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January 31, 2022

The Honorable Richard Hudson
United States House of Representatives
2112 Rayburn House Office Building
Washington, D.C. 20515

The Honorable Jim Banks
United States House of Representatives
1713 Longworth House Office Building
Washington, D.C. 20515

The Honorable Tom Cole
United States House of Representatives
2207 Rayburn House Office Building
Washington, D.C. 20515

Dear Representatives Hudson, Banks and Cole:

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 request for information (RFI) on Pandemic Preparedness; Public Health; and Supply Chains. As you consider policy approaches to address pandemic preparedness and related issues, we urge you to remember that national disaster and pandemic response infrastructure, as well as public health interventions, must be able to meet the unique physical, mental, developmental and social needs of all children.

The more than 220 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 delivery of care—regardless of payer—and serve as a vital safety net for uninsured, underinsured and publicly insured children. We are regional centers for children's health, providing highly specialized pediatric care across large geographic areas.

Children are not little adults and their health care needs, the delivery system to meet those needs, and support systems (e.g., schools, childcare settings) are different from those of adults. Children are constantly growing and developing, and disruptions in their care, trauma, social isolation, financial stresses, food and housing insecurity, and grief associated with a natural disaster or pandemic can have a significant negative impact on children's mental and physical health and their long-term well-being. This is especially true for children in underserved, under-resourced, and racial and ethnic minority communities who face a range of environmental and socio-economic challenges.

Pediatric care typically involves other family members or guardians, and requires extra time, monitoring, specialized medications and equipment, and specially trained health care providers who are compassionate and understand kids of all ages and from all backgrounds. Children's hospitals, unlike adult-focused medical facilities, are equipped to provide this child-centric care. However, children's specialty care is regional in nature, with children's hospitals serving large geographic areas. They are increasingly the only places in their region with the breadth of pediatric specialists and subspecialists, equipment and other resources required to treat children, particularly those with rare and complex clinical conditions. Furthermore, teams of pediatric specialists are typically concentrated near large children's hospitals, underscoring the regional nature of pediatric specialty care for high-acuity conditions.

As a result, it is not uncommon for children, particularly those with medical complexity or specialized health care needs, to travel out of their community, region or state to receive the care that can only be provided at a children's hospital. For these children, the children's hospital is the focal point of care, as pediatric specialists are frequently needed to provide expertise in treating their rare and complex clinical conditions.

Our following responses to relevant aspects of your RFI highlight the ways that any policy solutions focused on pandemic preparedness and the public health infrastructure can meet the unique needs of all children, including the very specialized needs of children with complex conditions.

Pandemic Preparedness

Question #1: The medical countermeasures (MCM) enterprise

- **What steps can Congress take to ensure the sustainability of our MCM response capabilities?** For MCMs to meet the needs of children, there needs to be a strong focus on research, development, procurement, strategy and guidance that can ensure timely access to sufficient pediatric-appropriate equipment, medications and supplies. Countermeasures must address not only immediate threats to children's physical health but also the impact of public health emergencies on children's long-term physical and mental health. In addition, formal linkages and communication systems must be established and used between key federal agencies—such as the Assistant Secretary for Preparedness and Response (ASPR) and FDA—and pediatric providers to ensure that the needs of children and their families are identified and incorporated into the planning and development of medical countermeasures.

  In particular, the advancement (clinical development and manufacturing) of MCMs for children must include pediatric formularies that support proper pediatric pharmaceutical dosing, as well as practical methods for appropriate medication delivery for children (oral, pediatric auto-injectors, etc.). In addition, priority should be given to research on pediatric dosing and formulations for medical countermeasures that are already approved for adults. Both properly dosed medications and delivery mechanisms must be available and ready for rapid deployment. Relevant federal agencies, such as the CDC, ASPR and FDA, should be authorized to develop a process that allows for the advance approval—through the emergency use authorization process—of off-label use of medical countermeasures for children before the declaration of a public health emergency. Finally, we urge Congress to ensure that research on pediatric countermeasures is not limited or delayed due to possible additional costs related to special protections required for children in clinical trials.

Question #2: Stocking and maintaining the Strategic National Stockpile (SNS)

- **Are there other products and MCMs Congress should explicitly require the SNS to stock?** The national stockpile must include emergency medications in age-appropriate delivery formulations, equipment and related supplies that meet children's needs. The stockpile's distribution system must include a communication structure on the availability of specific supplies to ensure the appropriate allocation of necessary pediatric supplies to all medical facilities. At a minimum, all emergency departments should be equipped with a basic kit that can be adapted for use with children and includes infant formula, diapers, safe sleeping facilities and other necessities for the care of infants and toddlers.

Question #3: Accelerated pathways for development, testing, and approval of vaccine candidates

- **What changes to the vaccine development and approval process proved most beneficial to the timely development of COVID-19 vaccines? What changes might the federal government have made that would prove more beneficial still?** There needs to be a strong emphasis on research and development specifically focused on pediatric vaccines. Those efforts must include the early (i.e., prior to the initiation of the emergency use authorization process) and ongoing input of pediatric pharmacists, providers, researchers, and suppliers who can provide their expertise regarding proper dosing, packaging, distribution, procurement and administration mechanisms appropriate for children of various ages. Mechanisms to solicit pediatric input must be coordinated across sectors to reduce duplication and fragmentation that could lead to errors in dosing, vaccine vial sizes, dilutions and related packaging and possible safety issues for children, as well as delays in access to needed vaccines.

- **As Congress looks toward the reauthorization of the Pandemic and All-Hazards Preparedness and Advancing Innovation Act, how might Congress codify what worked during the COVID-19 pandemic for future pandemics?** Any legislation addressing pandemic preparedness, including the Pandemic and All-Hazards Preparedness and Advancing Innovation Act, must continue, support and bolster existing pediatric-focused

initiatives at ASPR and HRSA, as well as the National Advisory Committee on Children and Disasters, and private sector entities such as the American Academy of Pediatrics and Children's Hospital Association. These initiatives are critical to ensuring that the national pandemic response infrastructure appropriately addresses the needs of children. These efforts and others throughout government must be aligned, coordinated, strengthened and adequately funded to support a shared pediatric mission and framework

Question #8: What other policy considerations should Congress examine concerning reauthorization of the Pandemic and All-Hazards Preparedness and Advancing Innovation Act?

It is imperative that Congress consider the full range of pediatric-specific strategies that are needed to ensure that children and their families have ready access to pediatric-appropriate care, including clinical, pharmaceutical and mental health interventions during a pandemic to support both their physical and mental health. Pandemic preparedness strategies must include coordinated pediatric care plans that address the operational capacity of the nation's medical facilities to meet children's physical and mental health needs—as well as their entire caregiving/support system—through appropriate staffing, specialized equipment, training and other child-centric resources. Given the regionalization of pediatric specialty care, children's hospitals' critical care and "surge" capacity for children is limited adding a significant level of complexity to the nation's capacity to meet children's needs. Therefore, it is particularly critical that pediatric experts, including children's hospitals, community pediatricians, pediatric specialists, child mental health providers, pediatric pharmacists, pediatric physical and occupational therapists, pediatric nutritionists and pediatric medical suppliers, are included in short and long-range planning.

Preparedness and response efforts also must include immediate targeted support to address pediatric workforce shortages and strengthen pediatric capacity to allow for the triage/consolidation of pediatric patients to centers best designed for their care. When a children's hospital is not in the general geographic area, more general improvements are needed to equip all hospitals and freestanding emergency facilities with the operational capability to provide care for children during a public health emergency. Those medical facilities should have age and size-appropriate equipment and medications, specific staff training on children's physical and mental health needs during a public health emergency, age-specific policies and procedures, as well as written pediatric interfacility transfer agreements and interoperability capabilities to allow for electronic access to specialized pediatric clinical and mental health care providers for remote consultations.

In addition, all medical facilities should be required to have policies and procedures for the provision of nutrition (e.g., formula), cribs and other appropriate sleeping accommodations, diapers, etc., for infants and toddlers. They also should be equipped to provide accommodations, including beds and food for the families of child patients during pandemic and disaster situations. Finally, the pandemic and disaster response system must include mechanisms to allow for the continuation of key pediatric services in the community. These include immunization programs, services for children with special health care needs, child nutrition programs, newborn screening, children's mental health services and other services for at-risk children.

Public Health

Question # 14: Social determinants of health

Early childhood is a critical period of human development that lays the foundation for lifelong skills and healthy development. When children's basic human needs are not met in early childhood, that experience can have long-term implications for health and achievement. As you consider public health interventions and strategies related to social determinants of health (SDOH), it is critical to specifically address the far-reaching short and long-term impacts that environmental, socio-economic challenges, and adverse experiences have on children's health and well-being, particularly children with complex or chronic medical conditions. The impact of multiple challenges can be cumulative, putting children at higher risk for both physical and mental illnesses, and higher health care costs as a result, well into adulthood. For example, CHA has conducted research using hospital admissions data from the Pediatric Health Information System and the Child Opportunity Index (COI) to look at how neighborhood context impacts health outcomes. Neighborhood context, measured by the COI, looks at different features of children's neighborhood environments, including air pollution, quality of housing, access to transportation, proximity to primary care providers and community economic

resources. This research found that children living in very low COI neighborhoods are at significantly higher risk of primary care preventable hospitalizations versus those in very high COI areas (80 per 1,000 children vs. 30 per 1,000 children.[1] Children who come from lower-income families are more likely to experience asthma, migraines/severe headaches and ear infections, after controlling for other factors.[2] Among children's hospitals, higher inpatient costs for four of five common pediatric conditions were associated with lower household income.[3]

Finally, and importantly, measuring the outcomes of SDOH policy and program initiatives for children is a very different process than measuring outcomes for adults. Child outcomes are often seen years down the road, rather than more instantaneously as is the case for adults. In addition, any savings in the cost of children's health care as a result of earlier interventions are best measured in the long rather than short-term. Child-centric models need to look to the future and the long-term savings that can be achieved by investing in this generation of children's health. Our detailed responses to your specific questions are below.

To what extent do federal health programs already account for and address social determinants of health? Medicaid and CHIP play a critical role in addressing SDOH affecting children and those efforts should be supported and bolstered. More than 50% of the beneficiaries on Medicaid are children, and Medicaid provides them with access to needed medical services so they can grow to become healthy and productive adults. Medicaid provides children access to a strong and comprehensive set of services through the Early and Periodic Screening, Diagnostic, and Treatment (EPSDT) benefit. This ensures children receive preventive services, such as immunizations and well-child checkups, as well as pediatric specialty, ancillary and therapy services, and behavioral health, vision and dental services. In addition, for children with complex medical conditions, Medicaid provides coverage or fills coverage gaps for services not covered by private insurance.

Better coordination is needed at the federal level amongst a range of programs and with Medicaid to adequately begin to address SDOH, particularly for children and youth and their families. For example, federal programs frequently rely on similar measures of eligibility but may still require burdensome and repetitive application processes to access or continue benefits. Potential solutions to these eligibility challenges are already under consideration by Congress and should be supported.

- **Medicaid and CHIP express lane eligibility**. Enacting express lane eligibility can help ease the burden on families by streamlining enrollment processes across programs with the same or very similar eligibility requirements.
- **Medicaid and CHIP 12-month continuous eligibility**. Enacting 12-month continuous eligibility for children on Medicaid and CHIP would reduce gaps in coverage and improve continuity of care. The temporary continuous eligibility protections in Medicaid and CHIP that will last for the duration of the public health emergency have reduced the eligibility churn that occurs when families have a temporary fluctuation in income or run into difficulties with paperwork, resulting in gaps in coverage.

In addition, Congress should incentivize states to build infrastructure that enable various programs' data systems to better integrate to facilitate better communication across systems and services is critical. Congress should also consider ways to expand access to payers' claims data. Claims data plays a critical role in the identification of gaps in care, resources used, etc. For example, claims data can show which enrollees have or have not complied with well-child check-ups and can partner with health systems and community members to help design interventions that include targeted outreach to patients.

- **How can Congress best address the factors that influence overall health outcomes in rural, Tribal, and other underserved areas to improve health outcomes in these communities?** Support for programs that reduce childhood poverty and create safe stable environments for children are essential to children's physical and

[1] For more information, see this study in *Pediatrics* (https://pediatrics.aappublications.org/content/148/2/e2020032755).
[2] Victorino CC, Gauthier AH. The social determinants of child health: variations across health outcomes – population-based cross-sectional analysis. BMC Pediatr. 2009;9(53).
[3] Fieldstone S, Zaniletti I, Hall M, et al. Community household income and resource utilization for common inpatient pediatric conditions. *Pediatrics*. 2013;132:e1592-e1601.

mental health. We urge you to specifically consider the needs of children as you consider strategies to address the needs of underserved communities. As you know, the COVID-19 pandemic has taken a serious toll on children's mental health as young people continue to face social isolation, ongoing uncertainty, fear and grief, and the impacts have been particularly profound for children in low-income and underserved communities. Even before the pandemic, children in underserved communities faced mental health challenges, and COVID-19 has only exacerbated them.

Program and policy approaches include evidence-based programs and interventions that provide support to parents and promote healthy development in infants and young children, such as the Maternal Infant and Early Childhood Home Visiting Program and Healthy Steps. Congress should explore methods to make funding more sustainable for these and other similar programs that have been proven to be effective.

Additionally, Congress should encourage CMS to prioritize innovative Medicaid pediatric payment models that support locally driven approaches to advance whole child health through targeted authorizations and funding support. Specific demonstration projects are needed that address the SDOH and social factors affecting children and youth, promote their social, emotional and behavioral development, and support those who are pregnant and postpartum. An essential piece of any demonstration program is a mechanism to share the outcomes and lessons learned broadly and across demonstration locations. CMS has taken some steps in this direction through the Centers for Medicare and Medicaid Innovation's Integrated Care for Kids (InCK) model—a child-centered model being tested by eight grantees that aims to reduce expenditures and improve the quality of care for children served by Medicaid and CHIP. These types of locally driven approaches are critical to sustainably addressing SDOH.

- **What flexibilities or authorities are needed to promote the adoption of policies and strategies in federal health programs to address these social determinants?** The COVID-19 pandemic forced innovations and emergency flexibilities across a wide array of programs, which should be thoroughly evaluated to see which changes might be made permanent. There are also some existing federal obstacles that make innovation to address the social and environmental needs of children and families more difficult.
  - Examples of promising flexibilities:
    - **Telehealth flexibilities** offered during the federal public health emergency have facilitated access to care and improved continuity of ongoing care, especially for child patients and their families who have transportation challenges. The ability to see patients in their home environment and increase family engagement has been a successful aspect of telehealth delivery, allowing providers to address issues they may not have known about if they only had a clinical encounter. Telehealth flexibilities were also particularly beneficial within mental health care, which lends itself well to virtual appointments. We support the continued inclusion of audio-only services, which enable equitable access to mental health care for children and families without adequate broadband coverage. We also support lifting geographic and originating site restrictions, which unnecessarily restrict access to care. In particular, we urge you to enact:
      - **S. 1798/H.R. 1397, the Telehealth Improvement for Kids' Essential Services (TIKES) Act**, which would promote access to telehealth services for children in Medicaid and CHIP, through guidance from CMS to states, and would study children's utilization of telehealth to identify barriers for children and families in accessing telehealth services and evaluate outcomes.
      - **S. 168/H.R. 708, the Temporary Reciprocity to Ensure Access to Treatment (TREAT) Act**, which temporarily authorizes licensing reciprocity for health care professionals providing in-person or telehealth services.
    - **Virtual options for social service programs** that started during COVID-19 have eased burdens on families and could be extended. Examples include new virtual intake options for WIC and virtual appointments within the Maternal Infant and Early Childhood Home Visiting Program.
    - **Emergency rental assistance and eviction moratoriums**, which have been helpful in stabilizing housing for families during the crisis.
    - **Streamlined application and reapplication processes**, such as express lane eligibility, helped with continuity of benefits for many federal programs, particularly SNAP and the National School Lunch Program. These flexibilities were utilized by children's hospitals that operate small food pantries and other

programs to reduce food insecurity in the children and families they serve. The Minnesota pandemic EBT roll-out is an example of a successful program with limited barriers to accessing services, as it targets families through established programs like SNAP and free and reduced lunch services.

In addition, we suggest that Congress explore ways to allow for the blending of funds across different sources to better support work to address SDOH. Congress can play a role directing cross-agency efforts to convene key stakeholders, including children's hospitals, to explore means of blending funds and to identify best practices that maximize the utility of federal funds. Congress could also create opportunities for states and local communities to receive technical assistance with the goal of creating innovative pooled funding strategies, such as the children's health and wellness funds.

- Examples of possible barriers:
  - **Federal fraud and abuse laws**, such as the federal Anti-Kickback Statute, can reduce children's hospitals flexibility to address the social needs of children and families.
  - **Medicaid medical loss ratio requirements for health plans** can serve as a disincentive to plans to adopt innovative solutions to SDOHs. There may be opportunities to modify Medicaid laws and regulations on medical loss ratios to better support and encourage health plan activities that address social determinants of health.
  - **Health Insurance Portability and Accountability Act (HIPAA) and other privacy constraints** may present barriers in the ability of patient and family information to flow between systems. In January 2021, the HHS Office for Civil Rights issued proposed modifications to HIPAA to support and remove barriers to coordinated care. While these changes can promote care coordination with social service agencies, community-based organizations and schools, there are also workflow and compliance barriers for providers related to the care of children that need to be addressed. For example, future policies must balance opportunities for enhanced collaboration with the need to maintain privacy and accounting for the unique needs and sensitivities in sharing child and adolescent health information.
  - **Family Educational Rights and Privacy Act (FERPA).** Challenges with navigating FERPA should be considered when coordinating care with non-covered entities that are integral in a child's care. Currently, children's hospitals must acquire authorizations to request records and coordinate efforts with nurses, occupational therapists, social workers or school-based providers involved in the provision of services included in a child's individual care plan, which may slow the progression of care.

- **What innovative programs or practices, whether operated by non-governmental entities or local, state, or Tribal governments, might Congress examine for implementation on a national scale?** There are many community-based partnerships and other programs to address SDOHs in children that could serve as models at a national scale. Some examples of innovative programs and practices that Congress might examine include:
  - **Children's hospitals' partnership with Lyft and Uber.** Transportation is critical to ensuring that children and families are able to access services they need. For example, one of the most common reasons for missing a well-child visit or pre/ postnatal checkup is the patient did not have a reliable way of getting to the doctor's office. One innovative approach to increase appointment adherence is to provide reimbursable rides to parents and minors.
  - **Minnesota's Preschool Development Birth through Five program** works to remove barriers so families with young children can access life-changing early childhood programs. In partnership with the Minnesota Departments of Education, Health and Human Services, this program aims to align education and care systems across the state.
  - **Omaha Healthy Kid's Alliance** has home visitation programs that offer home assessment and remediation for asthma triggers and lead exposure.
  - **California's ACEs Aware Initiative** screens patients for adverse childhood experiences and supports health care clinic changes that mitigate toxic stress response. Medical providers are compensated for doing these comprehensive screenings.
  - The **Building Community Resilience** process in Dallas serves as a central strategy and organizing platform to address health disparities and community equity.

- **Health Enhancement Communities** in Connecticut are select communities chosen by the state, which develop and execute community-driven action plans to improve child well-being and the physical health of residents through addressing poor health outcomes, health inequity and rising health care costs.

Question #20: Public health agency pandemic response

- **What actions covered by such agencies fall outside the scope of their core missions and should be moved, repealed, streamlined, or otherwise addressed?** We strongly support efforts to shore up the nation's public health system—led by the CDC—rather than any actions to streamline or restructure it. It is absolutely critical that CDC be enabled and empowered to fulfill its mission, and be allowed to develop and implement a nimble and appropriate public health response to the ongoing and any future pandemics.

Question #21: How can Congress better utilize existing programs to address the maternal health crisis?

Access to comprehensive coverage and benefits are critical for the health of the mother and baby during pregnancy, at birth and postpartum. More than half of all pregnant women rely on Medicaid for their pregnancy-related and postpartum benefits, and it is imperative that federal policy proposals do not negatively impact that coverage. Instead, Congress should act to strengthen all sources of health coverage for pregnant and postpartum women by extending Medicaid coverage to 12 months postpartum, promoting innovative delivery system and payment reforms and increasing reimbursement for specific services that promote necessary care.

- **Extending postpartum coverage to 12 months.** Congress gave states the option to extend Medicaid postpartum coverage to 12 months for up to five years under the American Rescue Plan Act. This a good first step to promoting the health and well-being of both the mother and baby, but Congress should require all states to extend coverage to 12 months so the needed support services are available to all new mothers, regardless of where they live.
- **Bundled perinatal episode of care.** The bundled perinatal episode of care model has been supported in the past by CMS and holds promise as a mechanism to advance integrated care for mothers and babies. States such as Arkansas, Ohio and Tennessee implemented a value-based payment strategy that makes a single payment for the provision of comprehensive perinatal services. This approach has been shown to improve health outcomes for the child and parent.
- **Integration of postpartum screenings into well-child visits**. In 2016, CMS issued an informational bulletin that clarifies that states may cover depression screenings for the mother as part of the Early and Periodic Screening, Diagnostic and Treatment (EPSDT) well-child visit schedule. We encourage Congress to take action to further encourage states to cover these screenings during the well-child visit and improve their reimbursement rates to incentivize providers to conduct the screenings and connect postpartum women to appropriate treatment.

In addition, it is important to consider what else the Medicaid program can do to support mothers within a pediatric care setting. Congress should consider federal policy changes to expand the reimbursable maternal health-related screening options under the Medicaid program to include screening and referrals for necessary lactation support, substance use disorder and other services that address social determinants of health during well-child visits. Congress also should direct CMS to provide guidance to states that clarifies what existing Medicaid authorities can be used for specific social-determinant related services, such as the use of family navigators to connect mothers and families with programs in the community that support access to food, housing and other necessary supports.

Supply Chain

Question #25: Generic drugs and drug shortages

- **Where are the greatest vulnerabilities in the drug and medical supply chains?** Our greatest vulnerabilities in the drug and medical supply chains exist where we have sole sourced (either one manufacturer, one nation or one region of a country) active pharmaceutical ingredients (API), raw materials or finished goods manufacturers. While this is a problem throughout the supply chain, it is particularly problematic in pediatrics, which already has a limited supplier market and pediatric supplies may not be prioritized in a crisis, creating a secondary pediatric emergency. It is critical the federal government take action to ensure that the needs of unique patient populations such as children are addressed and that resources are not redirected.

- **What steps can the United States take to diversify its supply chains?** It is especially important that the diversification of supply chains contributes to timely access to needed pediatric supplies and medications. In particular, pediatric supply chains should not be shut down or limited to accommodate non-pediatric "urgent needs" during a crisis. Even in a crisis, children must have access to needed medical supplies and pharmaceuticals. Pediatric products are produced in much smaller quantities but are critical to children' health.

  Diversification of the U.S. supply chain could be advanced through greater transparency in the manufacturing marketplace, including transparency regarding the origin of API and raw materials. To help the private sector improve supply chain resiliency domestically, the federal government should take action to increase transparency and encourage and strengthen public/private partnerships to address supply chain vulnerabilities including those for unique patient populations, such as children. In addition, financial barriers to domestic investment should be addressed at the federal level.

Question #26: For what drugs, biologics, and medical devices is the United States most reliant on foreign manufacturers?

We encourage Congress to partner with large group purchasing organizations (GPOs) and the Healthcare Supply Chain Association, which represents most GPOs, to gather this information. GPOs have extensive data and analytics regarding the sourcing and purchasing of adult and pediatric clinical supplies for most of the nation's hospitals.

Question #27: How might the federal government identify and implement public-private manufacturing models to improve and maintain domestic manufacturing capacity for drugs, vaccines, and medical countermeasures?

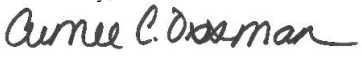
Congress should explore strategies to support the stabilization of the pharmaceutical supply chain that includes mechanisms to sustain the growing compounding pharmacy (503B) industry's role in the pediatric drug supply chain. For example, changes to current regulations related to 503B pharmacies should be considered to address limitations on their ability to quickly respond to drug shortages. These pharmacies play an important part in pediatric health care by taking adult-sized vials/dosages and compounding them into pediatric dosages in a safe way that protects patients and reduces waste. They are also important to supply chain resiliency because they can compound a drug from API and provide that drug back into a supply chain when it is on shortage. However, current regulations disincentivize the 503B pharmacies from investing in shortage mitigation efforts (e.g., testing a drug line, readying the product, investing in production) because they require pharmacies to stop production immediately after the shortage ends.

Question #30: What revisions and updates to current policies may be required in light of issues raised during the public health response to the COVID-19 pandemic?

Any changes to current policies should include a focus on pediatric essential supplies and pharmaceuticals and have contingency manufacturing plans. For example, 503B pharmacies could be prepared to make essential pediatric medications, and there should be a mechanism in place to ensure the consistent supply of blood and plasma. In addition, policies and procedures related to FDA approval of pediatric medical devices should be evaluated to ensure a way to expedite evaluation of new suppliers offering essential supplies. Furthermore, policy changes should include innovative solutions and lessons learned from the COVID-19 response. For example, employers could be encouraged to provide employees with paid time off for volunteer blood donations, distilleries can be financially incentivized to manufacture hand sanitizer, etc.

Again, thank you for this opportunity to respond to your RFI, and we look forward to partnering with you as you explore these issues further and their impact on our nation's children. If you have any questions or need additional information on any of these issues, please contact Jan Kaplan or 202-753-5384.

Sincerely,



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