



December 23, 2013

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

Re: Docket No. FDA-2011-N-0898

To Whom It May Concern:

Thank you for the opportunity to respond to the Food and Drug Administration's (FDA) request for comments on proposed regulations to address the permanent discontinuance or interruption in manufacturing of certain drugs or biological products. We write on behalf of the Infectious Diseases Society of America (IDSA) and the Pediatric Infectious Diseases Society (PIDS), which represent more than 10,000 infectious diseases physicians and scientists devoted to patient care, prevention, public health, education and research.

Shortages of key drugs used to fight infections represent a public health emergency and put patients at risk.<sup>1</sup> As illustrated in IDSA's letter to FDA dated March 14, 2013, anti-infective shortages can substantially alter clinical care and may lead to worse outcomes for patients, particularly as the development of new anti-infectives has slowed and the prevalence of multidrug-resistant pathogens has increased, causing a sharp decline in effective treatment options for many serious infections.<sup>2</sup>

We believe the proposed regulations, combined with the "Strategic Plan for Preventing and Mitigating Drug Shortages" (Strategic Plan) provide a promising path toward better oversight and management of the U.S. pharmaceutical supply, especially for drugs that are critically important to patients. While we remain concerned that this framework ultimately cannot ensure better manufacturing processes to prevent future shortages, we are hopeful that early notification will help the FDA work with these companies to identify and resolve the root cause of a particular shortage. We also support the inclusion of vaccines and other biologics under the reporting requirement, as shortages of routinely administered vaccines for infants and children have exposed the vulnerability of the supply of vaccines in the U.S.<sup>3</sup> Finally, we are pleased with the agency's designation of "medically necessary" products determined most vital to public health and lacking alternative therapies. When making a determination about whether a drug

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<sup>1</sup> Griffith MM et al. The Impact of Anti-infective Drug Shortages on Hospitals in the United States: Trends and Causes. *Clin Infect Dis.* 2012; 54(5):684-9.

<sup>2</sup> IDSA Letter to FDA, March 14, 2013. Available at, [http://www.idsociety.org/uploadedFiles/IDSA/Policy\\_and\\_Advocacy/Current\\_Topics\\_and\\_Issues/Advancing\\_Product\\_Research\\_and\\_Development/Bad\\_Bugs\\_No\\_Drugs/Position\\_Papers/IDSA%20Comments%20on%20Drug%20Shortages%20Task%20Force%20and%20Strategic%20Plan%20031413.pdf#search=%22drug%20shortage%22](http://www.idsociety.org/uploadedFiles/IDSA/Policy_and_Advocacy/Current_Topics_and_Issues/Advancing_Product_Research_and_Development/Bad_Bugs_No_Drugs/Position_Papers/IDSA%20Comments%20on%20Drug%20Shortages%20Task%20Force%20and%20Strategic%20Plan%20031413.pdf#search=%22drug%20shortage%22).

<sup>3</sup> Klein JO and Myers MG. Strengthening the Supply of Routinely Administered Vaccines in the United States: Problems and Proposed Solutions. *Clin Infect Dis.* 2006; 42:S97-103.

product is medically necessary, we strongly urge FDA to consider the absence of appropriate substitutes for certain antimicrobial products used to treat antimicrobial-resistant infections.

***FDA should outline plan to collaborate with other federal agencies and medical specialists to issue timely guidance for alternative therapies***

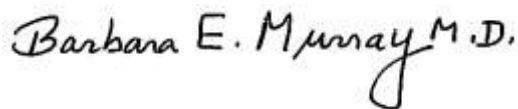
Timely clinical guidance on appropriate alternative therapies in the event of a drug shortage is critical to patient care and public health. We are pleased that FDA communication with patients, prescribers, pharmacists, and other governmental agencies is outlined in Appendix F of the Strategic Plan. We urge FDA to strengthen this plan by including FDA communication with the Centers for Disease Control and Prevention (CDC), the National Institutes of Health (NIH) and medical societies like IDSA and PIDS to develop and disseminate treatment guidelines during shortages. This would ensure that clinicians are equipped to provide the best possible care for patients in a shortage environment, and would reduce “off label” use of drugs not usually used for a certain indication because first and/or second line agents are not available.

***A clearly articulated mechanism for importation of certain drug and biological products should be included in the Strategic Plan***

In some cases, expedited importation of certain drug and biological products from outside the U.S. will be necessary to ensure appropriate patient care and protect public health. We urge FDA to amend the Strategic Plan to outline a pathway for the importation of certain products, combined with a stringent quality assessment. If a drug or biological product is determined "medically necessary" by FDA but only available from sources outside the U.S., FDA should have in place a mechanism for an expedited review. IV fosfomycin is an example of a critically-needed agent, unavailable in the U.S., which may be necessary when alternatives therapies are unavailable. The recent experience with meningococcal serotype B vaccine importation may also be instructive when devising a plan for speedy importation.

IDSA and PIDS stand committed to working with FDA to identify long-term solutions to drug shortages. These proposed regulations, combined with the Strategic Plan, represent a promising step forward, and we appreciate the opportunity to comment. Should you have any questions, please contact John Billington, IDSA's Sr. Program Officer for Health Policy at [jbillington@idsociety.org](mailto:jbillington@idsociety.org) or 703-299-0015.

Sincerely,



Barbara E. Murray, MD, FIDSA  
President, IDSA



David A. Kimberlin, MD, FIDSA  
President, PIDS