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June 1, 2016

[By Electronic Submission to www.regulations.gov]

Division of Dockets Management (HFA-305)
U.S. Food and Drug Administration
5630 Fishers Lane
Room 1061
Rockville, MD, 20852

Docket No. FDA-2016-D-1025-0002; Draft Guidance for Industry and Public Health Stakeholders: Emergency Use Authorization of Medical Products and Related Authorities

Dear Sir/Madam:

The Infectious Diseases Society of America (IDSAs) is pleased to offer comments on the draft guidance, "Emergency Use Authorization (EUA) of Medical Products and Related Authorities." As illustrated by the recent enterovirus D68, Ebola virus disease, and Zika virus outbreaks, IDSAs understands the clear and present danger posed by emerging infections and other public health threats. A streamlined regulatory pathway to rapidly review and approve diagnostics and therapeutics enables physicians, researchers, and public health authorities to rapidly respond to these outbreaks.

IDSAs appreciates that the draft guidance includes a number of improvements for *in vitro* diagnostics (IVD) sponsors, including specific instructions on safety and effectiveness data for applications and a new process to waive EUA approved IVDs for point-of-care use for the duration of its approval. IDSAs believes that these improvements will provide flexibility in meeting the FDA requirements for safety and effectiveness and enable a sponsor's IVD to more rapidly reach patients. However, our society is concerned that this draft guidance introduces delay and burden to the EUA process and also misses an opportunity to further aid clinical laboratories in understanding and navigating EUA submissions. IDSAs offers specific recommendations below to address these concerns.

Modify the requirement to seek support from relevant government stakeholders

The draft guidance now includes the statement "FDA recommends... non-governmental requesters first seek support from relevant governmental stakeholders that may be engaged in official response efforts (e.g., HHS ASPR, CDC, DoD, or state/local public health authorities) to ensure that the use encompassed by the request is appropriately coordinated and will not interfere with official response plans." IDSAs appreciates the importance of coordinating with official emergency

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responses. However, it is likely that agencies that are overwhelmed during emergencies will not be responsive to a sponsor request in a timely manner, which introduces a significant delay to a sponsor's EUA submission. Should a sponsor be unable to declare support from the relevant agency, it is also unclear whether the FDA would accept the EUA submission.

IDSA urges the FDA to modify this mechanism to avoid delays in EUA submissions. For example, the FDA can encourage -not require- sponsors to seek support from agencies. Another alternative is requiring that sponsors have made a good faith effort to contact relevant agencies, and if no response is received within a set timeframe, the sponsor can proceed with its EUA submission.

Consider additional support for clinical laboratory sponsors

IDSA agrees with FDA's statement that the majority of EUAs to-date have been from government entities. However, it is likely during a widespread emerging disease outbreak –as is possible with Zika virus– many clinical laboratories, such as sentinel laboratories in the Laboratory Response Network, may be driven to develop diagnostic tests to guide the care of their patients. These clinical laboratories may have special expertise suited to developing diagnostics to an outbreak that may be critical in circumstances where the testing capacity of public health agencies is overwhelmed. However, these clinical laboratories have limited financial and administrative resources and little familiarity with the EUA process. IDSA understands the need for high standards for an EUA, but remains concerned that these laboratories may be unable to navigate an EUA request in time to support a response to an outbreak.

IDSA believes this current guidance has made promising steps in improve flexibility to an EUA submission and urges the FDA to continue to examine how it can improve the EUA process for clinical laboratories with limited resources. One possible mechanism could be targeted outreach to clinical laboratories to educate them on preparing an EUA submission. An alternative could be an approach where past clinical laboratory sponsors can share their experiences and lessons learned during an EUA submission to guide prospective sponsors.

IDSA again appreciates the opportunity to comment, and looks forward to working with the FDA to further streamline the development of safe and effective responses to emerging public health emergencies. If you should have any questions, please contact Greg Frank, PhD, IDSA's program officer for science and research policy at gfrank@idsociety.org or 703-299-1216.

Sincerely,



Johan S. Bakken, MD, PhD, FIDSA
IDSA President

About IDSA

IDSA represents over 10,000 infectious diseases physicians and scientists devoted to patient care, disease prevention, public health, education, and research in the area of infectious diseases. Our members care for patients of all ages with serious infections, including meningitis, pneumonia, tuberculosis, HIV/AIDS, antibiotic-resistant bacterial infections such as those caused by methicillin-resistant *Staphylococcus aureus* (MRSA) vancomycin-resistant enterococci (VRE), and Gram-negative bacterial infections such as *Acinetobacter baumannii*, *Klebsiella pneumoniae*, and *Pseudomonas aeruginosa*, and, finally, emerging infectious syndromes such as Ebola virus fever, enterovirus D68 infection, Middle East Respiratory Syndrome Coronavirus (MERS-CoV), Zika virus disease, and infections caused by bacteria containing the New Delhi metallo-beta-lactamase (NDM) enzyme that makes them resistant to a broad range of antibacterial drugs.