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HHS Should Establish a Prevent Drug Shortages Initiative

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INTRODUCTION

Early in 2025, the U.S. Department of Health and Human Services (HHS) released a 2025-2028 Draft Action Plan for Addressing Shortages of Medical Products and Critical Foods and Strengthening the Resilience of Medical Product and Critical Food Supply Chains (referred to as the "Draft Action Plan" throughout this issue brief).[1] The Draft Action Plan, developed by the HHS Supply Chain Resilience and Shortage Coordinator with input from other federal partners, is the first HHS-level strategic plan designed to strengthen the resilience of medical product supply chains.

Reliable and resilient medical product supply chains are essential to the health and well-being of Americans. Patients rely on these complex supply chains every day to deliver life-saving and life-sustaining medicines and other critical medical products, including medical devices and components like syringes and IV bags. For decades, supply chain breakdowns have too frequently caused severe and chronic drug shortages, in some cases costing patients their lives. Addressing these challenges will play a crucial role in the Trump Administration's ability to achieve their goals of improving the health of Americans.

In this issue brief, we describe why a sustained HHS strategic planning and coordination effort is essential to creating a more reliable medical product supply chain that prevents and mitigates shortages. Building off of our previous publication on "Advancing Federal Coordination to Address Drug Shortages", we then lay out specific activities related to this effort that should be led by an HHS Prevent Drug Shortages (PDS) Initiative, potentially located in HHS' newly-announced Office of Strategy. Lastly, we propose specific objectives and metrics that could be used to catalyze action and measure progress in the pursuit of a more reliable medical supply chain.

Shortages, and the root causes driving them, are not problems that any one division within HHS – or any agency in the U.S. government – can tackle alone.

A coordinating body and resulting strategic plan, accompanied by appropriate authorities and resources, could catalyze the government and industry to take preventive action in advance of future crises or disruptions.

The focus of the Duke-Margolis ReVAMP Drug Supply Chain Consortium and this issue brief are on drug and biologic supply chains. However, many of these concepts should be applied to other medical product and critical food supply chains more broadly. As a result, our proposed PDS Initiative could form one prong of a broader HHS approach to bolster the resilience of supply chain for all products within HHS' purview.

[1] HHS also published an accompanying Draft Research Plan designed to orient research priorities in support of the goals of the Draft Action Plan.

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The Duke-Margolis ReVAMP Drug Supply Chain Consortium consists of a group of experts in supply chain, manufacturing, regulatory science, national security, and drug shortages from academia, private industry, governmental agencies, and additional relevant stakeholder groups. The Consortium's mission is to generate effective policy solutions that promote a reliable drug supply chain with advanced manufacturing capabilities and, ultimately, to improve patient outcomes by reducing the frequency and severity of drug shortages.

The recommendations and analysis in this white paper represent the thinking of Duke-Margolis researchers, which has been informed by Consortium activities and the expertise of its members. As part of Duke University, Duke-Margolis honors the tradition of academic independence on the part of its faculty, researchers, and scholars. Neither Duke nor the Duke-Margolis Institute takes partisan positions, but the individual researchers are free to speak their minds and express their opinions regarding important and pertinent issues. This white paper may not represent the opinions of every Consortium member. This publication is not intended to limit the ability of Consortium members to provide their own comments on behalf of their independent organizations.

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Disclosures

Stephen Colvill serves a board member for the End Drug Shortages Alliance and a volunteer advisor for Angels for Change.

About the Duke-Margolis Institute for Health Policy

The Robert J. Margolis, MD, Institute for Health Policy at Duke University is directed by Mark McClellan, MD, PhD, and brings together expertise from the Washington, DC, policy community, Duke University, and Duke Health to address the most pressing issues in health policy. The Institute's mission is to improve health, health equity, and the value of health care by developing and implementing evidence-based policy solutions locally, nationally, and globally. For more information, visit healthpolicy.duke.edu.

Why Is Federal Coordination on Drug Shortages Important?

Drug shortages are an incredibly complex and persistent problem that has affected the U.S. healthcare system for decades. FDA has listed over 1,000 new drug shortages since 2010, and the American Society of Health-System Pharmacists has also listed thousands of drug shortages since 2001. **These shortages, and the root causes driving them, are not problems that any one division within HHS – or any agency in the U.S. government – can tackle alone.** The U.S. Food and Drug Administration (FDA), with its significant expertise and authority to regulate drug manufacturers, has historically been tasked with much of the responsibility for addressing shortages, but experts increasingly recognize that chronic, recurring shortages are the result of misaligned incentives in purchasing and reimbursement – issues outside FDA's expertise and authority.

To further illustrate the need for coordination: if an FDA inspection finds objectionable conditions at a manufacturing site, FDA can issue a warning letter or take further regulatory action. But if market incentives encourage generic manufacturers to keep costs low above all else and do not reward investments in robust quality management, then the manufacturer has little reason to make costly investments to ensure that they can consistently meet or exceed FDA standards. On top of that, many aspects of a reliable supply chain, such as supply chain network planning, inventory management practices, redundancies, pharmaceutical contracting and sourcing, and other supply chain practices, are critical but outside of FDA's areas of expertise and authority. CMS, with its authority over reimbursement and payment policies that drive healthcare market incentives, and ASPR (recently reorganized under the umbrella of CDC), with its ability to directly fund manufacturing in the public health industrial base and exercise Defense Production Act and other authorities, are also critical actors in a comprehensive approach to addressing shortages, along with numerous other agencies within HHS. Preventing shortages is not the primary responsibility or focus of any of these entities, yet they all possess some of the authorities, expertise, and data needed for prevention and mitigation efforts. An April 2025 Government Accountability Office (GAO) report titled "Drug Shortages: HHS Should Implement a Mechanism to Coordinate Its Activities" drove this point home: "The FDA aims to prevent and respond to drug shortages, but can't do it alone." An HHS coordinating body on supply chains is necessary to ensure all these pieces of the whole work effectively in concert.

Another benefit a coordinating body would deliver is a shift toward a more proactive, prevention-focused approach to drug shortages. Many within HHS, including on FDA's Drug Shortage Staff, at ASPR, and elsewhere in the public and private sectors, work tirelessly and with great skill to respond to and mitigate the impacts of drug shortages as they occur. When a crisis catalyzes the supply chain into action, the entire industry has become quite effective at response activities, as evidenced by responses to recent major disruptions such as Hurricane Helene's impact on Baxter's North Cove facility, a tornado's impact on Pfizer's Rocky Mount facility, and many others. However, as is often the case in healthcare, preventing a problem is more effective than treating it after it occurs. **A coordinating body and resulting strategic plan, accompanied by appropriate authorities and resources, could catalyze the government and industry to take preventive action in advance of future crises or disruptions.**

Finally, there is distinct value in establishing such an initiative within HHS. As the federal government takes sweeping action on supply chains broadly, including through tariff policy and other steps, carefully considering the impacts of those actions on patient care is critically important. Leaders within HHS with expertise in the complexities of regulation, manufacturing, pricing, and payment in the healthcare setting should provide a voice within the federal government for potential patient care impacts from policy changes. A position tasked with many of these important responsibilities, the HHS Supply Chain Resilience and Shortage Coordinator, was established in 2023, but its funding is set to expire in May 2025. Going forward, an urgent priority of the Trump Administration should be to set its own vision for a medical supply chain coordination body tasked with laying out a strategic plan for addressing medical supply chain challenges – including ensuring the body is equipped with appropriate authority and funding. In the following section, we outline how a federal Prevent Drug Shortages Initiative should be established to achieve these aims for drug shortages and drug supply chains.

What Should a PDS Initiative Do?

First, the PDS Initiative should set concrete, measurable objectives for preventing drug shortages and promoting drug supply chain reliability – incorporating, to the extent possible, input from non-governmental stakeholders as well as the priorities of the Administration. To that end, the final section of this issue brief outlines some suggested objectives that have been refined through consultation with ReVAMP Consortium member organizations. Establishing concrete, measurable objectives such as these can serve as a catalyst to action outside of a time of crisis by defining what success looks like and aligning parties towards collective action.

Second, the PDS Initiative should identify and convene accountable parties within HHS and beyond to achieve those objectives. For some objectives, the PDS Initiative itself may be identified as the accountable party. As described previously, different agencies have different authorities and expertise that need to be brought together in a coordinated fashion to make meaningful progress. On an ongoing basis, the PDS Initiative should also identify gaps and outstanding needs for achieving desired objectives – for example, by identifying where Congress may need to grant additional funding or authorities to enable progress, where public-private partnership is needed, and where partnership with other federal agencies such as the Department of Defense or others may be beneficial. The HHS Supply Chain Resilience and Shortage Coordinator addressed many of these aims in a 2024 white paper, and this work may need to be updated in the future as the situation evolves.

Third, the PDS Initiative should function as a nexus for HHS drug supply chain expertise. This could include chairing the HHS Supply Chain Resilience and Shortages Working Group; liaising with Congress to help coordinate technical assistance on developing legislation; working with the Department of Commerce or U.S. Trade Representative to perform impact assessments and recommendations related to new tariff or other trade policies; and participating in any number of other cross-governmental or international efforts to promote supply chain security and resiliency.

Objectives and Metrics that an HHS PDS Initiative Should Consider

The Draft Action Plan lays out a set of four draft goals – Coordinate, Assess, Respond, and Prevent – for a cross-HHS effort on improving the resilience of medical product supply chains. Refinement and increased specificity around these goals is needed. In the remainder of this issue brief, we provide a list of Specific, Measurable, Achievable, Relevant, and Timely (SMART) metrics that could help to provide such increased specificity and to track HHS' success on each of the four goals. This list of proposed metrics is not intended to represent a comprehensive list of all important metrics – instead, it is intended to provide example metrics that could form a part of a comprehensive set of objectives and metrics developed by the PDS Initiative. Proposed timelines may need to be adjusted to ensure appropriateness and feasibility. The proposed metrics were developed in consultation with Duke-Margolis ReVAMP Drug Supply Chain Consortium members.[2, 3]

[2] The proposed metrics listed in this issue brief do not represent a unanimous consensus among ReVAMP Consortium members, and no part of this issue brief is intended to limit Consortium members' or member organizations' ability to comment on these topics independently.

[3] In March 2025, we surveyed ReVAMP Consortium members on the importance of including various potential metrics in this publication (scale of 0-10, 10= high importance and 0 = low importance). All proposed metrics included in this publication averaged a score of 7 or above. Other metrics that were under consideration but averaged a score below 7 are excluded.

GOAL 1: **COORDINATE**

Strengthen HHS's integrated approach to coordination, communication, and partnerships focused on improving the resilience of medical product and critical food supply chains.

As described above and in previous Duke-Margolis publications, strong cross-HHS coordination is foundational to an effective and comprehensive approach to preventing and mitigating drug shortages. We recommend the PDS Initiative consider the following metrics to assess progress toward this goal:

- **Align on SMART supply chain objectives and parties accountable for achieving the objectives, and publish in a final version of the Action Plan in 2025.**
- **Launch a public web page for the PDS Initiative in 2025.** This web page would serve as a convenient single point for stakeholders to receive updates on HHS' latest work on supply chains and shortages, progress toward key metrics such as those recommended in this issue brief, and opportunities to engage with HHS on addressing shortages. Separate from the avenues already available to notify FDA Drug Shortage Staff about active or impending shortages of individual drugs, engagements with the PDS Initiative would be focused on broader initiatives to preventively address systemic drivers of shortages.
- **Publish an annual supply chain resilience report from the HHS Supply Chain Resilience and Shortages Working Group or equivalent coordinating body.** This report should include a description of HHS' work on supply chains and shortages, including how agencies within and beyond HHS have collaborated on this work, and standardized reporting on progress toward key metrics such as those recommended in this issue brief. This annual report could be generated through a collaborative process that draws from and, where necessary, improves upon other existing reports. For example, this new annual report could draw from the existing annual FDA Drug Shortages report to Congress, although it may be helpful if FDA implemented a more granular and specific assessment of the causes of drug shortages. Increased specificity in reporting categories and better information provided by manufacturers on shortage causes could significantly improve the utility of publicly available FDA data on the most common causes of shortages.

GOAL 2: **ASSESS**

Increase availability and utilization of actionable insights into critical medical product and food supply chains for HHS.

While a great deal of data on drug supply chains and their vulnerabilities is already available, important gaps remain. HHS' future work in this space should avoid redundant information collection and, as the Draft Action Plan describes, focus not just on collecting information but validating and understanding existing data and furthering the availability and utilization of actionable insights from the data. These insights should drive improved decision-making in both shortage response and prevention activities. Importantly, this ASSESS goal should also be expanded to contemplate the availability and utilization of actionable insights for the private sector to drive improved contracting and purchasing decisions. We recommend the PDS Initiative consider the following metrics to assess progress toward this goal:

- **For a chosen list of essential drugs, perform an annual vulnerability assessment that categorizes drugs by level of vulnerability starting in 2025.** This list should then be used to guide and prioritize prevention and response efforts described under **Goals 3 and 4.** A previous Duke-Margolis white paper provided more detail on considerations for creating fit-for-purpose essential medicine lists to guide policy interventions, including accounting for essentialness to patient care and vulnerable populations. Any critical data gaps identified during such an analysis should guide and focus additional steps toward the "ASSESS" goals. Existing research can be leveraged toward this objective; for example, USP published a 2024-2025 Vulnerable Medicines List that HHS could leverage.
- **Improve compliance with volume reporting requirements for FDA-designated Essential Medicines from 53% (in Calendar Year 2023) to 80% or more by 2027.** The Coronavirus Aid, Relief, and Economic Security (CARES) Act in 2021 granted FDA the authority to collect information on volumes of certain products manufactured at FDA-registered sites, but compliance thus far has been mixed. The information these reporting requirements can provide – such as the volume of product sourced from various sites – is critical to understanding supply chain vulnerabilities and would provide much more actionable insights than FDA's existing information. FDA should clarify reporting roles among product sponsors and contract manufacturers, communicate with industry leaders regarding logistical challenges that may have contributed to low compliance rates, and seek to streamline and simplify the volume reporting process where possible while maintaining data integrity and utility. FDA could consider sending untitled letters to noncompliant manufacturers and posting untitled letters to the FDA website.
- **Finalize FDA Risk Management Plan Guidance as soon as feasible.** FDA was also granted by the CARES Act the authority to require manufacturers of certain drugs to maintain risk management plans for their products, and the Agency released a draft guidance for manufacturers in May 2022. Regulatory flexibilities and other incentives could be considered for manufacturers with high-performing risk management programs.

GOAL 3: **RESPOND**

Strengthen HHS response to shortages and supply chain disruptions.

While preventing shortages altogether should be the top priority, responding to and mitigating shortages and disruptions will continue to be a critical part of HHS' work. Some metrics proposed below have applicability in both the Respond and Prevent sections. We recommend the PDS Initiative consider the following metrics to assess progress toward this goal:

- **Reduce the average duration of a drug shortage by 50% by 2030.** While the number of new annual drug shortages peaked in the early 2010s, the duration of a drug shortage has risen in recent years. U.S. Pharmacopeia analysis found the average duration of a drug shortage in 2024 was over 4 years, up from about 3 years on average as of 2023. Changes to incentives, especially payment and reimbursement policies, are needed to drive quicker resolution of these shortages.
- **Reduce the number of active drug shortages by 50% by 2030.** The number of drugs in shortage is, of course, one of the most important metrics for assessing the success of any effort to prevent and respond to shortages. Appropriate precautions should be taken to ensure that the drug shortage list determinations are process-oriented, fair, objective, and not subject to manipulation.
- **Publish and disseminate best practices for product conservation and, when needed, allocation during scarcity or shortage.** Navigating situations with scarce supply or a shortage of an essential medicine forces actors throughout the drug supply chain to make difficult decisions about product allocation. When a disruption occurs in the supply chain, fears of shortages can drive many purchasers to attempt to stockpile more product, in some cases exacerbating the scarcity or shortage of the product. These decisions can have major impacts on which sites of care are affected, which patients are affected, and how severely they're affected. HHS should work with patients, providers, health systems, manufacturers, distributors, group purchasing organizations, and others, to develop allocation guidelines to help stakeholders navigate these situations as effectively as possible by minimizing patient impact and ensuring equity in allocation. ASPR's Technical Resources, Assistance Center, and Information Exchange (TRACIE) already offers a set of resources on Crisis Standards of Care that could be utilized and refined for the shortage response context.

GOAL 4: **PREVENT**

Incentivize investment in supply chain resilience through increased supply chain diversification, redundancy, and other strategies.

Shortage prevention is the ultimate goal. We recommend this goal be listed before response in the final Action Plan to emphasize the fact that prevention should be the primary aim. We recommend the PDS Initiative consider the following metrics to assess progress toward this most critical goal:

- **Reduce the number of annual new drug shortages by 50% by 2030.** Preventing new drug shortages is the most straightforward, quantifiable metric for progress under this goal.
- **Implement a drug supply chain reliability assessment tool with participation from at least 10 generic drug manufacturers by 2027.** Experts have consistently found that a lack of usable, standardized information on the relative reliability of different manufacturers of the same product makes it difficult for purchasers to choose more reliable suppliers, and difficult for suppliers to compete based on reliability (rather than an inordinate focus on price). We recommend that a standardized tool that assesses the varying levels of reliability among different generic manufacturers and products be paired with reimbursement reforms that incentivize purchasing from more reliable suppliers, but recognize that this may require Congressional action. The Drug Supply Chain Resilience Initiative developed by USP and the Resiliency Badging Program developed by the Healthcare Industry Resilience Collaborative are two examples of such programs.
- **Invest in domestic manufacturing capabilities to ensure 25% or more of API volume for vulnerable essential medicines comes from the United States by 2030.** While dependence on foreign manufacturing sites for essential medicine supply has not been a major cause of historical drug shortages, it does pose risks for future disruptions, as we have described in detail in other Duke-Margolis publications. Building up a robust domestic manufacturing base can help to alleviate these risks. Vulnerability assessments of supply chains for essential medicines as described under **Goal 2** should guide these investments. HHS should also prioritize research on geographic concentration and vulnerabilities in key starting material (KSM) manufacturing and set goals around onshoring production of some key starting materials (KSMs) for essential medicines.