Robert M. Califf M.D.
Commissioner
U.S. Food and Drug Administration
10903 New Hampshire Ave.
Silver Spring, MD 20993

October 12, 2023

Re: Medical Devices; Laboratory Developed Tests, Docket No. FDA-2023-N-2177.

Dear Commissioner Califf,

The American Association of Bioanalysts (AAB) and the National Independent Laboratory Association (NILA) value the opportunity to provide comments on Medical Devices; Laboratory Developed Tests, Docket No. FDA-2023-N-2177 issued by the U.S. Food and Drug Administration (FDA). We aim to provide substantive feedback that reflects the perspectives of stakeholders, ensuring that final versions of these rules are fit for purpose. This process is essential for meaningful stakeholder engagement and the development of effective policies and regulations. With this in mind, we are writing to request a 60-day extension of the comment period for the FDA's proposed rule on regulation of LDTs. The proposed rule has significant implications for our members and the entire laboratory industry. Thus, additional time is necessary for stakeholders to fully evaluate the proposed changes and the rule's impact.

NILA represents community, regional, and health system laboratories that serve a wide variety of communities and patient populations—many of which serve rural and underserved urban communities that are not served by the nation's largest clinical laboratories. NILA members provide a wide variety of vital laboratory services that include general biochemistry testing, genetic testing, infectious disease testing, toxicology, hematology, and more.

Thank you for your consideration.

Sincerely yours,

Mark S. Birenbaum

Mark Birenbaum, PhD
Executive Director