
Children's Hospital Association Statement for the Record

U.S. House Committee on Energy and Commerce Hearing

“Examining the Root Causes of Drug Shortages: Challenges in Pharmaceutical Drug Supply Chains.”

May 11, 2023

On behalf of the nation's children's hospitals and the children and families we serve, thank you for holding this hearing, “Examining the Root Causes of Drug Shortages: Challenges in Pharmaceutical Drug Supply Chains.” We applaud your efforts to ensure the U.S. is better prepared to respond to future drug and supply shortages and encourage you to prioritize the distinct needs of children, who represent 25% of the total U.S. population. We strongly support efforts to strengthen and stabilize the nation's 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.

We ask Congress to place a strong emphasis on pediatric-focused research and development, procurement strategies and guidance that can provide timely access to sufficient pediatric-appropriate medications and supplies. It is critical that Congress works with suppliers, industry associations and providers to mitigate the impacts of drug and supply shortages on patients and to guarantee that all available supply is shared, as appropriate, with children's hospitals to provide high-quality care. Pediatric care must include the needed drugs and supplies to administer them properly since they are created with children's growing bodies and smaller size in mind.

Drug and supply chain disruption implications for pediatric care

Children's hospitals have long faced shortages of critical drugs and supplies that their child patients rely on for treatment and recovery. A drug or supply shortage is particularly challenging in children's health care because pediatric care requires specialized medications, therapeutics and equipment. However, there are fewer manufacturers of pediatric-appropriate supplies, which means the pediatric supply chain is easily disrupted. In fact, a recent report¹ 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.

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, they 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.

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

Furthermore, children's hospitals experience shortages of pediatric supplies earlier than adult hospitals because manufacturers and distributors consider pediatric utilization to be less profitable. Products dedicated to this small, specific patient population do not provide the same return on investment as adult products, leading manufacturers to place less of a priority on those products in supply chain planning.

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 or supplies must be changed to alternatives, or worse yet, delayed or canceled all together 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 and supply 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.

Congressional Action Needed

The nation's drug supply chain infrastructure must be strengthened to prevent avoidable shortages of vital pediatric drugs and 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 for congressional action to prevent and mitigate pediatric drug and supply chain shortages are highlighted below.

Require manufacturer and distributor transparency. We urge Congress to ensure manufacturer and distributor transparency 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. Transparency on the availability of pediatric drugs and supplies 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. Congress should require the FDA to adjust its drug shortages list to provide a timely and accurate accounting of pediatric populations and pediatric drug formulations, including the potential for regional shortages.

Develop proactive shortage mitigation plans. Congress can reduce the risk of pediatric drug and supply shortages by encouraging the FDA to issue guidance and work with 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.

Strengthen funding support for research and development of pediatric drugs. We urge Congress to invest in pediatric-focused research, development and procurement of drugs, and to require the development of targeted strategies and guidance that can ensure timely access to sufficient pediatric-appropriate equipment, medications and supplies and a quick response to shortages. Congress should require resources to be directed to research on

pediatric dosing and formulations that are already approved for adults. Congress should also require properly dosed pediatric medications and delivery mechanisms to be available and ready for rapid deployment.

Efforts to address drug shortages throughout government must be aligned, coordinated, strengthened and adequately funded to support the needs of pediatric patients. Developing a more efficient and reliable supply chain will help children by allowing children's hospitals identify and leverage data to reduce supply spend, improve organizational effectiveness, and strengthen educational opportunities for clinical staff so pediatric patients received the highest quality products in a timely manner. Thank you again for your commitment to ensuring the needs of children are met when addressing drug and supply shortages. Children's hospitals stand ready to partner with you to advance policies that will make measurable improvements in the lives of our nation's children.