

Advancing Health in America

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Statement

of the

American Hospital Association

for the

Committee on Finance

of the

U.S. Senate

"Drug Shortages: Examining Supply Challenges, Impacts, and Policy Solutions

from a Federal Health Program Perspective"

December 5, 2023

On behalf of our nearly 5,000 member hospitals, health systems and other health care organizations, and our clinician partners — including more than 270,000 affiliated physicians, 2 million nurses and other caregivers — and the 43,000 health care leaders who belong to our professional membership groups, the American Hospital Association (AHA) thanks you for the opportunity to submit comments to the Senate Committee on Finance regarding the important topic of drug shortages.

America's hospitals and health systems have long been concerned about shortages of a wide range of drugs used to treat patients. Of particular concern to hospitals are the cascading impact of drug shortages on patients and the heightened stress on scarce hospital resources. Shortages can adversely affect patient care by causing delays in treatment, increasing the risk of medication errors and requiring the use of less effective alternative treatments. As a result, diseases that are curable or manageable for most patients, such as childhood leukemia, may not be able to be treated effectively.

When a drug is in shortage, hospitals must find an alternative drug to provide their patients. This process of finding and procuring an alternative drug can result in significant costs to the hospital. An analysis published in 2019 estimated that drug



shortages result in at least \$359 million annually in additional labor costs to hospitals.¹ Due to the increased cost and necessity of treating patients in a timely manner, especially in cases of cancer and other serious illness, it is important to ensure the pharmaceutical supply chain is protected and priority drugs are identified and given special attention so that continual access is ensured for patients.

However, it has become increasingly clear that our national pharmaceutical supply chain is fragile; this fragility poses significant risk to the patients and communities served by America's hospitals and health systems. Various businesses make up the pharmaceutical supply chain, including suppliers, manufacturers, distributors and group purchasing organizations. A disruption anywhere in the chain can create prolonged difficulties in pharmaceutical supply acquisition for providers, which can directly affect their ability to treat patients.

Exacerbating these difficulties is the "lean" or "just-in-time" framework of supply chain operations. There is effectively little buffer when disruptions occur. Distributors, manufacturers and health care providers have pursued this just-in-time supply chain approach with the goal of lowering costs so that health care is more affordable; however, during large scale emergencies and other disruptions in supply, the risks and added costs of such a strategy is clear. When those disruptions occur, providers often have little or no notice and can be left scrambling to acquire products necessary to care for the sick and injured.

To mitigate these challenges, strengthening the supply chain is crucial. A focus on increasing manufacturing redundancy, diversifying where raw materials are sourced and where products are manufactured, and "fattening" the overall supply chain will provide significant improvements. It will allow the supply chain to withstand expected and unexpected fluctuations in the supply of, and demand for, pharmaceutical products and protect it against future public health emergencies and natural disasters.

This year, the AHA has supported multiple bills in the Senate that take steps to address drug shortages and shore up the pharmaceutical supply chain, including the following.

Mapping America's Pharmaceutical Supply (MAPS) Act (S. 2364). A critical step in protecting America's drug supply chain is understanding its vulnerabilities from the beginning of production to the moment a drug is administered to a patient. The MAPS Act creates a plan for the Food and Drug Administration and the Department of Defense to map the U.S. pharmaceutical supply chain. The act also includes use of data analytics to identify and predict supply chain vulnerabilities and other national security threats. With the information collected and analyzed through the MAPS Act, it will be

¹ <u>https://wieck-vizient-production.s3.us-west-1.amazonaws.com/page-</u> <u>Brum/attachment/c9dba646f40b9b5def8032480ea51e1e85194129</u>

possible to begin addressing weaknesses in the pharmaceutical supply chain.²

Rolling Active Pharmaceutical Ingredient and Drug (RAPID) Reserve Act (S. 2510).

Pharmaceutical shortages and supply chain failures can have a devastating impact on patients. The RAPID Reserve Act would establish a program to improve supply chain resiliency for critical generic drug products, ensuring adequate supply is available even in the event of a shortage. The legislation awards contracts to eligible drug manufacturers requiring them to maintain a six-month buffer of these critical drugs and their active pharmaceutical ingredients to ensure continuous production flow. With adequate supply of necessary drugs, providers will be equipped to administer necessary, often lifesaving, drugs to patients.³

Pharmaceutical Supply Chain Risk Assessment Act of 2023 (S. 1961). The

Pharmaceutical Supply Chain Risk Assessment Act of 2023 would require a comprehensive risk assessment of the entire U.S. pharmaceutical supply chain. This overarching project will help provide critical information necessary to mitigate and prevent drug supply shortages. A disruption anywhere in the supply chain can create prolonged difficulties in pharmaceutical supply acquisition for providers, and avoiding these disruptions before they occur will benefit providers and the patients they serve.⁴

We thank you for the opportunity to submit comments the Senate Committee on Finance regarding drug shortages and look forward to continuing to work with you on this important issue.

² <u>AHA Letter of Support for the Mapping America's Pharmaceutical Supply Chain, or MAPS, Act of 2023</u> <u>AHA</u>

³ <u>AHA Letter of Support for the Rolling Active Pharmaceutical Ingredient and Drug, or RAPID, Reserve Act</u> of 2023 | <u>AHA</u>

⁴ AHA Letter of Support for the Pharmaceutical Supply Chain Risk Assessment Act of 2023 | AHA