Association for Accessible Medicines
Statement of John Murphy III, President & Chief Executive Officer
House Energy and Commerce Subcommittee on Health
"Lowering Health Care Costs for All Americans: An Examination of the Prescription Drug Supply Chain"
February 11, 2026

Chairman Griffith, Ranking Member DeGette, and the members of the Energy and Commerce Health Subcommittee, thank you for the invitation to testify today and the opportunity to comment on the critical topic of strengthening the pharmaceutical supply chain and bolstering domestic drug manufacturing. I am John Murphy III, President and CEO at the Association for Accessible Medicines (AAM).

AAM represents the manufacturers of finished generic and biosimilar pharmaceutical products, manufacturers of bulk active pharmaceutical chemicals, and suppliers of other goods and services to the generic and biosimilar pharmaceutical industry. AAM works to expand patient access to safe, quality, and effective generic and biosimilar medicines by promoting a positive regulatory, reimbursement, and policy environment and advancing education regarding the safety and effectiveness of generic and biosimilar medicines.

Generic and biosimilar medicines are a primary driver of prescription drug affordability in the United States. Their use generated $467 billion in savings in 2024 for patients and the health care system[1]. In our view, the savings generated by these medicines are actually depressed in the US market. A number of aspects of the current market, and regulations underlying it, are preventing full utilization of many generic and biosimilar medicines. This Committee, and Congress more broadly, have the opportunity to significantly unlock additional affordability simply by enhancing the market to produce and access lower-cost generic medicines.

[1] Association for Accessible Medicines, 2025 U.S. Generic and Biosimilar Medicines Savings Report (2025)

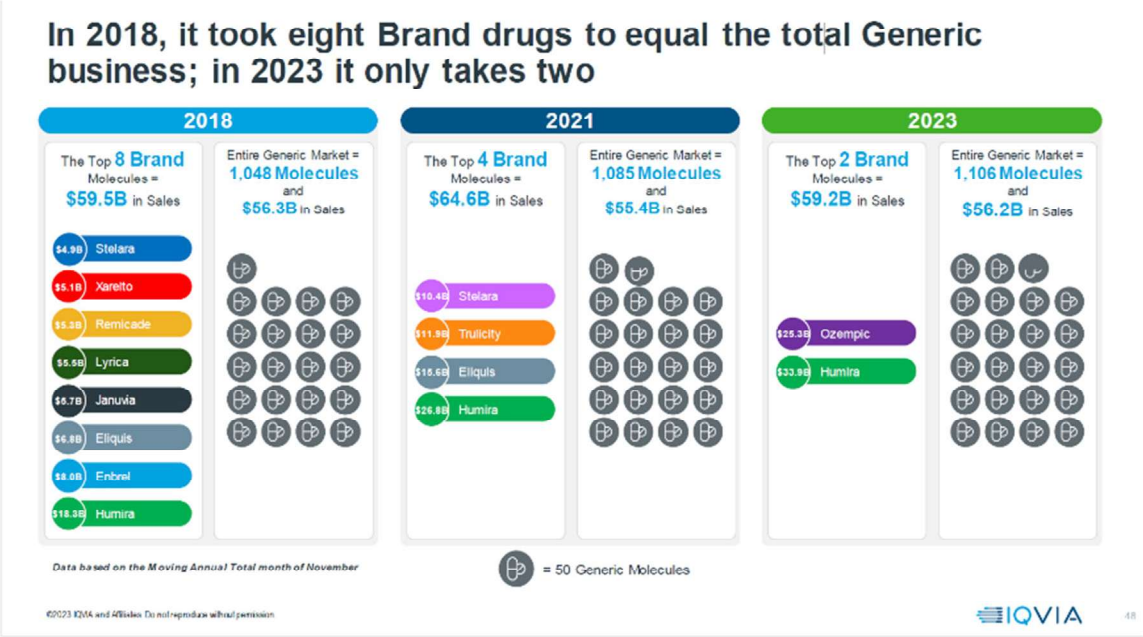
These affordability benefits accrue across public and private payers and are particularly important for patients managing chronic and complex conditions. The AAM 2025 Savings Report shows that Medicare and Medicaid together accounted for more than half of total generic and biosimilar savings, underscoring the role that these medicines play in supporting program sustainability and beneficiary access. Biosimilars are also delivering growing savings in high-cost specialty categories, generating more than $20 billion in 2024 alone as additional competitors continue to enter the market. Independent analyses consistently find that increased generic and biosimilar competition lead to lower prices without compromising quality or safety.[2]

In the healthcare system, generic drugs are the only sector that consistently results in **decreased** spending. 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.[3] This decrease in spending has consistently been the case since the passage of Hatch-Waxman in 1984. While generic drugs have been consistently 9 out of 10 prescriptions, their overall percentage of costs has declined from 27 percent in 2016 to 12 percent in 2024.

Despite the widespread use of low-cost generic and biosimilar medicines, overall prescription drug spending continues to rise due to spending concentration in a small number of high-cost brand and specialty products. As illustrated in the accompanying data, in 2018 it took eight brand medicines combined to equal total U.S. spending on all generic drugs. By 2023, spending on just two brand medicines, Ozempic and Humira, exceeded total spending on more than 1,000 generic medicines combined. This trend highlights how growth in spending on a limited number of high-

[2] IQVIA Institute for Human Data Science, The Impact of Biosimilar Competition in the United States (2023)
[3] IQVIA Contributors. (May 2023). The Use of Medicines in the U.S. 2023. https://www.iqvia.com/insights/the-iqviainstitute/reports-and-publications/reports/the-use-of-medicines-in-the-us-2023

cost products can outweigh the substantial savings generated by broad generic and biosimilar competition.



For generic manufacturers, increased affordability has coincided with sustained downward pressure on prices. Compared to 30 years ago, generic drugs are launching at lower prices and reaching lower long-term price levels. Historically, generic prices tended to stabilize at approximately 34 percent of the brand product's list price. Over the past decade, that figure has declined to approximately 22 percent, reflecting deeper and more prolonged price competition. While this trend has produced significant savings for patients and the health care system, it has also reduced margins for manufacturers operating in an already highly competitive market. Similarly, the significant consolidation of the purchaser market in the US, along with the growth in utilization and rebating tools between brand manufacturers and health plans have constricted meaningful access to many generic specialty and biosimilar medicines. For biosimilars

specifically, the US consistently lags both Europe and Canada in access to and approval of affordable biosimilar medicines.

Maintaining patient access therefore requires policies that preserve robust competition while supporting a stable manufacturing base. The affordability gains delivered by generics and biosimilars are the result of sustained market participation by multiple suppliers. Continued price erosion combined with rising fixed costs can increase the risk of market exits, reduced redundancy, and supply disruptions. At the same time, for more complex and specialty generics and biosimilars, purchasers that favor brands at the expense of marketed generics and that throttle access to patients these more affordable medicines decreases the investability of future generations of these medicines – depressing entirely the ability of this sector to grown and sustain the US market. Ensuring that manufacturers can continue to invest in production, quality, and supply-chain resilience is critical to maintaining reliable access to low-cost medicines for patients.

This success is not just an economic achievement; it is a lifeline for patients who depend on affordable medicines to manage chronic conditions, treat serious illnesses, and maintain their quality of life.

Continued access to affordable generic and biosimilar medicines depends on addressing a series of market and policy challenges:

1. **Regulatory Barriers:** Outdated and unnecessary FDA requirements delay the development and approval of lower-cost generics and biosimilars. To improve access to generics and biosimilars, FDA should strive for harmonization of approval and licensure requirements: including streamlining of biosimilar clinical trial requirements, and

codification of FDA's recently announced scientific determination that biosimilar medicines be deemed interchangeable upon approval, bringing US policy in line with most other major economies.

2. **Patent Abuse:** Brand-name drug manufacturers exploit the patent system through "patent thickets" that block generic and biosimilar competition. These anticompetitive tactics keep drug prices high and delay patient access to affordable alternatives.

    - Brand-name pharmaceutical companies are increasingly amassing a large number of patents in both the small molecule and biologic space. These large patent estates make it economically difficult for generic and biosimilar companies to meaningfully challenge these patents. Even when the patents may be largely invalid or avoidable, the sheer number of patents makes the litigation too burdensome and too expensive for a generic or biosimilar company. This Committee can work across Congress to address these patent thickets through the ETHIC Act and to ensure the USPTO maintains access to the Congressionally-created IPR process that allows a more affordable and efficient pathway to challenge these duplicative and abusive patent practices.

    - Skinny labels are a critical tool - provided for in the original Hatch-Waxman amendments - to expedite patient access to lower-cost medicines. Generic labels duplicate the brand's label, but where one use is patented, generics can simply drop the patented indication from their labeling. Recent Federal Circuit decisions have called skinny labeling into question. S. 43/HR 6485 provides safe harbor to ensure that this important practice continues.

- Congress should require greater transparency and consistency in the information that drug sponsors provide to both the Food and Drug Administration and the U.S. Patent and Trademark Office, including certifying that patent-related disclosures submitted to each agency are aligned and complete. Such requirements would help ensure that patent examiners and regulators work from the same set of material facts regarding patentability and drug approval, reducing gaps that can contribute to extended exclusivity. Additionally, providing a defense against patent infringement claims when a patent owner fails to disclose required information would reinforce compliance with these transparency obligations and support earlier generic and biosimilar market entry by reducing uncertainty in patent enforcement.

3. **Flawed Policies:**

- Medicare policies and practices by pharmacy benefit managers (PBMs) often reward the use of higher priced brand-name drugs over lower-cost generics and biosimilars. Formulary practices – both in the Medicare and private markets – should prioritize coverage of generic and biosimilar medicines once they become available to US patients. Current PBM incentives often prioritize rebates and fees tied to higher list price drugs rather than the lowest total cost to the program. Because rebates are paid after dispensing and PBM compensation is frequently linked to list prices, higher priced drugs can generate greater PBM revenue even when they increase overall Medicare spending.

- Medicaid policies penalize generic products with unpredictable rebates even when there are no price increases.

- These and other policies distort the market and directly harm patients, forcing them to pay more for the medicines they need.

4. **Overall sustainability:** Due to a lack of adequate reimbursement, generic medicines are increasingly at risk of shortages. Without systemic reforms to stabilize and incentivize the generic drug supply chain, patients could face dangerous interruptions in their treatment.

If these challenges are not addressed, the consequences will be devastating. America's patients will lose access to reliable, low-cost therapies. Taxpayers will bear a greater burden as healthcare costs soar. The very principles of competition and innovation that have driven the success of generics and biosimilars will be eroded.

If policymakers are serious about protecting patients and ensuring sustainable access to affordable medicines, they must act decisively to address these systemic threats. This requires a comprehensive plan, including:

- **Streamline Regulatory Pathways:** Ensuring quicker approvals, while maintaining FDA's high standard of safety, efficacy, and quality, will increase competition and lower prices. Policymakers should eliminate unnecessary FDA regulatory barriers that delay the approval of generic and biosimilar medicines, including through:
    - Streamlining FDA's approval process including the ability to utilize a global comparator
    - Removing redundant clinical studies for approvals of biosimilars that FDA no longer deems necessary, such as clinical efficacy studies for biosimilars
    - Updating the Biologics Price Competition and Innovation Act (BPCIA) to deem all biosimilars interchangeable

- **Curb Patent Abuse:** Congress should act to address practices that extend market exclusivity without corresponding innovation, including the growing misuse of terminal disclaimers. Terminal disclaimers are legal filings that tie the expiration of later patents to an earlier patent, but in practice they are often used to support serial patenting strategies that extend effective exclusivity and delay generic and biosimilar entry. Reforming this practice would strengthen competition and help reduce costs for patients and taxpayers.

- **Stop PBMs and Medicare Policies from denying patients access to new generics and biosimilars: Medicare and PBMs must stop prioritizing higher-priced brand-name drugs over generics and biosimilars.** Congress and the Administration should ensure patient access to new generic and biosimilar medicines and reform PBM practices by enhancing PBM transparency by focusing on prospective net effective cost guarantees and further discouraging practices supported by rebate walls. A greater focus on total net cost across all beneficiaries and medicines would better align incentives with program affordability. A greater use of low list price generics and biosimilars, particularly through models that do not rely on large rebate structures, could generate substantial savings for Medicare and other payers while maintaining patient access. Without reforms to align PBM incentives with total cost, continued underutilization of lower cost biosimilars risks weakening competition and increasing long term spending.

- **Ensure Adequate Reimbursement:** Given today's absence of biosimilar development for many of the biologics that will lose patent exclusivity in the next decade, Congress and the Administration should act to modernize the Medicare Part B reimbursement for biosimilars so that providers are not "underwater" – in many cases reimbursing providers below acquisition cost, and, as such, putting the biosimilar out of the reach for patients.

- **Rollback Harmful Federal Policies:** Too many federal policies actively harm generic and biosimilar competition.
    - Congress should fix the Medicaid Generics Penalty and update Medicaid inflation penalties so that they align with those in Medicare.

Ensuring continued access to affordable medicines requires timely and deliberate policy action. Generic and biosimilar medicines play a central role in controlling prescription drug costs and expanding treatment options for patients across the health care system. Policies that support robust competition, predictable market entry, and sustainable manufacturing are critical to maintaining these benefits. Without such measures, patients may face higher costs, reduced access, and fewer therapeutic options. A stable and competitive generic and biosimilar market is therefore essential to protecting both patient access and the long-term affordability of prescription medicines.