PREMIER TRANSFORMING HEALTHCARE TOGETHER®

June 5, 2023

Robert M. Califf M.D.
Commissioner
Food and Drug Administration
10903 New Hampshire Ave
Silver Spring, MD 20993-0002

Submitted electronically via www.regulations.gov

Re: Notification of a Permanent Discontinuance or Interruption in Manufacturing Under Section 506C of the Federal Food, Drug, and Cosmetic Act; Draft Guidance for Industry [Docket Number FDA-2020-D-1057-0008]

Dear Dr. Califf:

Premier Inc. appreciates the opportunity to submit comments to the Food and Drug Administration (FDA) on draft guidance entitled "*Notification of a Permanent Discontinuance or Interruption in Manufacturing Under Section 506C of the Federal Food, Drug, and Cosmetic Act [Docket Number FDA-2020-D-1057-0008]*." FDA is soliciting public comment on providing timely, informative notifications about changes in the production of certain finished drugs, biological products, and their corresponding active pharmaceutical ingredients (API) to help the Agency mitigate shortages. The FDA also seeks public comment on how FDA communicates information about products in shortage to the public.

As a leader in addressing drug shortages for almost twenty years, Premier is pleased to see FDA move forward with implementing provisions from the Coronavirus Aid, Relief, and Economic Security (CARES) Act that Premier played a significant role in passing in March 2020. Premier's comments on the draft guidance focus on reporting requirements for API and urge FDA to extend notification requirements regarding discontinuances and interruptions in the manufacturing of API to the manufacturer of the API itself.

I. Background on Premier Inc. and Our Leadership in Addressing Drug Shortages

Premier is a leading healthcare improvement company, uniting an alliance of more than 4,400 U.S. hospitals and health systems and 250,000 continuum of care providers to transform healthcare. With integrated data and analytics, collaboratives, supply chain solutions, consulting and other services, Premier enables better care and outcomes at a lower cost. A 2006 Malcolm Baldrige National Quality Award recipient, Premier plays a critical role in the rapidly evolving healthcare industry, collaborating with providers to co-develop long-term innovations that reinvent and improve the way care is delivered to patients nationwide. A key component of Premier's alliance is our Integrated Pharmacy Program, which combines essential clinical data with purchasing power to deliver reduced costs, improved quality, safety and resiliency, and increased knowledge-sharing among healthcare professionals.

Premier has been a leader in addressing drug shortages for more than twenty years and is committed to eliminating drug shortages from both a policy perspective via legislative and regulatory action as well as pursuing market-based solutions. Premier's ProvideGx program 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 1,600 hospitals across the nation, Premier's ProvideGx program creates long-term committed buying contracts that provide participating manufacturers with the surety needed to increase production. Premier's programs, including ProvideGx, currently provide hospitals access to more than 150 drugs that are or have been recently designated as shortage drugs.

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Since 2020, Premier's drug shortage programs have:

- Successfully resolved 14 drug shortages, resulting in their official delisting from the FDA shortage list.
- Ensured uninterrupted supply of many shortage drugs despite demand spikes of more than 150 percent during the pandemic.
- Continued to bring resiliency to the market by incenting the domestic manufacture of vital drugs through investments in VGYAAN and Exela Pharma Sciences, which combined are working to bring new, domestic sources of 20 different shortage drugs and counting.

A key component to Premier's success in mitigating drug shortages is the stringent contracting and vetting process manufacturers who wish to work with Premier must undergo. This includes sharing information regarding the location of their finished dose manufacturing and API source. In addition, all manufacturers participating in Premier programs are vetted to enable more geographically diverse production capability, adequate safety stocks and surge capabilities to meet sudden spikes in demand. Finally, manufacturers are asked to share their redundancy and contingency plans to ensure ongoing supply of product and mitigate risk. Premier maintains this level of information for almost 6,000 unique National Drug Codes (NDCs) and leverages the information to assign a supply chain resiliency risk score to each product. That score is then utilized by Premier and its hospital-led sourcing committees to make contracting decisions that are in the best interest of patient care and supply chain resiliency.

Premier's ongoing commitment to addressing drug shortages also includes diligent advocacy efforts over the years including serving as the lead proponent of the Mitigating Emergency Drug Shortages (MEDS) Act which was incorporated and signed into law as part of the CARES Act in March 2020. Premier's efforts resulted in amendments to the supply disruption notification provisions of the Federal Food, Drug, and Cosmetic Act which now require manufacturers to report additional information regarding (1) a permanent discontinuance in the manufacture of certain products; (2) an interruption in the manufacture of certain products that is likely to lead to a meaningful disruption in supply of those products in the United States; (3) a permanent discontinuance in the manufacture of API for certain products; or (4) an interruption in the manufacture of API for certain products that is likely to lead to a meaningful disruption in the supply of the API for those products. Furthermore, manufacturers are also now required to include full disclosure of the problems resulting in a shortage, information concerning the extent of a shortage, its expected durations, and other information the Secretary may require.

Premier is pleased to see the FDA move forward with implementing these provisions with release of this draft guidance. However, Premier is also concerned by the lag time of over three years in releasing the draft guidance since the passage of the CARES Act in March 2020. Drug shortages continue to plague the U.S. healthcare system and it is troubling to see the FDA take a passive approach to implementing its new statutory authority.

Premier will continue to innovate and collaborate across diverse stakeholders to address ongoing drug shortages.

II. Notification of Discontinuances and Interruptions by API Manufacturers

In drafting the MEDS Act, one of the major hurdles lawmakers were attempting to address was the downstream impact of any potential API shortages on drug shortages, especially given upwards of 80 percent of the world's API is manufactured overseas.[1] The heavy reliance on foreign manufacturing of API and raw materials has resulted in downstream drug shortages when a foreign manufacturer fails to meet cGMP or exits the market. For example, a recent valsartan recall was due to an impurity with the API and almost all manufacturers of the finished-dose relied on a single API manufacturer, resulting in a major shortage. Therefore, lawmakers crafted the MEDS Act to expand FDASIA Title X reporting requirements to

[1] https://www.consumerreports.org/cro/news/2014/04/are-generic-drugs-made-in-india-safe/index.htm

API manufacturers and require reporting of potential supply disruptions of API to the FDA, creating an early warning system that would allow the FDA upstream visibility to appropriately assess risk and rapidly work to identify alternative sources of supply.

The draft guidance outlines that notification requirements regarding discontinuances and interruptions in the manufacturing of API are only applicable to the manufacturer of the finished-dose product, not the manufacturer of the API itself. ***Premier has serious concerns that FDA's interpretation of the CARES Act provisions is counter to Congressional intent. In passing the CARES Act, Congress intended to create upstream visibility into potential disruptions in the pharmaceutical supply chain and hold API manufacturers accountable for reporting discontinuances and interruptions to help mitigate potential downstream shortages as early as possible***. Passing this burden to finished-dose manufacturers who may not have proper visibility into API production, supply, or market share to determine early warning signals of a potential shortage is counter to the intent of the legislative language which is to hold manufacturers of API accountable for supply chain sustainability. ***Therefore, Premier urges FDA to reevaluate its interpretation of the CARES Act provisions and extend notification requirements regarding discontinuances and interruptions in the manufacturing of API to the manufacturer of the API itself.***

III. Conclusion

In closing, Premier appreciates the opportunity to submit comments on the draft guidance "*Notification of a Permanent Discontinuance or Interruption in Manufacturing Under Section 506C of the Federal Food, Drug, and Cosmetic Act*." Premier looks forward to continuing to work with the FDA to finalize guidance and other policies to help prevent drug and biological shortages.

If you have any questions regarding our comments or need more information, please feel free to contact me at soumi_saha@premierinc.com or 732-266-5472.

Sincerely,

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Senior Vice President, Government Affairs
Premier Inc.