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Infectious Diseases Society of America

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[By Electronic Submission to [www.regulations.gov](http://www.regulations.gov)]

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

**Re: Comments on Docket No. FDA-2014-D-0363; Draft Guidance for Industry and Food and Drug Administration Staff: Expedited Access for Premarket Approval Medical Devices Intended for Unmet Medical Need for Life Threatening or Irreversibly Debilitating Diseases or Conditions.**

Dear Sir/Madam:

The Infectious Diseases Society of America (IDSAs) is pleased to offer comments on the draft guidance, "Expedited Access for Premarket Approval Medical Devices Intended for Unmet Medical Need for Life Threatening or Irreversibly Debilitating Diseases or Conditions." IDSAs 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 infections such as the 2009 H1N1 influenza virus and bacteria containing the New Delhi metallo-beta-lactamase (NDM) enzyme that makes them resistant to a broad range of antibacterial drugs.

Over the past several years, IDSAs has stressed the importance of innovative diagnostic devices for the care of patients suffering from infectious diseases (ID), most notably in our 2013 report, [Better Tests, Better Care: Improved Diagnostics for Infectious Diseases](#). Improved diagnostics can allow physicians to rapidly identify the pathogen infecting a patient and prescribe the most appropriate treatment, increasing the likelihood of a positive patient outcome. New ID diagnostics can also help identify patients eligible for antimicrobial drug clinical trials, inform infection control and other public health responses, and combat antimicrobial resistance by reducing the need for clinicians to treat empirically and potentially overuse antimicrobial drugs

The Food and Drug Administration (FDA) has a key role in facilitating the

development and review process of innovative diagnostics. This draft guidance represents a promising step in the right direction toward IDSA's recommendations to address the regulatory challenges to diagnostics research and development. By expediting the development, assessment and review of new medical devices subject to premarket approval (PMA), the FDA can bring medical devices to patients with unmet medical needs more rapidly while maintaining reasonable assurance of safety and efficacy.

We applaud the FDA's detailed comments highlighting the regulatory complexities of developing and testing in vitro diagnostic devices (IVD). In particular, IDSA wholeheartedly agrees with the accepted alternative experimental designs for IVDs subject to expedited access PMA (EAP), such as relying on banked samples from previous studies or enabling rare disease IVDs to use contrived samples for testing clinical validity. These alternative experimental designs will greatly facilitate the rapid development and review of innovative diagnostics.

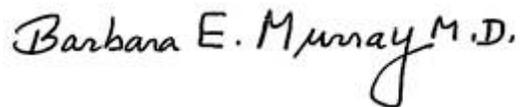
To demonstrate the significant impact this guidance can have for patients suffering from serious or life-threatening infections, we describe below three examples of diagnostic areas that are likely to benefit greatly from this draft guidance:

- 1. Diagnostics Tests for rare diseases, such as pathogens causing central nervous system (CNS) infections.** New IVDs that can reliably identify rare conditions, such as viral CNS infections, meet a significant unmet medical need. At this time, diagnosing these infections can be challenging and complex. Patients must often be treated empirically if infection is suspected, as the prognosis for untreated infection is quite poor. It is currently very challenging to bring such tests to market, due in large part to the difficulty in obtaining large enough sample populations to properly test the clinical validity of the devices. The criteria for EAP in this guidance could enable companies developing tests/devices to more feasibly evaluate their clinical validity. This would increase the availability of safe and effective devices for clinical care.
- 2. Large scale multiplexed molecular-based tests that target common, rare, and/or emerging pathogens.** The potential of molecular based tests to identify a large number of potential pathogens simultaneously makes them well equipped to provide clinically meaningful advantages over existing technologies. More rapid access to more detailed diagnostic information can better guide optimal patient care and may yield better patient outcomes. However, these devices also suffer major challenges not only in comparing against reference methods but also in obtaining the appropriate sample base to reliably verify the more rare pathogens in the panel. This can result in the target panel of these tests being reduced in order to meet the requirements for safety and effectiveness for PMA. This guidance will allow greater flexibility for device developers to test new wide scope IVDs for both common and rare pathogens, resulting in devices with a broader diagnostic scope being brought to the market. Also this could allow for more rapid approval of modifications to these tests as new and emerging pathogens are discovered and added to the panels.
- 3. Diagnostics with public health utility, such as tests for HIV or HCV incidence surveillance.** Diagnostics with a public health impact can address unmet medical needs

for both individual patients through early diagnosis, as well as informing the public health response by providing more detailed, timely information on disease incidence. These types of diagnostic assays can provide information on timing of infection (i.e., whether infection occurred within the last 6 months or further into the past). Individuals in the early stage are at highest risk of transmission to their partners, and treatment and contact tracing can be effective in lowering this risk. However, significant barriers exist for properly evaluating the performance of these tests in clinical cohorts. By allowing alternative experimental designs, the medical benefits of using these tests can be better validated. This can help verify uncertainties in the timing of infection while significantly streamlining the review process for devices with such a public health or surveillance design scope.

IDSA hopes these comments are useful to the FDA as the agency moves forward in their efforts to expedite the development process that brings devices to patients with unmet medical needs. Should you have any questions or concerns about these comments, please feel free to contact Greg Frank, PhD, IDSA Program Officer for Science and Research Policy, at [gfrank@idsociety.org](mailto:gfrank@idsociety.org) or 703-299-1216.

Sincerely,

A handwritten signature in black ink that reads "Barbara E. Murray M.D." The signature is written in a cursive, flowing style.

Barbara E. Murray, MD, FIDSA  
President