The Honorable Morgan Griffith
Chairman, Subcommittee on Health
House Committee on Energy & Commerce
2110 Rayburn House Office Building
Washington, DC 20515

The Honorable Diana DeGette
Ranking Member, Subcommittee on Health
House Committee on Energy & Commerce
2111 Rayburn House Office Building
Washington, DC 20515

Dear Chairman Griffith & Ranking Member DeGette:

Below are my answers in response to additional questions for the record submitted by members following my appearance before the Subcommittee on Health on Wednesday, June 11, 2025 at a hearing entitled, *"Made in America: Strengthening Domestic Manufacturing and the Health Care Supply Chain."*

The Honorable Erin Houchin

1. Mr. Murphy, the speed to onshore pharmaceutical manufacturing is largely determined by the speed with which manufacturers can construct and qualify a facility in the United States with the Food and Drug Administration (FDA). Can you give any suggestions to accelerate U.S. pharmaceutical domestic manufacturing and minimizing regulatory roadblocks while maintaining high safety standards?

> *a. For example, how can Congress encourage the FDA to think creatively to facilitate earlier FDA involvement with new or recapitalized U.S.-based sites to speed the availability of medicines made in the U.S.?*

Mr. John Murphy, III

We believe there may be several considerations and opportunities for the FDA, the states, and the elected officials to work collaboratively on this issue.

Before we focus on FDA, we should point out that incentivizing public-private collaboration for U.S. sites through grants, tax credits, or guaranteed purchase programs, would greatly help accelerate U.S. pharmaceutical domestic manufacturing.

Once a manufacturer has made the decision to build a new manufacturing facility or repurpose existing manufacturing sites/lines, there are several actions the FDA could take to help accelerate this process.

Enable Earlier FDA Engagement and Pre-Approval Collaboration

1. Encourage FDA to meet with manufacturers during the planning and construction phase, rather than waiting until facilities are fully built and validated.
2. Establish a "pre-construction/pre-validation inspection program" to identify compliance gaps early.
3. Consider developmental-phase and pre-submission inspections, allowing FDA to sign off on key quality systems in parallel with construction and tech transfer.
4. It would be helpful if the FDA collaborate with states on inspection activities to limit the need redundant inspections.
5. It would be helpful if the FDA work with EPA on certain environmental issues related to new facility construction.

Create a Dedicated FDA Domestic Manufacturing Task Force

- Congress can request FDA form an intra-agency working group to fast-track domestic manufacturing projects, involving:
  - Office of Pharmaceutical Quality (OPQ)
  - Office of Compliance and Office of Inspections
  - Office of Generic Drugs
- This team would coordinate reviews, inspections, and tech transfer approvals to compress the typical 5–7 year timeline for a new facility.

Regulatory Flexibility with Safety Maintained

- If a manufacturer has a strong compliance record, the FDA should consider certain changes be permitted without potentially having to inspect every proposed change.

- If a manufacturer has a strong compliance record, consider use of alternate inspectional tools that may fall under the Remote Regulatory Assessment (RRA) paradigm.

As mentioned briefly above, Congressional Support to Encourage FDA Creativity

- Statutory authority or appropriations can support early engagement programs and inspection resources to avoid delays caused by limited FDA staffing.
- Incentivize public-private collaboration for U.S. sites through grants, tax credits, or guaranteed purchase programs.

The Honorable Jake Auchincloss

1. The 340B program has grown substantially since its inception – the number of participating provider organizations has increased by 600 percent since 2000. It is now one of the largest federal prescription drug programs. What concerns do you have about how reimbursement policies affect generic manufacturing and supply-chain resilience?

Mr. John Murphy, III

In 2023, generics continued to demonstrate their value proposition -- representing 90 percent of all prescriptions filled but only 13 percent of all prescription drug spending. Generic and biosimilar medicines are the only segment of healthcare that consistently delivers lower costs. In fact, generic prices continue to experience severe deflation; the overall value of all generic sales in the U.S. has declined by $6.4 billion since 2019, despite increased volume and new generic launches.[1] Generic drugs save patients money. In 2024, the average out-of-pocket cost for a generic was $6.95; while the average out-of-pocket cost for a brand drug was nearly five times higher – at $28.69.[2]

A recent analysis by RAND found that generic prices in the U.S. average 16 percent less than other countries, and between 30 to 50 percent less than nations such as the U.K., Mexico, France and Japan.[3] This difference is the result of a hyper-competitive U.S. generic

[1] IQVIA Contributors. (May 2023). The Use of Medicines in the U.S. 2023. Accessible at: https://www.iqvia.com/insights/the-iqviainstitute/reports-and-publications/reports/the-use-of-medicines-in-the-us-2023

[2] IQVIA Institute. (April 2025). *Understanding the Use of Medicines in the U.S. 2025.* Accessible at: https://www.iqvia.com/-/media/iqvia/pdfs/institute-reports/understanding-the-use-of-medicines-in-the-us-2025/iqvia-institute-iqi-us-use-of-medicines-04-25-forweb.pdf

[3] RAND. (February 2024). International Prescription Drug Price Comparisons. Accessible at: https://www.rand.org/pubs/research_reports/RRA788-3.html

drug market in which prices can rapidly fall by 40 percent on average, and as much as 95 percent upon generic entry.[4]

With respect to 340B, in particular, as you are likely aware, the formula utilized for creating the Medicare drug pricing is carried over into the 340B program. In 2017, a new penalty was imposed on generic manufacturers participating in the Medicaid program. Targeting price increases exceeding the rate of inflation, the Medicaid Generics Penalty (MGP) ignores important market differences between generics and brand-name drugs. To better understand the impact of this penalty on generic manufacturers, AAM requested an in-depth analysis by Avalere Health, and the following includes their findings.[5]

According to Avalere Health, the rule unfairly penalizes manufacturers for price fluctuations outside of their control, increases the risk of drug shortages, and threatens the continued availability of low-cost generics to patients. Generic manufacturers may have price increases for items outside the manufacturer's control (e.g., purchasing pattern fluctuations, including changes in customer base and seasonal changes in product usage).

Further, pricing for generic drugs is highly affected by the commoditized nature of the multi-source generic market. Price competition in many generic markets has driven prices down to just above production costs, with minimal margins to absorb any fluctuations (e.g., increases in manufacturing or ingredient costs). This downward pressure may result in price increases for generic manufacturers when input costs increase or when there is a shortage. This is particularly likely when the benchmark is low, which occurs when a manufacturer enters the market after others or if it is an older generic drug (where there has been sustained price competition).

Given these problems, Congress should refine the Medicaid drug inflationary penalty and model it after the Medicare inflationary penalty, which takes into account the multi-source nature of the generic drug market.

While the U.S. generic market is clearly in peril, solutions are not far out of reach. In addition to changes to the MGP, policymakers must streamline FDA processes, curb patent abuse, stop PBMs and Medicare policies from denying patient access and rollback harmful federal policies – including IRA price controls.

The time to act in the best interest of America's patients is now!

---

[4] FDA. (December 2019). Generic Competition and Drug Prices: New Evidence Linking Greater Generic Competition and Lower Generic Drug Prices. Accessible at: https://www.fda.gov/media/133509/download

[5] Avalere. (February 2025). *The Medicaid Drug Rebate Program and Considerations for Generic Markets.* *https://advisory.avalerehealth.com/wp-content/uploads/2025/02/The-Medicaid-Drug-Rebate-Program-and-Considerations-for-Generic-Markets.pdf*