



December 1, 2023

Robert M. Califf
Commissioner
Food and Drug Administration
5630 Fishers Lane, Rm. 1061
Rockville, MD 20852

Re: Proposed Rule: Medical Devices; Laboratory Developed Tests (Docket No. FDA-2023-N-2177)

Dear Commissioner Califf:

The Association for the Advancement of Blood and Biotherapies (AABB) appreciates the opportunity to provide comments in response to the Food and Drug Administration's proposed rule entitled "Medical Devices; Laboratory Developed Tests (Docket No. FDA-2023-N-2177)". AABB is an international, not-for-profit association representing institutions and individuals involved in transfusion medicine and biotherapies. The association serves as the accreditation organization for relationship testing (DNA) facilities, which are a category of forensic DNA testing laboratories.

We acknowledge FDA's efforts to ensure the safety and efficacy of laboratory developed tests (LDTs). However, we have concerns regarding the FDA's assertion of "longstanding enforcement discretion" over tests intended solely for forensic (law enforcement) purposes, regardless of whether these tests are offered as LDTs. AABB requests that FDA clarify that the definition of "tests intended solely for forensic (law enforcement) purposes" does not include forensic tests, such as forensic kinship and relationship testing (DNA) tests that are exclusively used for legal and immigration proceedings, criminal investigations and identification of human remains, which fall outside of FDA's jurisdiction.

The absence of a clear definition for "forensic" in the proposed rule introduces ambiguity and confusion within the industry, potentially resulting in inconsistent application of regulations. FDA does not have authority to regulate forensic tests, such as forensic relationship (DNA) tests, which encompass genetic genealogy analysis. These types of forensic tests are not "intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease," "intended to affect the structure or any function of the body," or "recognized in the official National Formulary, or the United States Pharmacopeia, or any supplement to them."¹ Rather, relationship testing (DNA) facilities use forensic tests exclusively for legal and immigration proceedings, criminal investigations and identification of human remains.

It is important to note that relationship testing laboratories accredited by AABB for forensic DNA testing *do not* perform the same category of tests used at FDA's Forensic Chemistry Center. The AABB accredited relationship testing facilities *are not* forensic laboratories providing specialized laboratory services in analytical chemistry and molecular/microbiology related to adulteration/contamination, counterfeiting, and product tampering of FDA regulated

¹ 21 U.S.C. §321(h). 21 CFR §809.3(a).

commodities including drugs, dietary supplements, foods, cosmetics, veterinary feeds, tobacco products, and medical devices.

Additionally, forensic testing is separate from clinical testing and forensic DNA testing laboratories are not regulated by the Centers for Medicaid and Medicare Services (CMS) Clinical Laboratory Improvement Amendments (CLIA) since these labs do not “examine materials... for the purpose of providing information for the diagnosis, prevention, or treatment of any disease or impairment of, or the assessment of the health of, human beings.”² They do not perform “procedures to determine, measure, or otherwise describe the presence or absence of various substances or organisms in the body.”³

The National Institute of Justice (NIJ) with the Department of Justice is the lead federal governmental agency supporting forensic laboratories, including relationship testing (DNA) facilities.⁴ The NIJ in collaboration with the Federal Bureau of Investigation (FBI), which issues the FBI Quality Assurance Standards for Forensic DNA Testing Laboratories ensures the quality and safety of testing provided through standards and accreditation programs.⁵

AABB’s Relationship (DNA) Testing Laboratories Accreditation Program is based on AABB Standards and includes assessments for facilities performing relationship testing activities, including methods for forensic genetic genealogy DNA analysis. AABB Standards incorporate the Federal Bureau of Investigation (FBI) Quality Assurance Standards (QAS) for Forensic DNA Testing Laboratories, and ISO/IEC 17025:2017 General Requirements for the Competence of Testing and Calibration Laboratories. AABB collaborates with the American Association for Laboratory Accreditation (A2LA) to assess compliance with ISO 17025 and the FBI QAS for forensic DNA testing laboratories. Notably, AABB’s Accreditation Program is recognized by the U.S. Department of State, and U.S. Citizenship and Immigration Services.

We request that FDA clarify that the definition of “tests intended solely for forensic (law enforcement) purposes” only applies to tests within FDA’s jurisdiction; it does not capture tests performed by forensic DNA testing laboratories that fall outside of FDA’s purview.

Thank you for your attention to this important matter. We appreciate your ongoing efforts to safeguard the integrity of laboratory developed tests and look forward to your consideration of our concerns. If you have any questions or need additional information, please contact me at 301.547.3962 or sleppke@aabb.org.

Sincerely,

Susan N. Leppke
Senior Director, Public Policy and Strategic Partnerships

² 42 CFR §493.1.

³ 42 CFR §493.1.

⁴ About NIJ’s Office of Investigative and Forensic Sciences, *available at* <https://nij.ojp.gov/about-nij/about-nijs-office-investigative-and-forensic-sciences> (last visited November 8, 2023).

⁵ Federal Bureau of Investigations, Quality Assurance Standards for Forensic DNA Testing Laboratories *available at* <https://ucr.fbi.gov/lab/biometric-analysis/codis/quality-assurance-standards-for-forensic-dna-testing-laboratories> (effective date September 1, 2011).