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IDSA
Infectious Diseases Society of America

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Division of Dockets Management (HFA–305)
Food and Drug Administration
5630 Fishers Lane, Rm. 1061
Rockville, MD 20852

Re: Comments on Docket No. FDA–2013–D–1319; Draft Guidance for Industry on Pulmonary Tuberculosis: Developing Drugs for Treatment; Availability

Dear Sir/Madam:

On behalf of the Infectious Diseases Society of America (IDSA), thank you for the opportunity to respond to FDA's draft guidance for industry, entitled "Pulmonary Tuberculosis: Developing Drugs for Treatment." IDSA represents more than 10,000 physicians, scientists and other health care professionals devoted to excellence in patient care, prevention, public health, education, and research related to infectious diseases (ID) including tuberculosis. Our members care for tuberculosis (TB) patients directly, provide ID consultation to providers for TB and related co-infections, and conduct TB clinical trials, including through the Centers for Disease Control & Prevention's (CDC) TB Trials Consortium and the National Institutes of Health (NIH) Tuberculosis Transformative Science Group (TB TSG).

As noted in the document, there are several challenges related to the decades-old TB drugs, drug combinations, and treatment regimens in use today. These challenges warrant an urgent response to spur innovation in pharmaceutical development, clinical protocols, and health service delivery. The duration and complexity of today's TB treatments results in nonadherence and suboptimal clinical response, which in turn fuels prolonged disease, the emergence of drug resistance, and subsequent TB transmission. Moreover, adverse events associated with current regimens further contribute to nonadherence, and HIV co-infection can raise toxicity profiles and increase the risk of adverse drug interactions. Compounding these challenges, nationwide shortages of first- and second-line TB drugs and reagents, including isoniazid, ethambutol, and TB skin test antigen, have hampered our ability to properly diagnose and treat TB patients. Meanwhile, multi-drug resistant (MDR) TB and even extensively drug-resistant (XDR) TB continue to pose a substantial public health threat in the U.S. and globally.

For the first time since the 1960s, new TB drugs and shorter regimens are emerging that could significantly alter the course of treatment, saving lives and improving the quality of life for those living with TB. It is vital that this momentum continues.

The draft guidance represents a major step forward for the clinical development of improved TB treatment regimens. Many of the parameters outlined in the document

are already in use today by IDSA members leading various TB clinical trials. The guidance provides much-needed clarity for sponsors interested in TB product development, and this is especially important considering how few companies remain active in this therapeutics area. IDSA welcomes FDA's alignment with leading clinical researchers, and we endorse the guidance with enthusiasm.

Thank you for your efforts to advance TB treatment discovery and development. Should you have any questions, please contact John Billington, IDSA's Senior Program Officer for Health Policy at jbillington@idsociety.org or 703-299-0015.

Sincerely,

Barbara E. Murray M.D.

Barbara E. Murray, MD, FIDSA
President, IDSA