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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 Consideration of Enforcement Policies for Tests During a Section 564 Declared Emergency.

IDSAs 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 The draft guidance provides recommendations for the use of unapproved tests during a declared public health emergency (PHE) before widespread testing using approved tests is available. IDSAs would like to reiterate the need for access to laboratory-developed tests 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 declared PHE. Specific recommendations for changes in the final guidance can be found below.

According to the draft guidance, FDA "may find it appropriate to also issue an enforcement policy regarding the distribution and use of certain unapproved tests for which EUAs have not been issued to help further expand access to such tests as quickly as possible." IDSAs applauds this flexibility to help meet testing needs until there is an adequate supply of FDA tests available. In the guidance, FDA states that the need for accelerated availability of certain unapproved tests will be one of several criteria used to determine whether to issue an enforcement policy for such tests. 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 the Centers for Disease Control and Prevention (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, IDSAs recommends that the guidance be amended to include FDA consultation with state and local health departments and clinicians in affected areas. In addition, consideration of testing needs for all relevant specimen types should be considered (e.g., rectal swab for mpox virus, corneal swab for highly pathogenic H5N1

influenza), which may require expansion of testing beyond the CDC-developed/public health lab-conducted validation. It is also important to include nonprescription (i.e., home) rapid testing options that can be done as close to the patients as possible when the appropriate test options are available.

In the draft guidance, FDA states the agency will “periodically review any issued enforcement policy guidance to determine whether it needs to be changed or withdrawn.” Similar to the recommendation stated above, this review should include considerations of local/regional needs in accordance with the epidemiological evidence with regard to prevalence and spread of disease.

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.

Thank you for your consideration of our feedback on the proposed guidance for testing after 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 ebiggs@idsociety.org.

Sincerely,



Steven K. Schmitt, MD, FIDSA, FACP
IDSA President