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Statement for the Record

Submitted by

The Premier Inc. healthcare alliance

Safeguarding the Pharmaceutical Supply Chain in a Global Economy

House Energy and Commerce Subcommittee on Health

October 30, 2019

The Premier healthcare alliance appreciates the opportunity to submit a statement for the record on the House Energy and Commerce Subcommittee on Health hearing titled "*Safeguarding the Pharmaceutical Supply Chain in a Global Economy"* scheduled for October 30, 2019. We applaud the leadership of Chairwoman Eshoo, Ranking Member Burgess and members of the Subcommittee for holding this hearing to examine the state of the U.S. pharmaceutical supply chain and consider policy solutions to ensure that the U.S. is not overly reliant on foreign manufacturers of active pharmaceutical ingredients (APIs). ***Premier is committed to identifying and addressing the root causes of interruptions in the pharmaceutical supply chain and strongly supports the creation of a competitive marketplace to lower drug prices.***

Premier is a leading healthcare improvement company, uniting an alliance of more than 4,000 U.S. hospitals and health systems and approximately 175,000 other providers and organizations to transform healthcare. With integrated data and analytics, data-driven collaboratives, supply chain solutions, consulting and other services, Premier enables better care and outcomes at a lower cost.

Drug Shortages Threaten the Security of the Pharmaceutical Supply Chain and Patient Safety

Drug shortages continue to plague the healthcare system and have grown in both number and intensity in the past two years.[1] Drug shortages invariably impact patient care, adding time and expense as providers manage supplies and search for therapeutic alternatives that can be less effective and more costly, potentially delaying treatment. Drug shortages are also a major driver of skyrocketing costs contributing to over half a billion dollars in increased healthcare expenditures annually. A recent study found that prices for drugs under shortage increased more than twice as quickly as they would in the absence of a shortage adding $230 million a year to U.S. drug costs.[2] Another recent study found that the price of fluphenazine tablets in 2016 increased by over 2000% during a shortage.[3]

[1] FDA Public Hearing Identifying the Root Causes of Drug Shortages and Finding Enduring Solutions. Available at: https://healthpolicy.duke.edu/events/drug-shortage-task-force

[2] Hernandez I, Sampathkumar S, Good CB, Kesselheim AS, Shrank WH. Changes in Drug Pricing After Drug Shortages in the United States. Ann Intern Med; 170:74–76. doi: 10.7326/M18-1137

[3] Fox E. R., Tyler L. S. (2017). Potential association between drug shortages and high-cost medications. Pharmacotherapy 37, 36–42. 10.1002/phar.1861

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In addition to the increase in drug prices, drug shortages cause a multitude of downstream impacts to the healthcare system that increase healthcare expenditures such as:

- Increased labor costs associated with managing drug shortages, estimated to be $216 million annually.[4]

- Increased potential for adverse events, and consequently increased costs to the healthcare system such as increased hospital days, due to the unavailability of a critical medication. For example, a shortage of norepinephrine was significantly associated with increased mortality amongst patients with septic shock.[5] The FDA estimates that the norepinephrine shortage resulted in $13.7 billion of projected losses to the U.S. healthcare system.[6]

Congress has made major strides in helping to ensure a steady supply of pharmaceuticals and addressing drug shortages by enacting the Food and Drug Administration Safety and Innovation Act (FDASIA) Title X reporting requirements, the track and trace requirements of the Drug Quality and Safety Act, the Competitive Generics Therapy pathway, and others. These Congressional actions have made a significant contribution to the effort to reduce the impact of drug shortages, but more needs to be done to help eliminate drug shortages once and for all.

API or Raw Materials Shortages

More than 80 percent of API and raw materials required for drug manufacturing are manufactured overseas.[7] The heavy reliance on foreign manufacturing of API and raw materials results in downstream drug shortages when a foreign manufacturer fails to meet cGMP or exits the market. In addition, the extent and duration of API or raw material shortages is unknown and results in downstream impact on hoarding and the gray market. Furthermore, the Chinese Blue Sky Initiative is resulting in API and raw material manufacturers being required to either halt production or shut down resulting in concerns that this may further exacerbate shortages, and may result in increased shortages for oral solid dosage forms. Finally, new tariffs are also putting pressure on foreign manufacturers of raw materials and may lead to entities exiting the market resulting in downstream drug shortages.

For example, the recent valsartan recall was due to an impurity with the API and almost all manufacturers relied on a single API manufacturer, resulting in a major shortage. In addition, the recent injectable opioid shortages were exacerbated by an inability of the manufacturer to acquire the raw materials necessary for the injector.

Solutions to Help Ensure a Reliable Supply of API or Raw Materials and Eliminate Drug Shortages

[4] "Impact of drug shortages on U.S. health systems" (American Journal of Health-System Pharmacy, October 2011). https://www.ncbi.nlm.nih.gov/pubmed/21930639
[5] Vail, Emily, Gershengorn, Hayley, Hua, May, Walkey, Allan, Rubenfeld, Gordon & Wunsch, Hannah. (2017). Association Between US Norepinephrine Shortage and Mortality Among Patients With Septic Shock. JAMA. 317.DOI: 10.1001/jama.2017.2841.
[6] FDA Public Hearing Identifying the Root Causes of Drug Shortages and Finding Enduring Solutions. Available at: https://healthpolicy.duke.edu/events/drug-shortage-task-force
[7] Source: http://www.consumerreports.org/cro/news/2014/04/are-generic-drugs-made-in-india-safe/index.htm

Over the past 15 years, Premier has worked closely with high-quality manufacturers to encourage them to bring products to the market to ensure our health systems have an uninterrupted supply of vital medications for the patients they serve. As part of these efforts, Premier identifies safe, high-quality supply sources for drugs that are or may be at risk of being added to the national drug shortage list. Guided by health systems with more than 1,000 hospitals across the nation, this has directly led to the reliable supply of 15 critical shortage drugs in 2019, including metoprolol, cystine hydrochloride, sodium bicarbonate, diphenhydramine, hydromorphone, lidocaine, morphine and thiamine, with plans to introduce additional drugs from a target list of more than 60 products in months to come. This work, therefore, is not done, and we will not stop until we have eliminated drug shortages.

Creating permanent solutions to create a healthy drug market and ensure a reliable supply of drugs has been the mission of Premier since day one. We need, however, policy changes for us to continue to succeed in our work.

We are encouraged that Chairman Pallone and Committee Member Guthrie have devised a bipartisan solution aimed at reducing the quality and manufacturing problems that can threaten the supply of pharmaceuticals. H.R. 4866 would establish a national framework for incorporating continuous manufacturing into the development, review and approval process for drugs and biologics. This is an important component in a comprehensive legislative strategy to eliminate the multi-factorial causes of drug shortages; however, given there is no single cause of drug shortages, a more comprehensive approach is needed.

Premier is also advocating for additional bipartisan solutions to address the root causes of drug shortages that are contained in the Mitigating Emergency Drug Shortages (MEDS) Act (S. 2723), introduced this week by Senator Susan Collins (R-ME) and Senator Tina Smith (D-MN).

First, to create incentives to encourage on-shore manufacturing of API and raw materials, the MEDS Act would extend FDASIA Title X reporting requirements to API and raw material manufacturers, including strengthening the reporting requirements to include:

- Disclosure of the problem resulting in the shortage;
- Source of the API and any alternative sources for the API;
- Extent of the shortage, and the expected duration of the shortage; and
- Expected impact to distribution and availability in pharmacies to help understand the downstream impact on drug shortages.

The MEDS Act would further help safeguard the pharmaceutical supply by:

- Creating a priority pathway for the review of drug shortage applications;
- Requiring manufacturers to report redundancy and contingency plans to ensure ongoing supply;
- Requiring the Secretary to develop a report to Congress with recommendations on consumer notification of shortages;
- Studying FDA's efforts to improve intra-agency and inter-agency coordination to account for the downstream impact of cGMP violations, facility shutdowns, etc on shortages;
- Expanding the FDA drug shortage list to include regional shortages as well as shortages based on strength and dosage form; and

- Examining the risk to national security as a result of shortages.

We strongly urge the Subcommittee to adopt these sustainable, bipartisan legislative strategies alongside H.R. 4866.

In closing, the Premier healthcare alliance appreciates the opportunity to submit a statement for the record on the House Energy and Commerce Subcommittee on Health's hearing on safeguarding the pharmaceutical supply chain. As an established leader in approaches to tackling drug shortages that produce real, tangible results, Premier is available as a resource and looks forward to working with Congress as it considers policy options to address this very important issue.

If you have any questions regarding our comments or need more information, please contact Soumi Saha, Senior Director of Advocacy, at soumi_saha@premierinc.com or 202-879-8005.