July 3, 2024

Dockets Management Staff (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MD 20852

To Whom It May Concern:

Thank you for the opportunity to comment on the Food and Drug Administration's (FDA) draft Enforcement Policy for Certain In Vitro Diagnostic Devices for Immediate Public Health Response in the Absence of a Declaration Under Section 564.

IDSA represents over 13,000 infectious diseases (ID) physicians, scientists and other public health and health care providers specializing in the prevention, diagnosis and treatment of infectious diseases. The draft guidance provides recommendations for "immediate response" tests, as distinct from tests used in the regular course of medical care. IDSA would like to reiterate the need for laboratory-developed tests (LDTs) and commercial tests, typically used in combination with comprehensive clinical assessments, for expeditious diagnosis and management of infectious diseases in complex patients during both routine and emergency situations.

We appreciate the attention paid by FDA to testing needs during a disease outbreak or other public health emergency (PHE). However, as written, the draft guidance leaves labs with a level of uncertainty that will hamper testing availability, which can slow down response time and result in negative health outcomes for patients. Specific recommendations for changes in the final guidance can be found below.

Rapid Determination of Emergent Situation
According to the draft guidance, FDA will consult with the Centers for Disease Control and Prevention (CDC) on situations in which the enforcement policies described in section V.B of the preamble to the LDT Final Rule do not apply due to the emergent situation and public health needs. This determination should consider jurisdictional and regional impacts to allow rapid expansion of immediate response tests where there may be an early cluster(s) or surge of disease before it has spread to other states/regions. During the mpox outbreak of 2022, testing was delayed because CDC was tracking cases and testing capacity at a national level and did not adequately account for local needs in places like New York City that saw early spikes in cases. To facilitate adequate regional and local consideration, IDSA recommends that the guidance be amended to include FDA consultation with state and local health departments and clinicians in affected areas.

During the critical window before a PHE declaration is made, there is an urgent need to be able to quickly scale up high-quality and high throughput testing at commercial and academic laboratories, even if the outbreak is limited to a few geographic areas. The guidance should allow for testing to be quickly validated and expanded to include all relevant specimen types (e.g., rectal swab for mpox, corneal swab for H5N1), which may require expansion of testing beyond the CDC-developed/public health lab-conducted validation.

Warm Base of Testing Capacity
IDSA has previously commented on pandemic preparedness needs, including in response to the White House Pandemic Preparedness Plan. We reiterate here that FDA should collaborate with the Agency for

Strategic Preparedness and Response, White House Office of Pandemic Preparedness and Response and other appropriate agencies to establish predefined and funded reference and academic laboratory networks preauthorized by FDA to quickly develop ID diagnostics in pandemic conditions and begin biorepositories. Such a "warm base" for reference labs and others to be ready to perform tests in an emergent situation would provide the ability to rapidly scale testing and provide diagnostics with optimal turnaround time as a PHE is building. Labs also require easy access to sequences, extracted relevant nucleic acid, samples and quality assurance standards (e.g., controls) to quickly build, validate and utilize tests. In addition, FDA and other agencies should collaborate to designate pandemic assessment centers, i.e., institutions partnered with state health departments to coordinate activities to improve responses and alleviate supply chain issues. These partnerships can work strategically to maximize utilization of existing resources and decrease turnaround times on testing.

IDSA also recommends that FDA collaborate with other federal agencies to achieve the following:

- Promote the evaluation of novel diagnostics across the lifespan (pediatrics to geriatrics) and across the health lifespan (healthy to medically fragile).
- Deploy nucleic acid amplification tests and sequencing technology to community hospitals for use in day-to-day infection control to ensure these technologies can be seamlessly and rapidly utilized during an emergency.
- Engage academic medical centers, community hospitals and other health care facilities in the development of new diagnostics technologies.
- Fund personnel training on new technologies as well as the necessary equipment and reagents to facilitate rapid adoption of new technologies.

The following are areas IDSA feels need to be clarified from the draft guidance:

- What does FDA consider to be appropriately validated for an "immediate response" test? For CLIA-waived tests, there may be a need for rapid verification against a set "verification" panel to ensure test validity.
- FDA should clarify the limitations of allowing only tests labeled for prescription only. Will testing of patient-collected samples in a clinical setting be allowed under the guidance? When there is a need to have a large volume of patients tested, potentially with significant infection control requirements or high transmission risk for clinicians collecting samples, it is important to allow for patient self-collection of specimens when feasible.
- FDA should clarify the scope of "[laboratories] operating under an agreement (formal or informal) with the USG." It is not clear what type of informal agreements will be recognized under the guidance.

Thank you for your consideration of our feedback on the proposed guidance for testing prior to declaration of a PHE. IDSA stands ready to work with FDA to ensure continued access to ID testing. Should you have any questions, please contact Eli Briggs, IDSA director of public policy, at ebriggs@idsociety.org.

Sincerely,

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