehensive federal statutory scheme" under the Clinical Laboratory Improvement Act (CLIA), which requires continuous monitoring to ensure validity and reliability of LDTs. Higher complexity laboratories also undergo additional certification to ensure clinical validity of tests. The petition states "CLIA allows laboratories the flexibility to develop and validate LDTs quickly torespond to public health needs. Laboratories are able to update LDTs regularly as medicine advances, so that patients have access to the most advanced testing."

Importantly, LDTs differ from in vitro diagnostic (IVD) test kits which are packaged and commercially distributed and are regulated by FDA as medical "devices." LDTs, as ACLA points out, are laboratory services, not products, are not distributed, nor delivered or placed into market. They are "proprietary procedures for performing a diagnostic test using reagents and laboratory equipment… essentially know-how, not articles." According to ACLA's citizen petition, LDTs are not "devices" as defined in the FDCA, and lack the requisite commercial distribution required for FDA jurisdiction.

FDA regulation of LDTs would be contrary to the public health, stifling innovation and negatively impactingpatient access to this valuable category of diagnostic laboratory services,which includes "many "gold standard' DNA sequencing assays, newborn screening tests, and tests for rare diseases."

ACLA therefore urges that the FDA refrainfrom promulgating any guidance or rule purporting to regulate LDTs as "devices" under the FDCA, and to confirm that LDTs are not "devices" under the FDCA.

The full citizen petition can be found onACLA's website: www.acla.com.

ACLA is a not-for-profit association that represents the nation's leading providers of clinical laboratory services, including local, regional, and national laboratories throughout the United States. All ACLA members develop and perform LDTs.

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