LABORATORY ACCESS & BENEFITS COALITION

December 4, 2023

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

*Submitted electronically to regulations.gov*

Dear Dr. Califf,

The Laboratory Access and Benefits Coalition (LAB) appreciates the opportunity to comment on this proposed rule to modify the Food and Drug Administration's (FDA) definition of in vitro diagnostic products (IVDs) under the Federal Food, Drug, and Cosmetic Act.

The Laboratory Access and Benefits (LAB) Coalition is a diverse coalition of professionals across the laboratory industry working together to improve laboratory and testing policies. The LAB Coalition is committed to driving policies to create a more robust, sustainable, predictable, and accessible market for testing with a focus on improving care and outcomes for patients.

We are concerned that the proposed rule is an overreach of the FDA's authority and will have sweeping consequences for patients and the laboratory industry. Since our formation in 2021, LAB has sought to bring together various aspects of the testing industry to improve patient access to testing and diagnostic information and to support commonsense regulation of testing. FDA approvals should continue as a voluntary option for laboratories seeking to create diagnostics that are medical devices. To explore a new regulatory role for the FDA with respect to laboratory developed tests (LDTs), we proposed a pilot program approach to FDA's oversight of LDTs while Congress was debating whether to give FDA direct authority. We still believe that a pilot program is the right way to approach the monumental change FDA is proposing in this rulemaking. By working with industry to learn more about the practice of laboratory medicine and the modifications made to tests to achieve different diagnosis goals and by having the industry learn about FDA's robust processes in a pilot program, the FDA could achieve a more appropriately tailored approach to ensuring the safety and efficacy of LDTs than by lumping them into the existing definition of a medical device. Our pilot program could more accurately size the economic impact than the analysis provided by FDA – which our members believe is a gross underestimate and miscalculation.

Two things stand out in the background and legal authority sections. First, public health and safety are cited as the main need for FDA to alter the device definition. However, in footnote 10 FDA states that it "has not confirmed the veracity of the allegations or facts in every complaint, report, and allegation. Nevertheless, collectively this information points to potential problems among IVDs offered as LDTs."[1] We do not believe that suspicion and belief are appropriate grounds for expanding FDA's regulatory reach, and we urge FDA to consider a more nuanced and evidence-based approach to LDT regulation focused on addressing actual, verified issues and controversies. Additionally, the history of FDA's view of LDT regulation is lacking one

[1] 88 Fed. Reg. 68006 *at* 68011.

major artifact. On November 18, 2016, FDA released a statement that it would not finalize the 2014 draft guidance on LDTs:

> *The FDA believes that patients and health care providers need accurate, reliable, and clinically valid tests to make good health care decisions – inaccurate or false tests results can harm individual patients. We have been working to develop a new oversight policy for laboratory developed tests, one that balances patient protection with continued access and innovation, and realize just how important it is that we continue to work with stakeholders, our new Administration, and Congress to get our approach right. We plan to continue our view of an appropriate risk-based approach in the near future. It is our hope that such an approach will help guide future discussions.*[2]

This decision by FDA to no longer pursue direct review of LDTs in 2016 was made even though the final guidance had already been submitted to the Office of Management and Budget for review. FDA's authority to regulate LDTs should not shift with political winds, and yet both the decision to refrain from regulating LDTs in 2016 and the recent proposal to reverse course and regulate them came after the transfer of power to a new administration. We urge FDA to recognize that Congress is the sole body that can grant FDA direct authority over LDTs and withdraw this proposed rule.

In the meantime, FDA should work directly with the Centers for Medicare and Medicaid Services (CMS) Clinical Laboratory Improvement Amendments (CLIA) office to modernize the review of laboratory tests. Should additional authorities or oversight be needed, an appropriate balance can be struck by Congress through working directly with CMS and FDA. LAB believes that CMS' CLIA office should be actively engaged in this discussion. CMS has been absent from previous attempts by FDA to gain authority over LDTs through legislation like the Verifying Accurate, Leading-edge IVCT Development Act (H.R. 2369).[3] LAB believes that testing oversight could be improved through CLIA, but unilateral action by the FDA to expand the products subject to device review will not be successful. Instead, LAB urges FDA and CMS to work directly with the laboratory community – not just the device community – to modernize testing oversight.

*Enforcement Discretion*

FDA proposes to end its enforcement discretion over LDTs in this rulemaking. Enforcement discretion implies that FDA possesses the authority to regulate LDTs, and LAB does not believe that FDA has this authority. Several sections of the proposed rule request feedback on whether FDA should maintain enforcement discretion over particular types of tests or sections of the laboratory community, such as academic medical centers. LAB believes that FDA should continue to withhold direct review of LDTs of all the products and sections of the industry mentioned in the rule, and FDA should instead work with CMS on modernizing testing oversight. The last major attempt to modernize testing oversight occurred when CLIA was passed in 1988, and FDA was absent from those conversations and debates. Instead, FDA refers to actions in 1997 that signaled its policy of enforcement discretion while maintaining authority to directly regulate.[4] LAB believes that any authority to regulate LDTs has been waived through the agency's actions

[2] This statement is no longer available on FDA's website, but references to it can be found online HERE and HERE.
[3] *Available at* https://www.congress.gov/bill/118th-congress/house-bill/2369?q=%7B%22search%22%3A%22VALID%22%7D&s=1&r=1
[4] 88 Fed. Reg *at* 68015.

since 1988 if they even existed when the Medical Device Amendments passed in 1976. A continuation of enforcement discretion would subject the testing industry to the threat of potential compliance depending on who is leading the agency, and this type of uncertainty is inappropriate. Patients and the testing industry deserve clarity and consistency.

Additionally, FDA's proposal to continue non-enforcement over tests that resemble tests developed in 1976 raises the difference between manual and automated processes. LAB urges FDA and CMS to rethink whether tests and laboratory operations should be subject to more strict scrutiny simply because the laboratory personnel have adopted some level of automation. The Department of Health and Human Services should promote efficiency and improvement of lab operations and not simply suggest that the use of any automated process creates a medical product that requires separate application, fees, and review. LAB urges CMS and FDA to work directly with the testing industry to modernize oversight and review of diagnostic products.

Regarding the phasing out of FDA's current policy, LAB believes that incremental and gradual policy changes of this scale are always preferable and more likely to succeed. We urge FDA to consider rethinking this proposal and to instead work with CMS on a more consistent and modern oversight structure for the testing industry. Many laboratories are unfamiliar with device reporting requirements and the many nuances of FDA compliance, and these proposals will create significant cost for the testing industry, even if they are phased. If FDA or Congress is not prepared to provide compliance resources to laboratories, we suggest rethinking this proposed rule entirely so that patients can continue to receive innovative and personalized diagnostics and laboratories can continue to operate and diagnose those patients.

We believe that the economic impact analysis understates the compliance cost to the industry and overstates the savings that will be generated through increased safety. Additionally, the user fees projected in the analysis show that FDA expects to nearly double its revenue related to medical devices. Even if that figure is accurate, we do not think that the testing industry will be able to afford those fees and the associated legal and compliance costs. Further, we are not confident that this additional revenue would be sufficient to resource FDA to adequately review all the LDTs it proposes. We again urge FDA to remove this proposed rule and work with CMS and the testing industry on a modernized system of laboratory oversight.

We appreciate the opportunity to comment on the proposed rule and look forward to working with you to ensure the safety and efficacy of diagnostic tests without placing undue burden or incompatible review on highly skilled and qualified laboratories.

Sincerely,

Brett Meeks
Executive Director

CC:
Jeff Shuren
Director, Center for Devices and Radiological Health