RE: Duke-Margolis Institute Comment on Draft Drug Shortage Prevention and Mitigation Act

Dear Chairman Wyden, Ranking Member Crapo, and members of the Committee,

The Duke-Margolis Institute for Health Policy ("Duke-Margolis" or "the Institute") appreciates the Committee's ongoing work to address chronic drug shortages, as well as ongoing opportunities to provide feedback to the Committee on its proposals.

The Duke-Margolis Institute's mission is to improve health, health equity, and the value of health care through practical, innovative, and evidence-based solutions. Duke-Margolis has conducted years of research and stakeholder engagement aimed at promoting drug supply chain reliability and preventing drug shortages, most recently including the work of the Duke-Margolis ReVAMP Drug Supply Chain Consortium that was founded in 2023. Through the Consortium, we're working to generate effective policy solutions that promote a reliable drug supply chain to improve patient outcomes by reducing the frequency and severity of drug shortages.

The recommendations herein do not necessarily represent the views of Consortium Members and are not intended to limit the ability of Consortium members to provide their own comments on behalf of their independent organizations but are informed by the Institute's work with Consortium Members.

While we recommend some modifications to the draft "Drug Shortage Prevention and Mitigation Act" below, we generally support the Senate Finance Committee's proposed approach to address drug shortages through the implementation of new demand-side policy steps. These steps, with some modifications, would promote a collaborative approach where all supply chain stakeholders – payers, providers, group purchasing organizations, wholesalers, manufacturers, and others – jointly share in the responsibility to prevent drug shortages on behalf of patients. The Committee's proposal shares many common features with the approach proposed in our recent Health Affairs article on this topic. If designed and implemented effectively, this approach can save providers time and money by preventing shortages that leave them scrambling for scarce medicines, enable group purchasing organizations, wholesalers, and others to expand committed contracting models while reducing provider burden through streamlined and aggregated reporting, and allow manufacturers of essential generic medicines more stability and certainty of a robust market for their products. **Most importantly, this approach can help to ensure patients have access to the drugs they need when they are needed.**

Below is a summary table of our recommendations and a rationale for implementing demand-side steps to address drug shortages. Our full recommendations are included in our full comment letter.

We look forward to engaging with the Committee and other stakeholders as the draft legislation continues to be refined.

Sincerely,

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I. Introduction

As noted by the Senate Finance Committee (the "Committee"), shortages in the supply of prescription drugs present a persistent and growing challenge in the United States, with the number of drug shortages reaching an all-time high in May 2024 per the American Society for Health-System Pharmacists. Drug shortages are associated with higher mortality rates, medication errors, delays in life-saving cancer treatment and other critical medical procedures, and significant financial costs to the health care system.

The current market for generic drugs too frequently consists of manufacturers that can supply generic drugs at low prices but not reliably and consistently. Supply-side incentives targeted towards manufacturers and demand-side incentives targeted towards purchasers are both needed to shift towards a more reliable supply. Below, we lay out the particular importance of and the rationale for implementing new demand-side incentives such as the Committee's proposal.

Below is a summary table of our recommendations and a rationale for implementing demand-side steps to address drug shortages. Our full recommendations are included in our full comment letter.

Acknowledgements

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Disclosures

Mark B. McClellan, MD, PhD, is an independent director on the boards of Johnson & Johnson, Cigna, Alignment Healthcare, and PrognomIQ; co-chairs the Guiding Committee for the Health Care Payment Learning and Action Network; and receives fees for serving as an advisor for Arsenal Capital Partners, Blackstone Life Sciences, and MITRE.

Stephen Colvill, MBA, is Executive Director and Co-Founder of RISCS, a non-profit drug supply chain rating and certification organization with a mission to prevent drug shortages. Stephen serves on the board of the End Drug Shortages Alliance and as an advisor for Angels for Change.

II. Summary of Recommendations (see full recommendations in our full comment letter)

Public-Private Partnership	We recommend the legislation include the establishment of a public-private partnership tasked with supporting the Secretary in determining certain criteria for Program eligibility, identifying drugs that may be added to the initial list of applicable generics, developing drug supply chain reliability initiatives, developing and verifying compliance with certain core and advanced standards, and potentially other steps if appropriate.
Reporting and Recordkeeping Requirements	Reporting burden on providers and program participants should be limited as much as possible, and the Program should thoughtfully ensure that adequate incentives are in place for provider participation where parsimonious reporting is required. Importantly, the draft does not require any changes to individual patient billing or claims processes or the DRG bundled payment methodology, and we agree this is likely appropriate to limit provider burden. The Program should also allow providers to delegate most or all reporting to GPOs or wholesalers, where demand and purchasing is already aggregated and centralized.
Core Standards	We first recommend that the Core Standards for agreements between payment-eligible providers and manufacturers should explicitly identify the volume commitment amounts along with specific contract start and end dates laid out by applicable generic. We also recommend that Core Standards for contracts that are entered into by payment-eligible providers should generally restrict changes to the volume commitment amounts prior to the contract end date for each applicable generic, except under limited circumstances. Pricing or price challenges should not be a factor in enabling changes to the volume commitment amounts before the contract end date.
Manufacturer Reliability Agreements	Information sharing alone does not mean that the information will be standardized, usable, and timely so that it can effectively inform supplier selection. Initially, the Secretary should be authorized to require in MRAs that manufacturers participate in one or more "drug supply chain reliability initiative" in each of the areas of overall drug supply chain reliability, quality management maturity, drug product quality, and potentially other categories. We recommend the Secretary develop a core or advanced standard that provides payments to providers who select suppliers with one of the higher scores on drug supply chain reliability initiatives relative to the other suppliers of the same applicable generic.
Defining Applicable Generic Manufacturers and Private Labelers	In the case where the same entity does not manufacture the product, own the ANDA, and commercialize the product, the best approach for managing distributed responsibilities may be to assign responsibility to the ANDA holder.
Advanced Manufacturing / Manufacturing Technology Modernization Plans	In addition to the Advanced Standard for Advanced Manufacturing, we recommend development of one "drug supply chain reliability initiative" that would enable manufacturer adoption of Manufacturing Technology Modernization Plans (MTMP), with certain high-level information generated by this initiative to be shared through MRAs in the Program.
Buffer Inventory Standards	Encouraging buffer inventory as a preventive step before a shortage has begun can be a productive policy. However, buffer inventory payments should not be made for drugs when they are in shortage. Centralized buffer stocks managed by a distributor, group purchasing organization, and/or manufacturer are likely more efficient and less likely to lead to unintended adverse consequences than stock held at the provider level.

III. Rationale for Demand-Side Policy Reform to Address Drug Shortages

As described in our Health Affairs article on this topic, demand-side policy reforms that drive changes in drug purchasing and contracting practices are necessary to align incentives in support of more consistently reliable manufacturing. Demand-side intervention is a critical complement to any steps on the supply side because, absent any change in demand-side incentives, market pressures will continue to push toward the lowest cost rather than reliability. Demand-side incentives at the provider level have the added benefit of being able to be more closely tied to improving patient outcomes, the ultimate aim of policies designed to prevent drug shortages.

On the other hand, supply-side incentives targeted towards manufacturers are another important policy tool, especially in certain areas such as increasing public health emergency preparedness and promoting manufacturing technology modernization. However, supply-side incentives alone are insufficient to address the economic root causes that drive chronic shortages of older generic medicines. Historically, supply-side incentives have been used to encourage new market entrants by subsidizing start-up costs. These policy interventions often affect only a point in time without ensuring long-term market sustainability – manufacturers that receive supply-side incentives often still face an ongoing market disincentive to supply products that have a low marginal profit. In addition, providing government grants or contracts to all appropriate manufacturers of generic medicines at risk of shortage is likely to be prohibitively costly and complex to administer.

The Committee's draft proposes price-based incentive payments to providers that are contingent on committed contracts (and ultimately orders/purchases) between manufacturers and providers, with similar features to our proposed approach in Health Affairs. Price-based incentive payments could alternatively be made directly to manufacturers, similar to the approach used in the U.S. Department of Agriculture's now-defunct direct farm payment program, which would enable subsidies to at least initially go more directly to manufacturers. However, even if incentive payments are made directly to manufacturers instead of providers, providers will likely be able to negotiate lower prices and thus aim to capture any excess subsidy value that other supply chain stakeholders do not directly invest in meeting program requirements. Moreover, no government body is currently well-equipped to administer such a program as CMS does not generally make payments directly to drug manufacturers. As a result, demand-side reforms that can be more closely tied to patient outcome impacts is likely the most feasible and efficient approach.

The most important aspect of a new payment program is to ensure that the payments are contingent upon strong supply chain reliability and contracting standards that drive meaningful change in the priorities and investment decisions of manufacturers and other supply chain stakeholders. Strong standards will necessitate that demand-side incentives flow up the supply chain to where new investments are needed and also help to ensure that the proposal's intended result of preventing drug shortages is achieved.