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

Sincerely,

Stephen Colvill
Thomas Roades
Cameron Joyce
Gerrit Hamre
Mark McClellan

Duke | MARGOLIS INSTITUTE for Health Policy

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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.

I. Summary of Recommendations

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.

II. 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. In Appendix A below, we lay out the particular importance of and the rationale for implementing new demand-side incentives such as the Committee's proposal.

While we recommend some modifications to the draft "Drug Shortage Prevention and Mitigation Act" below, we generally support the 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 the drugs they need when they are needed. We look forward to engaging with the Committee and other stakeholders as the draft legislation continues to be refined.

III. Feedback on Specific Sections of the Drug Shortage Prevention and Mitigation Act

a. Public-Private Partnership

Certain elements of the "Medicare Drug Shortage Prevention Program" (referred to here as the "Program") may be too detailed to lay out entirely in legislation, may require specialized expertise to execute effectively, or may need to evolve in a dynamic market over time. **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.** This entity should include representative input from all the organization types eligible for the Program, as well as patients or patient advocates representing a variety of patient populations, and could be empowered to take on certain responsibilities if directed by the Secretary, or advise the

Secretary on the implementation of the Program when appropriate. Public-private support could benefit some of the following key tasks:

- Developing drug supply chain reliability initiatives: Some work has already been started to advance various drug supply chain reliability initiatives. The Program could leverage a public-private partnership to build on existing frameworks to create standardized tools that can be used by program participants in making contracting and purchasing decisions. The white paper "Policy Considerations to Prevent Drug Shortages and Mitigate Supply Chain Vulnerabilities in the United States," published by HHS in April 2024, lays out a proposal for a Manufacturer Reliability Assessment Program administered through a nonprofit, non-governmental accreditation body that could be used as a model. Duke-Margolis' 2023 issue brief "Addressing Drug Shortages Through Quality Management Maturity and Supply Chain Reliability Programs" proposes a similar model, a Drug Supply Chain Reliability Program. A dedicated effort to foster the creation, development, and maturation of drug supply chain reliability initiatives is needed, particularly in the generic sterile injectables market.
- Defining applicable generic manufacturers vs. private labelers: As described in the following section titled *Defining Applicable Generic Manufacturers and Private Labelers*, legislative definitions of various entity types may unintentionally include, exclude, or mis-categorize certain parties relative to the Program's intent. It may be appropriate to provide flexibility for the Secretary to develop a specific definition, informed by the public-private entity (including advice on complex cases) and public comment that most accurately captures the eligible organizations.
- Facilitating information sharing through Manufacturer Reliability Agreements: A public-private partnership could enable an information technology infrastructure for sharing MRAs that would create standardization and efficiencies.
- Identifying additional products for Program eligibility: The draft legislation gives the Secretary authority to expand the list of products eligible for the Program based on assessments of shortage risk or actual shortage, needs of different patient populations, and other considerations. A public-private entity may be helpful in identifying priority products or product categories that should be prioritized within the Program or included in later Program years.

b. 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.

Some reporting on drug purchases to CMS will be necessary to identify when a provider has purchased an eligible drug through a committed contract with a program participant or through another contract, as well as what volume was purchased. Reporting at the provider level will represent a burden for many participating providers. **To significantly limit this burden, the Program should allow providers to**

delegate their purchasing reporting to GPOs or wholesalers, where demand and purchasing is already aggregated and centralized. In this approach, straightforward reporting mechanisms should enable all purchases for a given provider to be captured in the bulk reporting from that GPO or wholesaler, while enabling the provider to separately report other purchases such as direct purchases from manufacturers if necessary. The Committee could also consider how manufacturer reporting of direct sales to providers could further limit provider burden. The Committee could also consider if the reporting requirements in the draft around number of units administered by providers can be eliminated in favor of the other reporting requirements around number of units purchased.

c. Core Standards

As noted by the Committee, one of the most important aims of the Program is to encourage meaningful purchase volume commitments and stable pricing between program participants and manufacturers. As currently written, the Core Standards' requirements around required contract terms and pricing stability certifications do not appear sufficient to accomplish this aim. The following modifications would strengthen the Core Standards.

- Price Challenges

Contracting practices that are currently prevalent often enable purchasers to switch suppliers before the contract term expires if a lower short-term price becomes available from another supplier. These contract changes are often enabled through contractual "price challenge" terms. Price challenges are effective at driving down drug costs shortly after a drug loses patent exclusivity, but price challenges can be counterproductive for older, already-inexpensive generic drugs at risk of shortage because they remove certainty of demand for manufacturers. Due to the steps required to comply with Manufacturer Reliability Agreements, Pricing Stability Certifications, and other aspects of the Program, suppliers of various applicable generics in the Program will not always be the cheapest supplier at any given point in time and thus will be vulnerable to price challenges if they are not restricted.

To address this issue, 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. The identification of this information could be delegated by the providers to the program participants and would provide additional assurance of supply to providers and assurance of demand to manufacturers.

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. Examples of these limited circumstances may include extreme disruptions such as a manufacturer product discontinuation, bankruptcy, public health emergency, or force majeure event. **Pricing or price challenges should not be a factor in enabling changes to the volume commitment amounts before the contract end date.**

- Allowance for Upward Price Adjustments

Contracting practices that are currently prevalent, including "most favored nation" clauses that require manufacturers to provide their lowest pricing to the purchaser with whom they are contracting, usually significantly limit generic drug manufacturers' ability to adjust prices with normal inflation over time.

While the core standards section does specify that price adjustments in the event of a natural disaster or severe supply chain disruption should be permitted, we recommend also including an allowance for manufacturers to adjust their pricing with normal inflation outside of the event of a severe disruption.

- Maximum Committed Volume Percentages

The Program currently lays out an initial minimum committed volume percentages of 40% of the provider or institution's usage of a drug, increasing in later years to 60% and then 75%. The coexistence of high-performing manufacturers with modestly higher prices and lower-performing manufacturers with modestly lower prices is an important aspect of a healthy market. To achieve this aim, we recommend including a maximum committed volume percentage for each provider, perhaps 75%, that would cap the amount of volume for each applicable generic that would be eligible for incentive payments. By helping to ensure that a portion of the market remains uncommitted and thus more accessible to non-participating manufacturers and new manufacturer entrants, this cap would help to reduce manufacturer barriers to entry and reduce market exits. The Secretary could also incorporate certain exceptions to minimum and maximum committed volume percentages to ensure an appropriate balance between the positives and negatives of committed contracts in terms of improving reliability of drug access.

- Encouraging Vetting and Selecting Reliable Suppliers

We recommend the removal of section (d)(3)(B)(ii)(I), which enables providers to receive the new Medicare incentive payments if their committed suppliers are unable to supply. As currently written, this section reduces provider incentives to vet and select more reliable suppliers. Contracts with suppliers that are unable to supply for a significant period due to an extreme event could instead be moved to a new supplier, as also described in the price challenge section above, and providers may additionally choose to negotiate failure to supply terms with suppliers to cover the loss of incentive payments. If this section is retained, the new Medicare incentive payments should be implemented in a way that still encourages diligence in contracting – for example, by reimbursing only a portion of additional costs incurred when suppliers fail to deliver.

d. Manufacturer Reliability Agreements

Manufacturer Reliability Agreements (MRAs) are a critical element of this proposal, and as currently written, they may encourage some additional supply chain reliability information sharing between manufacturers and drug purchasers.

However, information sharing alone does not mean that the information will be standardized, usable, and timely so that it can effectively inform supplier selection. Some information provided through MRAs may be useful, but much of the information will likely be redacted as proprietary.

In addition, any single program participant or provider will only receive information from manufacturers with whom they have MRAs in place and only on a limited number of drugs from each of those manufacturers. This will not provide an adequately holistic view of the market that would enable individual program participants and providers to assess risks and incorporate supply chain insights into supplier selection. Also, some program participants and providers may lack the expertise in pharmaceutical manufacturing necessary to interpret much of the information shared. Even with

additional information available, program participants may still have an incentive to contract with unreliable suppliers that are marginally less expensive (see section above on "Encouraging Vetting and Selecting of Reliable Suppliers"). As a result, we recommend focusing efforts on creating additional supports that drive manufacturer participation in standardized "drug supply chain reliability initiatives" and to ensure that manufacturers that are identified as reliable in such initiatives experience higher demand. Absent additional supports, manufacturers may lack motivation to participate in drug supply chain reliability initiatives.

We appreciate the Committee's inclusion of "drug product quality initiatives" within the draft legislation. Manufacturer participation in initiatives that generate actionable insights for drug purchasers regarding the relative reliability of various manufacturer and product supply chains can effectively enable competition on reliability rather than lowest price alone. However, we recommend replacing the term "drug product quality initiatives" with "drug supply chain reliability initiatives", in line with our recommendations in previous publications and for the reasons described in the box below.

Drug Supply Chain Reliability Initiatives

A **reliable supply chain** ensures that patients have safe and effective drugs, in adequate quantities, when they are needed**. Product quality** and **quality management maturity** are necessary, but not sufficient alone, to achieve a reliable supply chain. In a reliable supply chain, manufacturers of drugs display a high level of quality management maturity and robustness that enable sustained production and delivery of quality products over time. When a manufacturing quality issue or another disruption occurs, a sufficiently reliable supply chain avoids patient impact through practices such as backup raw material suppliers, manufacturing flexibilities and redundancies, inventory buffers, and risk management plans. Some of these reliable supply chain steps fall outside of the realm of product quality or quality management maturity practices. We believe the term "drug supply chain reliability initiatives" would more accurately reflect the Committee's intent and help to avoid unintentional implications that lower scores in certain evaluations (such as QMM) indicate that certain drugs may not be safe and effective.

Going forward in this document, we use the term "drug supply chain reliability initiatives" for the reasons outlined above.

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. This will promote participation among manufacturers and, critically, provide more standardized information for providers choosing between supplier options. This would not amount to a blanket requirement that manufacturers participate in specific drug supply chain reliability initiatives – those not wishing to participate in any specific drug supply chain reliability initiative could select another initiative in the same category or forgo participation in the overall Program. The Secretary would have the discretion to determine whether and when such initiatives are mature enough for inclusion in the MRAs. Some examples of potential model initiatives that could be considered include the Healthcare Industry Resilience Collaborative's Resiliency Badging Program, the International Society for Pharmaceutical

Engineering's Advancing Pharmaceutical Quality Program, the US Pharmacopeia's Medicines Supply Map and vulnerability scores, and others.

The next step toward improving purchasing behavior is to encourage providers to contract with manufacturers that perform better in drug supply chain reliability initiative evaluations. **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.** Safeguards can be put in place to ensure this approach does not cause significant market exits of lower-performing manufacturers. For example, we describe in the Core Standards section above how a cap can be put on the percentage of purchases through committed contracts that can qualify for incentive payments. This cap would help to retain a range of manufacturers in the market and also reduce barriers to entry for new manufacturers, while still driving improvements in overall reliability.

Importantly, this proposed approach bases payments on relative scores of manufacturers, rather than absolute scores available in the drug supply chain reliability initiative. It may be the case that no manufacturer achieves the highest score available; even so, providers should be incentivized to contract with those that are shown to be relatively more reliable.

Figure A: Illustration of an advanced or core standard encouraging providers to select more reliable manufacturers.

Manufacturers of Applicable Generic X	Drug Supply Chain Reliability Initiative Scores (1=lowest, 5=highest)
Manufacturer A	4
Manufacturer B	3
Manufacturer C	5
Manufacturer D	3

→ Providers that buy from Manufacturer A or C would receive an additional payment

Manufacturers of Applicable Generic Y	Drug Supply Chain Reliability Initiative Scores (1=lowest, 5=highest)
Manufacturer A	4
Manufacturer B	3

→ Providers that buy from Manufacturer A would receive an additional payment

Existing drug supply chain reliability initiatives are nascent and have not been highly adopted across the industry because of limited incentives for their use to date. Delaying implementation of the new core or advanced standard recommended above until after initial program implementation may be appropriate to help ensure drug supply chain reliability initiatives are more mature and well-validated. **A dedicated effort to foster the creation, development, and maturation of drug supply chain reliability initiative should be a priority led by a public-private partnership, as described in the previous section on that topic.**

e. Defining Applicable Generic Manufacturers and Private Labelers

In its current form, the Program understandably focuses on a straightforward version of the supply chain in which a manufacturer contracts with a GPO, wholesaler, and/or provider. In this scenario, as shown in Figure B, the finished dosage form (FDF) manufacturer that physically manufactures the product is the

same organization that holds the ANDA, and the same organization that markets and commercializes the product. This is a common arrangement, but these responsibilities, as shown in Figure C, are also commonly distributed across different entities in the supply chain.

Figure B: A straightforward supply chain with one entity responsible for manufacturing, holding the ANDA, and commercializing the product.

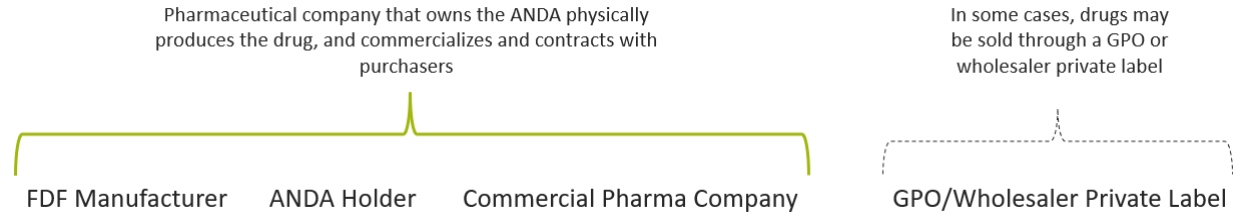

Figure C: A more complex supply chain with responsibilities distributed across different specialized entities.

The Program currently appears to center responsibilities around the entity in the "FDF Manufacturer" role above. Some elements of the Program, such as Manufacturer Reliability Agreements, are best fulfilled by the "FDF Manufacturer," but other elements, such as Pricing Stability Certifications or other contractual terms, must be taken on by the entity in the "Commercial Pharma Co" role. I**n the case where the same entity does not play all three pharmaceutical company roles above, the best approach for managing these distributed responsibilities may be to assign responsibility to the ANDA holder**. The ANDA holder could enter into Manufacturer Reliability Agreements with program participants and, if contracting out its manufacturing process, be responsible for ensuring that the contract manufacturer complies with the relevant terms of the Manufacturer Reliability Agreements. The ANDA holder may also choose to delegate responsibility for commercial items, such as contracting with program participants in a way that meets Core Standards, compliance with Pricing Stability Certifications, and Average Sales Price (ASP) reporting, to a commercial pharmaceutical company that performs the marketing and commercial organization role.

The definitions of private labels in the draft should allow flexibility for the Secretary to categorize organizations in a way that reflects the realities outlined above and the intentions of the legislation. We recommend considering updating the definition of private label in the draft to "a drug that is marketed or distributed under a distinct trade name by an entity that is not the marketing authorization holder." We also recommend including an allowance for ANDA holders to choose to delegate responsibility for commercial items to another commercial pharmaceutical company without the arrangement being considered a private label in the Program – this is notably different from a GPO or wholesaler private label.

Additional rationale for the above approach is provided in Appendix B.

f. Advanced Manufacturing / Manufacturing Technology Modernization Plans (MTMP)

As described in other ReVAMP Consortium publications, the adoption of advanced manufacturing technologies (AMTs) has been primarily concentrated in innovative, branded drugs, and rarely in generic sterile injectable (GSI) manufacturing, as economic pressures facing GSI manufacturers discourage the significant up-front investments required for AMTs. The advanced manufacturing definition that the Program references (which we understand to be section 506L of the Federal Food, Drug, and Cosmetic Act that created the Advanced Manufacturing Technologies Designation Program) was designed primarily for innovative drugs being considered for initial FDA reviews. This definition is important for spurring adoption of the most cutting-edge technologies in innovative products but is a very high bar relative to the current state of the GSI manufacturing field.

Manufacturing technologies that are well-understood by FDA and used by some manufacturers are not likely to be considered "advanced" by the current definition. However, technologies that are no longer consider "advanced" have often not been adopted to the ideal level among GSI manufacturers – or even, in some cases, at older manufacturing sites used for branded drugs. Technologies and methods such as electronic record keeping, automated visual inspection, novel container-closure systems, modernized sterilization equipment, new heating and cooling systems, and effective employee development and training programs are not used consistently enough in the GSI manufacturing field. Encouraging modernization in these areas is critical to ensuring a reliable manufacturing infrastructure.

Accordingly, 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. The MTMPs could be developed by manufacturers in collaboration with the public-private partnership mentioned above (and include FDA input) and would lay out steps that the manufacturer will take to modernize the technologies used in the manufacture of the applicable generic to meet or exceed industry benchmarks. Importantly, these plans need not center on the adoption of one specific advanced technology, nor would the adoption of one new technology necessarily be sufficient for the acceptability of an MTMP. Dozens of discrete technologies may be used in the manufacture of one product, and the goal of an MTMP should be to raise the technological standard throughout the process to an acceptable industry benchmark. The PPP could share with CMS a list of manufacturer-product combinations that meet acceptable industry benchmarks or have accepted MTMPs in place and could have discretion over the core components that should be included in such plans as well as related details such as the frequency with which they should be updated and how improvements can be verified. Public comment to inform these determinations would likely be appropriate.

g. Buffer Inventory Standard

Duke-Margolis previously provided comment on a CMS Proposed Rule to offer payments to hospitals and providers for maintaining a buffer inventory of certain essential medicines. Some of our key recommendations from that comment also apply to the buffer inventory provisions of this draft.

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. Providers should not be encouraged during a shortage to keep a significant stock of needed drugs in inventory rather than administering them to patients in need, as this will harm patients and exacerbate the effects of the shortage for other institutions. Payments for buffer stock inventory should be temporarily discontinued at a minimum while a drug is listed on the FDA Drug Shortage List.

These proposed payments, if implemented, would be most effective if accompanied by shelf-life extension efforts. Holding an adequate buffer stock is more difficult for products with shorter expiration dating. For example, after considering timing from manufacturing to quality control release, distribution timelines, normal variability in supply and demand, and common business norms that involve quarantining product with less than 12 months before expiration for destruction, a drug with an 18 months shelf-life often has a window of less than 3 months available for holding a buffer stock. Congress should consider how to reduce obsolescence costs and encourage manufacturers to run stability studies to seek longer expiration dating.

In addition, 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. Best practices for equitable allocation and inventory management and preventing waste should be followed.

Finally, payments to providers for maintaining a buffer inventory (whether an enhanced 6-month inventory or a core standard 3-month inventory) could be made on a quarterly basis, like payments for meeting other core and advanced standards. Eliminating divergence in payment schedules will standardize the process of distributing payments, and it will enable buffer inventory payments to be more responsive to the shortage status of applicable generics – specifically, to pause payments for buffer inventory during times of shortage.

h. Other

Outcomes Measures: The Outcomes Measures section that would retroactively reward providers if they bought from manufacturers who actually delivered a reliable supply and enabled patient access has significant potential for positive impact. However, questions on this scorecard approach remain, including how often shortages can be fairly and accurately tied to missteps by a specific manufacturer(s), expectations for higher payments to address payment uncertainty, feasibility of program administration, and a need for coordination between CMS and FDA. If these questions can be addressed, then outcomes-based payment programs would provide strong incentives for drug purchasers to use reliable suppliers. To support this, CMS and FDA could pilot the creation of a sample scorecard under a memorandum of understanding.

Aligning duration of program provider agreements, contractual volume commitments, and program applications: In the current draft, program provider agreements between payment-eligible providers and program participants, along with program participation agreements, can change (with applicable generics added or removed) on an annual basis, while the contractual volume commitments between program participants and manufacturers would last for 2-3 years. The Committee should consider how to align these durations to enable long-term volume commitments. The Committee could also consider

if there is a workable method to enable new volume commitments to be added on an annual basis without also enabling existing volume commitments to be removed before contract expiry.

Provisions related to Medicaid inflation penalty rebates and 340B pricing: These provisions are likely to improve the ability of manufacturers to invest in reliable manufacturing of these drugs, as Duke-Margolis noted in a previous comment letter on draft legislation with similar provisions. We recommend studying and quantifying the potential impact of these proposals on manufacturers, providers, government, and other stakeholders. This study could analyze, for various sets of drugs, the percentage of volume that goes through 340B contracts compared to the rest of the market, 340B prices compared to average manufacturer net prices, and other areas. The sets of drugs that could be evaluated could include essential injectable drugs vs all injectable drugs, generics vs brands, and other groupings.

"Core" and "backup" suppliers: We recommend considering identification of "core" and "backup" suppliers rather than one "primary" supplier and one "secondary" supplier. This would enable program participants and providers to split their volume across more than two suppliers if they choose, which can increase supply chain redundancies. In this scenario, program participants and providers could still be required to identify at least one "core" and at least one "backup" supplier that meet the current draft's criteria for "primary" and "secondary" suppliers. In addition, it is usually much more efficient for a provider to standardize all their purchases to one manufacturer for a given generic drug. As currently written, the program would require payment-eligible providers to stock two manufacturer versions of every applicable generic. Instead of having each provider stock a primary and secondary supplier, the Committee should consider including the "core" and "backup" supplier distinction at the program participant level. The program participant could then, for example, ensure that at least 10% of total volume for the payment-eligible providers that contract with them go to the backup supplier.

Total standard inventory: Though defined clearly in subsection (f), total standard inventory is not an intuitive term for the concept described. We recommend the terms "standard annual demand" or "standard annual units administered" as more straightforward options.

Certain redundant reporting requirements: Under "Reporting and Recordkeeping Requirements," clauses (i)-(iii) require payment-eligible providers to report the total volume and units purchased on contract through primary and secondary suppliers, as well as units purchased from other manufacturers and entities during a program year. Clause (vii) requires them to report units purchased off-contract during the same period, which may be redundant. Information reported under clauses (i)-(iii) already shows off-contract purchases, and clause (vii) may be struck.

Aggregation of applicable generics: Under "Applicable Generic Defined," the draft legislation specifies that applicable generics must be injectable or infused drugs, but under clause (iii) on aggregation states that all dosage forms should be aggregated as a single applicable generic. All dosage forms of an injectable or infused drug will often include solid oral dosage forms, which are outside of the intended scope of this legislation. The language on aggregation should be clarified to ensure solid oral dosage forms of generic sterile injectable drugs are not unintentionally made eligible for incentive payments.

Applicable incentive percentages: Under "Methodology for Assigning Base Applicable Incentive Percentages to Applicable Generics for Meeting Core Standards," we appreciate the discretion allowed for the Secretary to assign higher incentive percentages for generics subject to persistent shortages as

specified in sub-clause (I). We recommend another sub-clause be added to allow similar discretion based on a generic's essentialness to patient care or lack of clinically viable alternatives. In other words, the Secretary should be granted discretion to assign higher incentive percentages if a generic is life-saving, identified on an official list of essential medicines, or has no clinically viable alternatives.

Appendix A: 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.

Appendix B: Changes to Definitions of Applicable Generic Manufacturers and Private Labels

Under the draft text of the Drug Shortage Prevention and Mitigation Act, in some instances the FDF Manufacturer would be considered an applicable generic manufacturer, while the ANDA Holder and Commercial Pharma Co would be considered a private labeler and subject to pricing markup restrictions. We do not believe this is the intention of the draft text.

Efficiencies are created when contract manufacturing arrangements allows the FDF Manufacturer to specialize in the physical process of manufacturing, while the ANDA Holder and Commercial Pharma Co manages other processes like regulatory filings, negotiating with contracting entities, arranging for the drug to be distributed properly, marketing, managing serialization vendors, pharmacovigilance, government price reporting etc. The legislation as written may not allow these entities to leverage their relative strengths.

Rewriting the definitions of Applicable Generic Manufacturers and Private Labelers for the purposes of the Program could alleviate these issues, but any new definition may have its own unintended consequences. We recommend the Committee weigh potential unintended consequences as it refines this legislation.