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June 5, 2023

Dockets Management
Food and Drug Administration
Dockets Management Staff (HFA-305)
5630 Fishers Lane, Rm 1061
Rockville, MD 20852

Re: Notifying FDA of a Discontinuance or Interruption in Manufacturing of Finished Products or Active Pharmaceutical Ingredients Under Section 506C of the FD&C Act Draft Guidance (Docket No. FDA-2020-D-1057)

Dear Commissioner Califf,

On behalf of over 200 children's hospitals across the country, the Children's Hospital Association (CHA) appreciates the opportunity to provide comments on the Food and Drug Administration's (FDA) draft guidance, *"Notifying FDA of a Discontinuance or Interruption in Manufacturing of Finished Products or Active Pharmaceutical Ingredients Under Section 506C of the FD&C."* We applaud the FDA's efforts to ensure that the U.S. is better prepared to respond to future drug shortages and encourage you to prioritize the distinct needs of children, who represent 25% of the total U.S. population. We support this guidance and offer several recommendations to further strengthen it to address the unique challenges facing the pediatric drug supply chain.

We strongly support efforts to strengthen and stabilize the nation's drug supply chain to forestall shortages, particularly those that could affect children's health, to help ensure that our nation's most vulnerable patients have access to safe and effective health care. It is critical that you work with manufacturers and suppliers, industry associations and pediatric providers, including children's hospitals, to specifically address and mitigate pediatric drug and related supply shortages. It is also critically important to guarantee that all available supply is shared, as appropriate, with children's hospitals so they can continue to provide high quality specialized care to children who need it. Pediatric care relies on uniquely formulated drugs to support proper pediatric pharmaceutical dosing, as well as practical methods for appropriate medication delivery for children (such as oral, pediatric auto-injectors, etc.) that are created with children's growing bodies and developing systems in mind.

Implications of drug supply chain disruption for pediatric care

Children's hospitals have long faced shortages of critical drugs and related supplies that their child patients rely on for treatment and recovery. A drug supply shortage is particularly challenging in children's health care because pediatric care requires specialized therapies and the appropriate equipment to administer them. However, there are fewer manufacturers of pediatric-appropriate drugs and related supplies, which means the pediatric supply chain is easily disrupted. In fact, a recent report[1] finds that more than half of pediatric drugs had only one to two manufacturers currently supplying the dosage form most used by children's hospitals.

[1] Pediatric Drug Shortage Trends and Best Practices for Mitigation Strategies. Children's Hospital Association and Vizient. 2020.

As a result, children's hospitals are disproportionately impacted by drug shortages compared to non-pediatric hospitals. Children's hospitals spend more hours managing shortages than non-children's hospitals—51 hours compared to 36 hours per drug shortage. This additional time is often dedicated to compounding replacement products into safe pediatric dosage forms and as a result, children's hospitals are more than twice as likely to hire additional staff. Children's hospitals report that, on average, the cost to manage one drug shortage from onset to correction is approximately $50,000, in addition to the actual cost of the drug itself.

In addition, pediatric essential drugs, such as antineoplastics and plasma products used to treat critical conditions including sepsis, cancer and immune deficiencies, are more likely to be impacted by shortages. Ongoing drug shortages also affect lifesaving electrolytes, including calcium chloride, magnesium, potassium, sodium, and certain acids, which are essential for maintaining the health of nerves and muscles, including those in the brain, heart, lungs, and other vital organs.

Shortages impact care protocols when drugs must be changed to alternatives, or worse yet, delayed or canceled altogether because an appropriate substitute specifically geared for pediatric patients is not as readily available. Sometimes the location of care must abruptly change—care intended to be provided in a community setting close to a child's home may have to be moved to a setting further away, requiring parents to take off work and children to miss school. Drug shortages can lead to adverse clinical outcomes for pediatric patients, such as increased rates of drug errors and possible disease relapse, with potentially detrimental impacts on their long-term health and well-being.

Solutions to address pediatric drug and related supply shortages

The nation's drug supply chain infrastructure must be strengthened to prevent avoidable shortages of vital pediatric drugs and related supplies and to adapt and respond quickly to shortages with the goal of providing high-quality products to deliver optimal child health. Several key opportunities to further strengthen the FDA guidance and prevent and mitigate pediatric drug shortages are highlighted below.

Ensure that pediatric-specific shortages are an integral part of the requirements related to manufacturer and distributor transparency. We strongly support the guidance's focus on manufacturer transparency and urge the FDA to include specific language that would require manufacturer and distributor transparency related to pediatric products throughout the supply chain, including the location of production and a clear timeline on product availability. The absence of this timely information hinders proactive steps that providers, policymakers and suppliers can take to collaboratively prepare for and mitigate possible shortages of essential pediatric drugs and related supplies. Transparency on the availability of pediatric drugs is vital for providing life-saving treatments to patients.

Ensure that an appropriate accounting of pediatric drugs is included on the FDA drug shortages list. We strongly support the FDA's efforts to communicate drugs and biological products in shortage and urge you to specifically require a timely accounting of pediatric populations and pediatric drug formulations, including the potential for regional shortages.

Develop proactive pediatric shortage mitigation plans. While we support the requirements related to mitigation of shortages generally, we urge the FDA to require manufacturers and distributors to have proactive shortage mitigation plans and/or competition in production of pediatric products that are often sole-sourced or under-resourced.

Finally, we strongly encourage the FDA to issue additional pediatric-specific guidance and work closely with other governmental agencies to ensure that efforts to address drug shortages throughout government are aligned, coordinated, and strengthened to support the needs of pediatric patients. Developing a more efficient and reliable pediatric pharmaceutical supply chain will help children's hospitals identify and leverage data to reduce supply spend, improve organizational effectiveness, and strengthen educational opportunities for clinical staff so pediatric patients receive the highest quality products in a timely manner.

We thank you for the opportunity to provide comments and look forward to continuing to work with you to improve children's health care. Please contact Natalie Torentinos at natalie.torentinos@childrenshospitals.org or (202)753-5372 should you need more information.

Sincerely,

Aimee C. Ossman
Vice President, Policy Analysis
Children's Hospital Association