

## Policy Options to Address Future Chemotherapy Shortages

### Authorize Policies to Mitigate Drug Shortages in the Pandemic All Hazards Preparedness Act (PAHPA) Reauthorization

- ***Drug Shortage Prevention Act (H.R. 3008)***
  - This bipartisan legislation would require manufacturers to notify FDA of increased demand no more than 48 hours after a sustained increase in demand for a drug, active pharmaceutical ingredient (API), or excipient for six consecutive weeks, including for over-the-counter medicines, and subsequent notification 30 days after the initial submission.
  - This policy is tied to drugs on the FDA's essential medicines list, which needs to be expanded to include the chemotherapies currently in shortage as well as any others that are widely used.
  - This would help address shortages stemming from surges in demand but not disruptions in supply.
- ***Revise the mission of the Assistant Secretary for Strategic Planning and Response (ASPR)***
  - ASPR should prioritize the availability of the top essential medicines across all product types, not just medical countermeasures and pandemic-related products.
  - Currently, ASPR focuses on emergency events such as natural disasters and pandemics. Its focus should be expanded to include the availability of top essential medicines regardless of the reason for a shortage.
- ***Include policies to build resilient supply chains to prevent future shortages.***
  - Develop standards and best practices to promote sustainable private sector contracts (e.g. between manufacturers and Group Purchasing Organizations/Pharmacy Benefit Managers) while accounting for proprietary and commercial concerns.
  - Provide tax credits for the domestic manufacturing of domestic manufacturing of drugs, API, personal protective equipment, and diagnostics as proposed in the bipartisan Manufacturing API, Drugs, and Excipients (MADE) in America Act (H.R. 2707).

## Provide Funding for These FDA Programs in FY 2024

- **Quality Management Maturity (QMM) Program**
  - QMM is the state attained when drug manufacturers have consistent, reliable, and robust business processes to achieve quality objectives and promote continual improvement. According to the FDA, the root cause for many drug shortages is the absence of incentives for manufacturers to strive for more than simply meeting current good manufacturing practice (CGMP) regulations and to develop mature quality management systems.
  - The FDA Drug Shortages Task Force recommended creating this program for which a pilot was recently completed. Congress should fund this program, which would be voluntary for manufacturers, for manufacturing facilities to be measured and rated.
- **Risk Management Plans (RMP) Program**
  - RMPs proactively assist in the prevention of human drug product and biological product shortages, and can provide stakeholders with a framework to proactively identify, prioritize, and implement strategies to mitigate hazards that can cause a supply disruption.
  - Drug purchasers lack insight into the QMM and supply chain practices of manufacturers, which caucus economic incentive programs. Drug purchasers should have insight into manufacturers' RMP rating to make informed decisions about drug purchases. Additionally, FDA should prioritize these programs for the production of generic drugs.

## Inclusive Engagement of Key Stakeholders

- To comprehensively address the nation's chemotherapy drug shortages, it is crucial to involve all key stakeholders, including drug manufacturers, health care providers, and patients, in the policy-making process. Engaging a variety of stakeholders will provide valuable insights into the complex landscape of drug manufacturing and challenges experienced by providers and patients. By including all stakeholders, we can foster a collaborative approach that considers the expertise and interests of manufacturers, healthcare providers, and patients alike.