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August 24, 2023

The Honorable Cathy McMorris Rodgers
Chair
Committee on Energy and Commerce
United States House of Representatives
Washington, DC 20515

Re: E&C Discussion Draft *"Stop Drug Shortages Act"*

Dear Chair McMorris Rodgers,

On behalf of the nation's children's hospitals and the patients and families we serve, thank you for the opportunity to respond to your discussion draft, *Stop Drug Shortages Act*. We appreciate your efforts to ensure the nation 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 strongly support efforts to strengthen and stabilize the nation's drug supply chain to forestall—and address—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.

The more than 200 children's hospitals that comprise the Children's Hospital Association (CHA) are dedicated to the health and well-being of our nation's children. Children's hospitals advance child health through innovations in the quality, cost and care delivery—regardless of payer—and serve as a vital safety net for uninsured, underinsured and publicly insured children. Medicaid, on average, provides health insurance coverage for half of children's hospitals patients and for some children's hospitals patient mix, closer to three-quarters. Though children's hospitals account for only 5% of hospitals in the U.S, they account for about 45% of all hospital days for children on Medicaid. We are regional centers for children's health, providing highly specialized pediatric care across large geographic areas.

Children's hospitals have long faced shortages of critical drugs and related supplies that their vulnerable patients rely on for treatment and recovery. A drug shortage is particularly challenging in children's health care because pediatric care requires specialized therapies and the appropriate equipment for their safe administration. There are also fewer manufacturers of pediatric-appropriate drugs and related necessary supplies, which means the pediatric supply chain is easily disrupted—putting children's health at risk.

Children's hospitals, and the patients we serve 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.

Below please find our detailed recommendations on specific provisions of the draft that we believe will strengthen the legislation and help ensure that the nation's supply chain is prepared to forestall and mitigate shortages, particularly those with implications for children's health.

Pediatric Recommendations for 340B Provisions

The 340B program supports children's hospitals in their mission to serve low-income and underinsured children, regardless of their insurance status. Children are largely insured by Medicaid and the Children's Health Insurance Program, but children's hospitals qualify for 340B because a significant shortfall exists between the cost of care and Medicaid payment. Children's hospitals depend on the 340B program to provide vulnerable patients with access to life-saving medications. The program has been a critical resource for children's hospitals in helping offset low Medicaid reimbursement rates and enabling them to further stretch resources to support initiatives that provide essential care to children and their families. We believe that the 340B program is working as intended to help safety net providers, including the more than 50 children's hospitals that take part in the program.

Exempting Generic, Sterile Injectable Drugs from the 340B Drug Discount Program (Section 201).

We encourage Congress to preserve access to generic drugs in the 340B Drug Discount Program and to work with manufacturers on the establishment of appropriate reimbursement for pediatric generic drugs. The financial support provided by the 340B program as a result of pharmaceutical manufacturers reducing outpatient generic and other drug prices enables children's hospitals to serve vulnerable patients, improve access to care and provide more comprehensive services. For example, some hospitals have used the savings to partially subsidize the cost of providing behavioral health services, annual flu vaccinations, affordable generic prescription drugs and hemophilia treatment centers.

However, due to a low return on investment, fewer manufacturers pursue generic-abbreviated new drug applications for pediatric populations. The determination of adequate prices and reimbursement levels for generics (and all drugs) must account for all aspects of their development, as well as their delivery to the patient, including risk of handling and professional services—such as compounding, infusion, counseling, etc.

Study on Penny Pricing and Other Price Setting Policies (Section 202).

We encourage Congress to task the Government Accountability Office with studying the business practices of drug manufacturers in response to penny pricing. Penny pricing is an important tool to ensure that manufacturers do not raise prices above inflation. However, there is no publicly available report to demonstrate the frequency of these activities.

We also urge Congress to establish guardrails to prevent problematic actions that could impact access to drugs subject to penny pricing. For example, the producer of a leukemia drug that was successfully used in pediatrics for many years was recently subject to penny pricing. The manufacturer later announced the removal of the pediatric application—without clinical justification—for a more profitable drug. These types of unwarranted changes in pediatric drug availability coming from manufacturers' inappropriate reactions to penny pricing can lead to uncertainty in the supply chain for our most vulnerable populations.

Guidance on Preventing Diversion During Shortages (Section 203).

We are pleased the draft legislation tasks the Health Resources and Services Administration with issuing guidance to covered entities on ways to prevent diversion when sharing 340B-covered drugs during shortages. In addition to 340B drugs, we encourage Congress to explore mechanisms to share all essential drugs during shortages with the appropriate safeguards against diversion, especially pediatric-specific essential drugs like chemotherapy treatments. It is critical that suppliers and government agencies ensure that all available drug supply—and the appropriate data to advance drug supply chain efficiencies—is shared to meet the health care needs of patients who need them.

To that end, we encourage Congress to consider additional ways to address diversion, such as authorizing the FDA to provide certain Drug Supply Chain Security Act (DSCSA) exceptions to allow for streamlined sharing of information on drug product data among manufacturers, wholesalers, providers and pharmacies during shortages. For example, under current restrictions, hospitals can share a product only when linked to a specific prescription. An exception that allows providers to share product based on anticipatory needs during a shortage, rather than solely based on patient-specific needs, would be especially impactful in addressing pediatric drug shortages. Children's hospitals are at a disadvantage when a specific drug becomes short as compared with adult hospitals, which are more likely to be consolidated and can easily trade products.

In addition, we recommend that manufacturers and/or distributors receive civil penalties for selling drugs to the gray market. The purpose of the DSCSA is to enable a secure, confidential flow of data along the pharmaceutical supply chain to ensure patients receive the medications they need. When companies operate outside distribution channels not authorized by drug manufacturers, medications are diverted out of the legitimate supply chain. For example, the pediatric cancer drug—methotrexate—has been sold to the gray market and is experiencing a shortage. Diversion of this essential pediatric drug causes delays in chemotherapy infusions and risks child patients' long-term health outcomes.

Pediatric Recommendations for the Food and Drug Administration (FDA) Provisions

The FDA's authority must be strengthened to give it the tools 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. It is critical that the FDA work with manufacturers, suppliers and pediatric providers—including children's hospitals—to specifically address and mitigate pediatric drug and related supply shortages.

Incentive for Shelf-life Extension Studies (Section 502).

We support awarding an additional month of exclusivity for shelf-life extension studies, but protections should be in place to prevent manufacturers from setting unreasonable prices during the exclusivity period. In particular, we urge Congress and the FDA to explore safe and effective pathways—as part of the shelf-life extension studies—to allow pediatric providers to use expired pediatric drugs to avoid and mitigate shortages. Expiration dates guarantee a certain length of stability, but many medications can have much longer shelf lives than labeled. For example, an expired supply of the pediatric cancer drug, methotrexate, could still be safe to use, as long as providers have accurate and appropriate information about its shelf life.

Furthermore, expiration dating can present particular challenges to medical countermeasure (MCM) stockpilers because, in most cases, MCMs that have reached their labeled expiration date cannot be used. However, testing has shown that certain properly stored medical products can be used beyond their labeled expiration date if they retain

their stability. [1] For MCMs to meet the unique needs of children in the event of a pandemic or natural disaster there needs to be a strong focus on procurement, strategy and guidance that can ensure timely access to—and rapid deployment of—sufficiently stable pediatric-appropriate medications. Policies and procedures that help maximize the use of an existing pediatric medication supply—including those that may be expired—can be a critical tool for providing needed medications to child patients during shortages or as an MCM during a pandemic or natural disaster.

Providing for a Lag Period for Outsourcing Facilities to Compound and Distribute Drugs in Shortage (Section 503).

We support providing an extended period for 503B outsourcing facilities to distribute drugs after they appear on the drug shortage list. We urge Congress to consider extending that lag period to at least a year to allow more time for these facilities to recoup their expenses and for hospitals to recover from the shortage impact.

503B compounding facilities can play a vital role in preventing the impact of pediatric drug shortages. For example, earlier this year, children's hospitals across the country started to see a shortage in albuterol, which prompted hospital/supplier collaboration. Just when the manufacturers of albuterol in the U.S. stopped production, there was an uptick in off-season RSV, flu and COVID-19 that created a shortage when it was needed most. A 503B outsourcing facility that provides compounded pediatric medication worked with children's hospitals to secure the active pharmaceutical ingredients for albuterol. This partnership among hospitals and compounding facilities proved crucial when ensuring a stable supply chain for pediatric patients. More time for 503B facilities to compound and distribute shortage drugs would be a useful mechanism to meet ever present shifts in demand as we experience during this recent surge.

Additional Information on Generic Drug Active Pharmaceutical Ingredients (API) (Section 504).

We support requiring generic drug application holders to include more information on API manufacturers to better monitor the supply chain and mitigate potential triggers that could lead to pediatric drug shortages. It is important to consider the formulation components and the potential for any adverse effects in a vulnerable age group, especially for children.

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. The API is particularly crucial when determining dosage, clinical effects and adverse drug reactions for a pediatric patient. Furthermore, during a crisis like the COVID-19 pandemic or a natural disaster, information about the API manufacturers is especially vital as difficulty in determining the sourcing and vulnerabilities of API supply puts children who rely on unique drug formulations and delivery methods at risk.

Conclusion

Finally, efforts to address drug shortages throughout government must be aligned, coordinated, strengthened and adequately funded to specifically support the needs of pediatric patients. Developing a more efficient and resilient

[1] Expiration Dating Extension | FDA

pediatric drug supply chain is essential to ensuring that our child patients receive the highest quality products in a timely manner.

Thank you again for the opportunity to provide feedback. We look forward to working with you to ensure the needs of children are met when addressing drug shortages. Please contact Natalie Torentinos at Natalie.Torentinos@childrenshospitals.org or (202) 753-5372 should you need more information.

Sincerely,

Aimee Ossman
Vice President, Policy
Children's Hospital Association