NASTAD

444 North Capitol Street NW, Suite 339
Washington, DC 20001
(202) 434.8090 | NASTAD.org

November 17, 2023

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

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

Dear Commissioner Califf:

NASTAD is pleased to provide comments regarding FDA's proposal to phase out its general enforcement discretion approach for laboratory developed tests (LDTs) so that in vitro diagnostic (IVD) products manufactured by a laboratory would fall under the same enforcement approach as other IVDs.

Testing to identify infection is essential to achievement of the goals of the National HIV Strategy, 2022-2025, Ending the HIV Epidemic goals, the Viral Hepatitis National Strategic Plan: A Roadmap to Elimination for the United States, 2021-2025, and to advancing and ensuring health equity.

State and local public health departments provide and support testing services for HIV, viral hepatitis, and sexually transmitted infections (STIs) in a wide range of settings, which are focused on reaching and engaging vulnerable populations who often lack access to testing resources in conventional health care settings. As such, public health departments are deeply committed to ensuring access to testing which is safe and of the highest quality, and which provides accurate and timely results essential to facilitating linkage to treatment, and to preventing transmission.

NASTAD is deeply concerned that FDA's proposal to phase out its general enforcement discretion for LDTs will make it substantially more difficult to adopt new tests or modify existing tests to meet urgent, and emerging public health needs. For critical areas of HIV, viral hepatitis, and STI testing, LDTs are the only or most appropriate, and most timely tests available. Priority populations for public health testing programs include black, indigenous, and other people of color (BIPOC); gay, bisexual, and other men who

have sex with men (MSM); and people who use drugs (PWUD), populations for which stigma remains a substantial barrier to accessing testing services and who are disproportionately impacted by these infections.

To facilitate and ensure access to HIV, viral hepatitis, and STI testing for these priority populations, public health programs have adopted alternative sample types, such as dried blood spots; testing of additional sample types, such as is used for extra-genital STI testing; and have implemented modifications of testing methods necessary to efficiently and effectively accomplish testing for multiple related infections.

Home-testing programs implemented by public health departments also provide critical access to HIV, viral hepatitis, and STI testing services for BIPOC, MSM, PWUD, and other populations served by public health programs, including testing associated with PrEP. These programs employ both point-of-care "self-tests", as well as LDTs to test specimens self-collected by clients and submitted to a partner laboratory.

Use of alternative sample types, additional sample types, modification of test methods, along with home-testing programs are testing strategies that are critical to ensuring access to and utilization of public health testing programs by vulnerable populations. Implementation of FDA's proposed rule change to phase out its general enforcement discretion approach for laboratory developed tests (LDTs) will have a deep, negative impact on public health HIV and viral hepatitis elimination efforts.

Public health laboratories and clinical laboratories that partner with public health programs do not have the financial resources, or administrative capacity that would be required to submit IVDs offered as LDTs through FDA review processes. Implementation of FDA's proposal would have deleterious effects on public health budgets which are already inadequate and deeply constrained.

Public health departments would have to choose between ceasing to offer testing responsive to community needs and public health priorities, or to divert resources critical to supporting community testing services. Realistically, public health departments would be unable to continue to offer IVDs as LDTs for HIV, viral hepatitis, STIs, and related infections, thereby undermining public health efforts by eliminating access to critical testing resources thereby delaying identification of infection, engagement in treatment, undercutting public health surveillance, and, most crucially, exacerbating health inequities.

We appreciate that FDA's proposal would not apply to HIV, viral hepatitis, and other tests used in conjunction with public health surveillance activities. However, as we have described, public health departments operate and maintain a deep commitment to support community-based testing for HIV, viral hepatitis, STIs and related infections. IVDs provided as LDTs are foundational and critical to the success of these public health testing programs, and elimination efforts, and thereby are essential to advancing health equity.

Public health programs have deep knowledge of the health needs and barriers to testing of the diverse communities they serve, and they have the trust of these communities. Public health programs partner with public health or other clinical laboratories which possess the scientific and practical expertise appropriate to developing, evaluating, and performing IVDs offered as LDTs. As such, NASTAD strongly recommends that FDA continue enforcement discretion for HIV, viral hepatitis, STI and related IVDs offered as LDTs when conducted in conjunction with public health prevention and control programs.

Thank you for the opportunity to provide commentary. Please contact me at slee@NASTAD.org with questions.

Sincerely,

Stephen Lee MD, MBA, DHSM
Executive Director
NASTAD