October 19, 2023

Chairman Brett Guthrie
Committee on Energy and Commerce
Subcommittee on Health
2125 Rayburn House Office Building
Washington, DC 20515-6115

Dear Chairman Guthrie:

On behalf of the developers, manufacturers and distributors of FDA-approved generic and biosimilar prescription medicines, the Association for Accessible Medicines (AAM) thanks you for the opportunity to provide, in writing, our extended responses to questions from the hearing entitled "Legislative Proposals to Prevent and Respond to Generic Drug Shortages."

**The Honorable Cathy McMorris Rodgers**

1) **Mr. Gaugh, can you explain how the inflationary rebates included in the Inflation Reduction Act (IRA) could further erode sterile injectable manufacturers' ability to invest in manufacturing improvements?**
2) **How would exempting sterile injectables that are at risk of experiencing shortages from the IRA's inflationary rebates allow manufacturers to devote resources to avert such shortages?**

**Answer:**
Inflation penalties in Medicaid and Medicare can create significant challenges for generic drug production. It is important to note that the discretion to waive or reduce these only applies to Medicare inflation penalties and not those in the Medicaid program. AAM believes that CMS can better utilize this authority to reduce shortages or prevent shortages from worsening.

Inflation penalties on low-priced generics such as sterile injectables can prevent a manufacturer from taking a small but meaningful price increase that may be the difference between realizing a sustainable return and being forced to exit the market. Moreover, inflation penalties such as those in the Medicaid program can affect a generic manufacturer even when it has not taken a price increase. Because generic manufacturers, unlike brands, operate in highly competitive markets, a product's average manufacturer price (AMP) can vary significantly from quarter to quarter as a result of changes in customer purchasing patterns that are outside of the manufacturer's control. This means that these penalties, in addition to being financially onerous, are highly unpredictable. This creates additional uncertainty and financial challenges that a manufacturer must navigate in determining whether to remain in a low-margin market.

We therefore encourage Congress to update the generic drug Medicaid Inflation Penalty to align with the inflation penalty included in the Inflation Reduction Act (IRA). The IRA applies the inflation penalty to single-source generics and gives the Department of Health and Human Services authority to exempt products in or at risk of shortage.[1] Applying this to the Medicaid inflation penalty and broadly

[1] Pub. L. 117–169

exempting generics that are at risk of shortage would more appropriately address the unique features of the generic drug market and, by doing so, help ensure sustained patient access to treatment.

**The Honorable Robert E. Latta**

1) **FDA currently requires drug manufacturers to report when there is an interruption in manufacturing that is likely to lead to a meaningful disruption in supply of a product in the U.S. Further, FDA already recommends that companies notify them when there is a sudden, unexpected spike in demand, even when not due to a manufacturing issue. How do your member companies avoid or mitigate a shortage and how do they cooperate with the FDA?**

**Answer:**
Our member companies do projections to forecast the demand for their drug products and plan their production to meet the demand. Manufacturers order key starting materials and other ingredients and schedule the production time in facilities in order to manufacture their products to meet the forecasted demand. Additionally, manufacturers conduct routine maintenance of their facilities and work with contract manufacturing organizations ("CMOs") to ensure they are operating according to production schedules. However, unexpected events, such as natural disasters, unexpected shortages of active pharmaceutical ingredients (API) or critical components such as glass vials, stoppers, and IV bags, manufacturing line breakdowns or adverse inspectional observations that affect a members' facility or that of another manufacturer, may cause unanticipated spikes in demand. As required by law, AAM's members notify FDA when they anticipate a meaningful disruption in the supply of one of their products in the U.S., and they work with FDA's Drug Shortage Staff to mitigate a potential shortage or alleviate the effects of the shortage. For example, they will work with FDA to investigate the root cause of the shortage and review possible risk mitigation measures for remaining inventory.

2) **This Committee is evaluating different proposals to better understand how to address potential shortages. However, sometimes reports in increases or decreases, which happen often, don't result in a shortage, or don't have any immediate consequences for patients. What are your thoughts on companies that would be required to speculatively report, with the threat of penalties for failure to do so? Could this result in expanded FDA authority in which they receive additional noise and data that ultimately does not have any positive results?**

**Answer:**
AAM shares the concern that requiring companies to speculatively report with the threat of penalties for failure to do so could lead to additional noise in the system without positive results and, in fact, could contribute to additional generic product discontinuations that would increase rather than decrease shortages. Under such a system, manufacturers are more likely to err on the side of over-reporting to avoid penalties. As mentioned in my testimony, manufacturing generic drugs is a highly competitive, low-margin industry. Generic prices are decreasing, drug purchasers are becoming more concentrated, new generics are not adopted as quickly, an increasing number of generics are never launched in the U.S. due to limited commercial opportunities, and registered manufacturing sites are declining. This additional reporting would unnecessarily burden industry without commensurate benefit. AAM recommends that Congress avoid imposing new requirements on companies to submit data that may be highly speculative and, therefore, unlikely to help to alleviate shortages.

On pages 8 and 9 of my testimony, I included several recommendations to reduce regulatory and manufacturing challenges that could have a more direct impact on alleviating drug shortages without

unnecessarily increasing the burden on industry. For example: Empower the FDA Drug Shortage Staff to engage with CDER and ORA staff during the inspection planning process prior to the actual inspection to work with manufacturers and build on their track record of successfully mitigating shortages.

3) **Some companies may not have an idea, unless their ingredient suppliers told them previously, that an ingredient they provided that went into a particular product of theirs had seen an increase in orders for several consecutive weeks. How would these penalties be given if a company was honestly unaware of increased purchases, and they did not have the appropriate information provided to them? Is there a way to best streamline and encourage communications that incentivize transparency?**

**Answer:**
The H.R. 3008, the Drug Shortage Prevention Act, under consideration by the Committee would require a manufacturer of a critical essential medicine to notify the Secretary of Health and Human Services ("the Secretary") of a permanent discontinuance in the manufacture of an active pharmaceutical ingredient ("API"), an excipient, or any other input in the final dosage form of such drug, or an interruption in the manufacture of such ingredients, excipients or inputs that is likely to lead to a meaningful disruption in the supply of the ("API"), or an increased demand for such a drug, API, excipient, or other input that is likely to lead to a shortage. (See Section 2.a.)

Most generic drug manufacturers obtain their API, excipients, and other drug inputs (e.g., glass vials, stoppers, IV bags) from other upstream manufacturers and would not likely have the information unless the ingredient or input supplier notified the manufacturer of the finished drug product of the increased demand and possible disruption in the supply. The reporting requirements should apply to the upstream manufacturers of the APIs, excipients and inputs into critical essential medicines. A list would need to be created of critical essential medicines and the ingredients or inputs that could disrupt their supply, and the reporting requirements should be placed directly on those manufacturers and not on the downstream manufacturer of the finished drug product.

**The Honorable Anna Eshoo**

1) **During your hearing, you spoke about how drug manufacturers invest in quality. Please elaborate by providing the following for the top 10 generic sterile injectable manufacturers selling on the U.S. market:**
   **a) Number of facilities manufacturing generic sterile injectables.**
   **b) Average, median, minimum, and maximum capital reinvestment rates for these facilities for each year between 2018-2022.**
   **c) Explain variations in capital reinvestment rates.**
   **d) Are there other investments in quality that are not captured in the capital reinvestment rate? Please elaborate.**

**Answer:**
AAM is a trade association representing individual manufacturers, and with this we are unable to answer detailed financial questions about our members as this type of information is confidential to individual companies, and not shared with AAM. Our suggestion is to reach out to the individual manufacturers for additional context. Specific to the number of facilities manufacturing generic sterile injectables (1a), manufacturers are required to report listed facilities to the Food and Drug Administration which in turn provides the FDA access to this type of individual and collective

information. Additionally, manufacturers are now required to submit volume data to the FDA as provided by the CARES Act.

**2) In your testimony, you mentioned price pressures through government programs lead manufacturers to discontinue products. Please elaborate on the mechanism through which this can happen. Please provide evidence that these dynamics have led to manufacturers discontinuing products.**

**Answer:** Recent years have witnessed sustained pressure on generic prices through government programs and policies as well as purchaser consolidation. As I noted in my testimony, the 2015, enactment of a new price inflation penalty in the Medicaid program for generics[2] was based on brand medicines and neglected important differences in market function. For instance, because it holds a monopoly, a brand manufacturer controls its price, but a generic manufacturer's average price fluctuates due to decisions, outside of its control, by purchasers and other generic competitors. As a result, generic manufacturers now face millions of dollars in rebate "penalties" on generics that have not been subject to a price increase.[3] These unpredictable, onerous payments undermine the financial viability of low-margin generic markets. This was foreseen by a 2017 analysis concluding the penalty would "increase uncertainty, reduce revenues, encourage manufacturers to exit the market, and discourage the entry of new manufacturers… [and would] have the unanticipated and unintended consequence of increasing the likelihood of shortages for generic medicines."[4]

(In comparison, the IRA applies the inflation penalty to single-source generics and gives the Department of Health and Human Services authority to exempt products in or at risk of shortage.[5])

Moreover, use of the 340B drug purchasing program continues to grow.[6]

Each of these policies, combined with pressure from large, consolidated buying groups and Group Purchasing Organizations, reduces the value of generic prescriptions to the manufacturer. In fact, IQVIA estimates that the total value of all generics sold in the US (including the additional volume from new generic launches) has fallen by $6.4 billion in the past five years. It should therefore be no surprise that product discontinuations have numbered over 3,000 since 2010 and many generics are never launched.[7]

**3) What is the Association for Accessible Medicines' position on drug importation to alleviate drug shortages?**

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[2] Public Law No: 114-74.

[3] Association for Accessible Medicines. "CPI Penalty on Medicaid Generic Drugs Threatens Patient Access to Affordable Medicine" (September 2017) Available at: https://accessiblemeds.org/resources/press-releases/cpi-penalty-medicaid-generic-drugs-threatens-patient-access-affordable

[4] Manning and Selck, "Penalizing Generic Drugs with the CPI Rebate will Reduce Competition and Increase the Likelihood of Drug Shortages" (September 2017). Association for Accessible Medicines. Available at: https://www.accessiblemeds.org/sites/default/files/2017-09/Bates-White-White-Paper-Report-CPI-Penalty-09-12-2017.pdf

[5] Pub. L. 117–169

[6] IQVIA Institute for Human Data Science. "The 340B Drug Discount Program Exceeds $100B in 2022" (April 2023) Available at: https://www.iqvia.com/locations/united-states/library/white-papers/the-340b-drug-discount-program-exceeds-uds100b-in-2022

[7] Association for Accessible Medicines. "Drug Shortages: Causes & Solutions" (June 2023). Available at: https://accessiblemeds.org/sites/default/files/2023-06/AAM_White_Paper_on_Drug_Shortages-06-22-2023.pdf

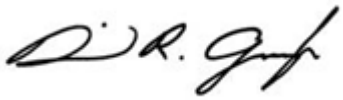
We understand this question is being asked relating to the ongoing drug shortages for oncology products. With this, AAM appreciates the FDA's efforts (specifically CDER's Drug Shortage Staff) and willingness to work with Industry to mitigate drug shortages and feel their ability to utilize regulatory discretion as needed is a necessary tool in doing so.

The FDA's assessment process to approve a drug product is the global gold standard and this high standard reassures the American public that their product is safe, efficacious and of high quality.

The FDA utilizes importation as a regulatory discretion tool on a case-by-case basis. However, importation of unapproved products that have not gone through the rigorous FDA assessment process serves as a temporary band-aid to the larger drug shortage problem. We urge Congress to consider our testimony and our listed recommendations on page 8 and 9 as potential tools to help solve the larger drug shortage issue.

Again, we thank you for the opportunity to testify in front of your committee on an issue of such importance. Drug shortages affect all Americans and we want to serve as a partner with Congress to help alleviate this crisis. Please do not hesitate to contact me for any with any future questions.

Sincerely,



David Gaugh, R.Ph.
Interim President & CEO

CC: The Honorable Anna Eshoo