

## Strategies to Address Antimicrobial Drug Shortages

### June 2020

#### Background

The Infectious Diseases Society of America (IDSA) and its HIV Medicine Association (HIVMA) are concerned about the current number of critically important antimicrobial drugs in short supply in the United States. While drug shortages have been an issue for infectious diseases (ID) and HIV physicians over the past several years, the COVID-19 pandemic has exacerbated this problem.

Despite important steps taken by the U.S. Food and Drug Administration (FDA) to increase its capacity and infrastructure for reporting and monitoring drug shortages and prioritizing review of new products, ID and HIV physicians report shortages that appear to be worsening and that are impacting patient care and public health.

#### Scope of Drug Shortages

Due in part to supply chain disruptions fueled by COVID-19, the following antimicrobial drugs are in short supply as of May 26, 2020<sup>1,2</sup>. These drugs are used to treat bacterial infections in patients with COVID-19:

- Azithromycin (injection and tablets)
- Meropenem injection
- Ampicillin sodium and sulbactam sodium injection
- Ceftazidime injection
- Doxycycline hyclate injection

In a [survey](#) conducted by the Emerging Infections Network in 2016, **73 percent of respondents reported that a drug shortage affected patient outcomes**. A 2016 U.S. Government Accountability Office [report](#) on drug shortages concluded that, while the number of total new drug shortages had generally decreased since 2011, the number of ongoing shortages remained high.

#### Impact on Patient Care and AMR

Antimicrobial drugs are critical for treating patients with severe COVID-19 who are hospitalized, placed on ventilators, and at heightened risk for secondary bacterial infections like pneumonia. When these drugs are unavailable, ID physicians are forced to choose alternative treatment regimens that are not as effective and may lead to poorer patient outcomes, are often associated with increased adverse effects (or toxicity) and the development of antimicrobial resistance. A [study](#) of patients in Wuhan, China found that 50% of patients who died as a result of COVID-19 had secondary bacterial infections.

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<sup>1</sup> [Food and Drug Administration](#)

<sup>2</sup> [American Society of Health-System Pharmacists](#)

Drug shortages often limit the physician's ability to provide the appropriate anti-infective with the narrowest spectrum of activity for treating a specific infection, resulting in the use of a broad-spectrum drug that can induce drug-resistant mutations in the microbial flora of patients as well as the institutional environment. Patient health may also be compromised when drug shortages force practitioners to use an unfamiliar agent, sometimes at an inappropriate dose and duration, which also favors the development of resistance and toxicity.

### Policy Recommendations

The issue of drug shortages is complex and will require a combination of interventions to be resolved. In October 2019, the FDA released a [report](#) that identified three root causes for drug shortages:

- a lack of incentives for manufacturers to produce less profitable drugs;
- a lack of recognition and reward for manufacturers' "mature quality systems" that focus on continuous improvement and early detection of supply chain issues; and
- logistical and regulatory challenges that make it difficult for the market to recover from a disruption.

In addition, data from the [July 2016 GAO report](#) on drug shortages indicate the persistence of anti-infective drug shortages and underscore the need for a more robust response from the federal government to ensure patient access to these life-saving drugs.

### **IDSA recommends the following potential solutions:**

- Congressional passage of the *Affordable Drug Manufacturing Act* (H.R.5501/S.3162), a bill that would establish the Office of Drug Manufacturing within HHS for the purposes of addressing prescription drug shortages as well as lowering prices and increasing access to critical medicines.
- Congressional passage of S.3780 and S.3781:
  - S.3780: Encourage domestic advanced manufacturing of critical drugs and devices to address economic, health and security concerns; combat drug shortages; and promote increased domestic diversification of pharmaceutical and medical device supply chains.
  - S.3781: Increase reporting of, help mitigate potential shortages related to, and promote accountability and transparency for pharmaceuticals and medical devices.
- Improved real-time communication between FDA, the pharmaceutical industry and health care practitioners to identify the causes and impact of drug shortages and actions that can be taken to prevent drug shortages and to discuss progress.
- Congressionally directed strengthening of FDASIA reporting requirements to provide greater transparency regarding the causes of current and future shortages.
- Create federal incentives for manufacturers to perform routine maintenance to production lines to prevent closures that typically cause shortages and have established

back-up plans to continue manufacturing drugs during remediation of production line issues and other maintenance to ensure continued supplies.

- FDA, CDC and the pharmaceutical industry should develop and implement policies to encourage improvements in manufacturing practices, including increasing diversity in manufacturing plant locations, helping ensure multiple manufacturers are not all relying on a single supplier, and increasing transparency regarding manufacturing practices in order to better anticipate future drug shortages.
- Additional incentives to enhance reliable production of important drugs, and a national stockpile similar to the Strategic National Stockpile (SNS) for specified drugs.
- Establishment of a list of priority drugs for medicines that do not have a second line drug or alternative treatment for FDA and manufacturers to focus on.
- Increased federal funding for antimicrobial stewardship activities at CDC to improve and optimize antibiotic utilization to ensure these drugs are available when they are most needed.

IDSA and HIVMA remain committed to working with federal and industry partners to identify long-term solutions to anti-infective drug shortages. If you have questions, please contact Haley Payne, IDSA's Public Health Policy Manager, at [hpayne@idsociety.org](mailto:hpayne@idsociety.org).