NEMOURS CHILDREN'S HEALTH | Well Beyond Medicine

National Office of Policy & Prevention

1201 15th St. NW
Ste. 520
Washington, DC 20005

Ranking Member Anna Eshoo
272 Cannon House Office Building
Washington, DC 20515

Congressman Richard Hudson
2112 Rayburn House Office Building
Washington, DC 20515

Dear Ranking Member Eshoo and Congressman Hudson:

Thank you for the opportunity to provide comments regarding the reauthorization of the Pandemic and All-Hazards Preparedness Act (PAHPA). The programs authorized by this legislation, and addressed under the Coronavirus Aid, Relief, and Economic Security (CARES) Act (Public Law 116-36), are of critical importance to our nation and our health care supply chain. Without a strong, resilient supply chain of critical medical devices and other medical products, families and children can experience delays in receiving necessary health care services, potentially resulting in medical emergencies or negative health outcomes. Our recommendations below are informed by our direct experience with the Food and Drug Administration (FDA) assisting us in addressing a supply chain issue. We fully support efforts to give the FDA the visibility and tools it needs to maximize its ability to serve this vital function.

The CARES Act granted the FDA additional, temporary authorities (under the current Public Health Emergency (PHE)) to require that manufacturers submit information to the FDA about supply chain disruptions. It gave the FDA authorities to enhance its ability to identify, prevent, and mitigate possible medical product shortages by enhancing visibility into supply chains.

We are concerned that without a permanent extension of these emergency authorities, the FDA will no longer be able to require medical device manufacturers to notify it of significant interruptions and discontinuances of critical devices. While the FDA will maintain its authority to detect and address other potential medical product shortages, it is critical that **Congress authorize an extension of the requirement for device manufacturers to notify the FDA of significant interruptions and discontinuances of critical devices outside of a PHE.** Additionally, we support FDA authorities to require manufacturers to develop and share **risk management plans**, particularly for sole-source suppliers, and identify alternate suppliers and manufacturing sites.

When the FDA has information about critical shortages and the tools to address them, there are direct, positive impacts on patients. In our case, Nemours Children's Hospital, Delaware experienced critical shortages of a specific size of endotracheal tube (ETTs) in late 2022, at a time when we were experiencing high volumes of flu and RSV cases. ETTs are widely used for pediatric patients in the emergency department and during surgical operations. They allow health care providers to deliver oxygen, protect airways and/or administer anesthesia. In the most dire cases, without these

devices, pediatric patients with severe lung disease cannot sustain adequate blood oxygen levels for organ function. In late December, we projected that we only had enough ETTs for a few days and were unable to identify supply from our regular vendors or other hospitals. Upon our request, the FDA provided immediate assistance to our team to identify vendors that had ETTs in stock. We have since been able to obtain several months of inventory and believe we will have sufficient supply going forward. Without this assistance, our team was planning to seek overseas sources to address the critical shortage we were experiencing.

We urge you to provide the FDA with the authorities it needs to have maximum visibility into supply shortages beyond the expiration of the current PHE. Device shortages are not always tied to declared PHEs. In fact, the RSV outbreak that was a major contributing factor to our depleted supply was not considered a PHE. There are many factors impacting medical device supply chains. Early notification of supply chain disruptions, coupled with the FDA's ability to mitigate shortages, would provide significant benefit to patients and save lives. For this reason, Nemours Children's Health supports the permanent extension of the requirement for device manufacturers to notify the FDA of significant interruptions and discontinuances of critical devices outside of a PHE. We also support new authorities for the FDA to require manufacturers to develop and share risk management plans.

Thank you for your consideration.

Sincerely,

Daniella Gratale, MA
Associate Vice President, Federal Affairs
Nemours Children's Health