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IDSA
Infectious Diseases Society of America

July 22, 2014

[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

Re: Comments on Docket No. FDA-2014-D-0090; Draft Guidance for Industry and Food and Drug Administration Staff: Balancing Premarket and Postmarket Data Collection for Devices Subject to Premarket Approval

Dear Sir/Madam:

The Infectious Diseases Society of America (IDSA) is pleased to offer comments on the draft guidance, "Balancing Premarket and Postmarket Data Collection for Devices Subject to Premarket Approval." 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 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, IDSA 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 This draft guidance represents a promising step in the right direction toward IDSA's recommendations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 deciding that post-approval studies may be appropriate at the time of Premarket approval (PMA), the FDA can more rapidly make available novel diagnostic devices with reasonable assurance of safety and efficacy to patients with unmet medical needs. Post-market data can allow FDA to continue to clarify uncertainties regarding the benefits and risks of the device.

IDSA wholeheartedly agrees that for medical devices addressing unmet medical needs, greater uncertainty about the benefit-risk profile of the device should be accepted and by shifting data collection from the pre-market to post-market phase, urgently needed life-saving devices can reach patients more rapidly. For a patient with a serious or life-threatening infection that cannot be identified in a sufficiently rapid manner to substantively impact care and outcomes, FDA must appropriately weigh the risk of approving a new diagnostic test based upon a smaller premarket data set against the risk of not having urgently needed new diagnostics. Along with the FDA's sister guidance on expediting access to medical devices for unmet medical needs, the criteria for accepting post-market data collection will greatly facilitate the rapid development, review and approval of innovative diagnostics.

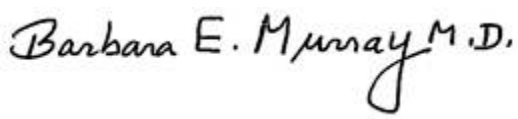
To demonstrate the significant impact this guidance can have for patients suffering from serious or life-threatening infections, we describe below two examples of diagnostic areas that are likely to benefit greatly from this draft guidance:

1. **Viral load tests used to monitor response to therapy.** Viral load tests can play a role not only in identifying diseases but also in optimizing the appropriate duration of treatment. Tests that can quantitatively establish pathogenic burden in patients, such as recent tests for cytomegalovirus (CMV), can also be used to establish the duration of treatment with optimal efficacy, cost-effectiveness, and patient outcome. When disease occurrence is rare, it is difficult to identify an adequate number of patients to establish the monitoring claim. By allowing PMA approval of these tests, post-market data can be collected to better validate the medical benefits of using these tests as guides for treatment response while not unnecessarily delaying patient access to these important tools.

2. **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 post-market data collection to better confirm these tests' medical benefits, uncertainties in the timing of infection can be validated 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 or 703-299-1216.

Sincerely,



Barbara E. Murray, MD, FIDSA
President