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IDSAs Headquarters

1300 Wilson Boulevard
Suite 300

Arlington, VA 22209

TEL: (703) 299-0200

FAX: (703) 299-0204

EMAIL ADDRESS:

info@idsociety.org

WEBSITE:

www.idsociety.org

December 13, 2011

The Honorable Tom Harkin
Chairman
Health, Education, Labor and Pensions
Committee

United States Senate
Washington, DC 20510

The Honorable Michael Enzi
Ranking Member
Health, Education, Labor and Pensions
Committee

United States Senate
Washington, DC 20510

SUBJ: Infectious Diseases Society of America's Statement for the Senate Health, Education, Labor and Pensions (HELP) Committee December 15, 2011 Drug Shortages Hearing

Dear Chairman Harkin and Ranking Member Enzi:

On behalf of the Infectious Diseases Society of America (IDSAs), I write to commend your leadership in holding a hearing on the issue of drug shortages and request that you include this statement in the Senate HELP Committee hearing record. IDSAs members are acutely concerned with drug shortages, specifically in the area of anti-infective drugs, and their impact on patient care and public health. We have submitted comments to the Food and Drug Administration (FDA) on this issue and look forward to working with you to develop solutions to this critical health crisis that is deepening across the spectrum of health care.

IDSAs is devoted to infectious diseases (ID) patient care, prevention, public health, education and research. Our nearly 10,000 members care for patients of all ages with serious infections, including influenza, meningitis, pneumonia, and tuberculosis; resistant bacterial infections caused by methicillin-resistant *Staphylococcus aureus* (MRSA) as well as Gram negative bacteria such as *Pseudomonas aeruginosa*, *Klebsiella*, *Acinetobacter baumannii*, and *Escherichia coli* (*E. coli*); cancer and transplant patients who have life-threatening infections caused by unusual microorganisms; foodborne disease such as Salmonella; HIV/AIDS; and emerging infections like the 2009 H1N1 influenza virus and severe acute respiratory syndrome (SARS).

Anti-Infective Drug Shortages Are Increasing

In recent years, ID practitioners have seen a steep increase in anti-infective drug shortages. In 2011, IDSAs's Emerging Infections Network (EIN), a provider-based emerging infections sentinel network funded by the Centers for Disease Control and Prevention (CDC), polled its users to determine how many had experienced drug shortages.¹ Of the 634 respondents, seventy-eight percent indicated a need within

¹Susan Beekman, RN, MPH et al, Antimicrobial Agent Shortages and Adverse Patient Outcomes: Results of a 2011 Survey of Infectious Diseases Physicians. Researched for and Presented at IDSAs's 2011 Annual Meeting in Boston.

the past two years to modify their antimicrobial agent of choice because of a drug shortage. Survey respondents confirmed ongoing shortages with anti-infective injectables. Fifty-two percent of respondents believe that the resulting change in treatment adversely affected patient care or outcomes.

According to the FDA, which issued a report on drug shortages in October 2011 (www.fda.gov/DrugShortageReport), antibiotics were the second largest therapeutic drug class to experience shortages during 2010 and 2011 (13%), second only to oncology agents.

The Impacts of Anti-Infective Drug Shortages on Patient Care and Public Health

Anti-infective drug shortages adversely impact patient care by limiting the availability and choice of antimicrobials. In such situations, ID practitioners are forced to choose alternative treatment regimens that often include drugs with higher toxicity, poorer treatment outcomes, more prolonged and expensive duration of treatment, more expensive agents, broader spectrum drugs, and long-term morbidity from inadequate treatment and longer hospitalizations. The problem is even more acute for pediatric practitioners, because there are fewer antimicrobials that can be tolerated by infants and children.

Drug shortages also exacerbate the serious public health problem of antimicrobial resistance, as they may limit the practitioner's ability to provide the anti-infective with the narrowest spectrum of activity appropriate for treating a specific infection. This often results in the use of an otherwise unnecessary broad-spectrum drug, pressuring the microbial flora of patients and institutions into resistant mutations. Antimicrobial resistance is already a serious problem, estimated to cost the U.S. health care system over \$20 million annually as well as more than \$30 billion in societal costs and more than 8 million additional patient days spent in hospitals each year. Public health, as well as patient care, also may be compromised when drug shortages force practitioners to use an unfamiliar agent, sometimes at an inappropriate dose and duration, which again favors the development of drug resistance. Finally, antibiotic shortages further compound increasing patient morbidity and mortality that exists due to the alarming lack of new antibacterial drugs in development.

Recent Anti-Infective Shortages with Significant Patient Care & Public Health Impact

IDSA leaders recently informally identified the four most prevalent shortages of anti-infective sterile injectables since 2009 with the greatest potential impact on patient care and public health.

These include:

- **Amikacin**—used for infections caused by drug-resistant Gram negative bacteria (e.g. *Pseudomonas aeruginosa*, *Klebsiella*) often seen in vulnerable populations, such as immuno-compromised and intensive care unit patients, as well as mycobacterial infections, and is especially important in treatment of drug-resistant gonorrhea;
- **IV Trimethoprim-Sulfamethoxazole (TMP/SMX)**—used for infections caused by certain drug-resistant Gram-negative bacteria (e.g. *Stenotrophomonas*), and is the 'drug of choice' for moderate-to-severe *Pneumocystis pneumonia* in immuno-compromised patients;
- **IV Acyclovir**—used for treating neonatal herpesvirus infections and adult herpesvirus infections, including disseminated and neurologic herpes simplex and varicella zoster virus infections. Alternatives such as IV Foscarnet have far worse safety profiles, with toxicities including renal failure and electrolyte disturbances; and

- **IV Clindamycin**—a critical agent in the treatment of severe skin and soft tissue infections due to streptococci, staphylococci and anaerobes; bone and joint infections, and protozoal infections, such as toxoplasmosis.

IDSA leaders also have noted with concern, global shortages impacting the availability of antibacterial, antimalarial, and antimycobacterial (e.g., anti-tuberculosis) agents. It is inevitable that resistance will continue to increase globally if practitioners are forced to rely on an ever-dwindling number of drugs. The European Society of Clinical Microbiology and Infectious Diseases (ESCMID) highlighted this problem in 2007, stating that antibiotic shortages were widespread throughout Europe (69% of respondents) and were driving resistance through the use of more expensive, broad-spectrum, less efficacious substitute agents.²

Recommendations to Resolve the Drug Shortages Problem

The issue of drug shortages is very complex and will likely require a combination of solutions. IDSA shared the below recommendations with FDA and urges you to consider providing congressional leadership to require or incentivize these activities.

Overall recommendation:

- Strengthen communication between the FDA, the pharmaceutical industry, and health care practitioners to identify actions that can be taken to prevent drug shortages, and to discuss progress.

Recommendations for the federal government:

- FDA should work with the pharmaceutical industry to conduct a root cause analysis of previous shortages and identify current vulnerabilities.
- The FDA, CDC, and the pharmaceutical industry should establish an ‘early warning surveillance system’ that better anticipates, detects and monitors shortages *and that*:
 - ensures diversity in manufacturing plant locations,
 - ensures multiple manufacturers are not all relying on one supplier, and
 - more effectively estimates when a shortage will be resolved.
- Determine how best to develop guidelines for the use of alternative agents during antimicrobial shortage events that give practitioners additional information on use when first-line agents are not available.
- Create either incentive strategies (including reimbursement models) to enhance reliable production of critical drugs or a national stockpile similar to the Strategic National Stockpile (SNS) for specified critical drugs.

Recommendations for health care facilities:

- Treat drug shortages as an extension of normal disaster planning in which hospitals and other health systems have a strategy and awareness campaign to manage them.
- Encourage open communication (or formalized communication) between physicians and pharmacists regarding drug shortages, appropriate use of alternative agents, and resolution of shortages.

²ESCMID’s Study Group for Antibiotic Policies’ response to the European Commission’s Consultation on “The Future of Pharmaceuticals for Human Use in Europe” Version 19 July 2007
http://www.escmid.org/fileadmin/src/media/PDFs/2News_Discussions/2Position_Papers/ESGAP_Position_Paper_on_Antibiotic_Drug_Shortage.pdf

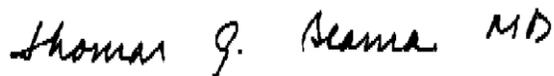
- Establish effective antimicrobial stewardship programs to promote efficient administration of appropriate therapies. By eliminating the inappropriate use and reducing the over-prescribing of antimicrobial agents, stewardship programs will preserve critical therapies that are in short supply.

Conclusion

IDSA applauds your leadership in holding a hearing to address the serious problem of drug shortages. Infectious diseases practitioners continue to experience shortages in critical anti-infective drugs. At the same time, our patients face greater threats due to increasing rates of antimicrobial resistance. Shortages adversely affect patient care and outcomes through long-term morbidity from inadequate treatment, longer hospitalizations, and sometimes death. Shortages are a driver of overall healthcare costs, stemming from longer treatment and the significant markup in drug prices for substitute or broad-spectrum agents often seen during shortages. As such, it is imperative to patient care and public health that long-term solutions to drug shortages be identified and implemented.

IDSA stands committed to working with Congress, federal agencies and other stakeholders to identify long-term solutions to anti-infective drug shortages. Should you have any questions, please do not hesitate to have your staff contact Amanda Jezek, IDSA's Director of Government Relations at ajezek@idsociety.org or 703-740-4790.

Sincerely,

Handwritten signature of Thomas G. Slama MD in black ink.

Thomas G. Slama, MD, FIDSA
President

Cc: Members of the Senate Health, Education, Labor and Pensions Committee