



Association for Accessible Medicines
Statement for the Record
House Committee on Oversight and Reform
Hearing on Prescription Drug Prices
January 29, 2019

Introduction

The Association for Accessible Medicines (AAM) applauds Chairman Cummings, Ranking Member Jordan, and the House Committee on Oversight and Reform for its leadership in holding today's hearing on the rising cost of prescription drugs.

Patients continue to struggle to afford the high cost of certain medications. High launch prices on new brand biologics and annual price increases on existing brand-name drugs, combined with an increasing trend of anti-competitive tactics designed to delay or prevent competition from more affordable biosimilars and generics, are pushing access to medicines out of reach for too many patients.

That's why lowering prescription drug prices continues to be the top health care priority for America's patients. In the latest Politico/Harvard poll, respondents ranked lowering the cost of prescription drugs as the number one priority – with 94 percent of Democrats and 89 percent of Republicans saying, "it is extremely important," for Congress to take action.¹

As the Oversight Committee examines the affordability challenges of high-priced prescription drugs, it is essential to understand the differences between the brand-name and generic drug markets and how the different pharmaceutical supply chains operate. Not only is the Food and Drug Administration's (FDA) approval process different for generics and brand-name drugs, but their respective markets and the path by which they reach patients diverge significantly, with important policy implications. These differences lead to different outcomes for patients, differences in the amount of spending funded by taxpayers, and differences in what consumers pay for health care coverage.

Independent research and data, however, demonstrates one undeniable conclusion. Brand-name drug prices continue to rise, while generic drug prices continue to fall. Brand-name drugs comprise only 10 percent of prescriptions filled annually by patients, but now constitute 77 percent of all spending on prescription drugs.² In contrast, the amount spent on generic medicines has declined for the last 30 consecutive months.³

¹ Politico-Harvard, "Americans' Health and Education Priorities for the New Congress in 2019," January 2019.

² AAM, "Generic Drug Access & Savings Report," July 2018.

³ Morgan Stanley, Monthly YOY Generic Prescription Drug Sales, January 2019.



These trends present public policy challenges and necessitate meaningful action by Congress and the Administration to lower the cost of prescription drugs for patients.

The Generic Drug Market is Fundamentally Different than the Brand Drug Market

The pharmaceutical industry in the United States is predicated on a balance between innovation and access. Brand-name drug companies are rewarded for inventing and developing new treatments and cures. In return for the innovation, current law provides brand-name drug companies with 12 years of guaranteed market exclusivity (i.e., a monopoly) for biologics and 20 years for each patent. There is also extra monopoly time provided to incentivize pediatric drug development and orphan drugs. During the period of patent and marketing exclusivity, brand-name drugs are priced and sold free from competition and discounts or rebates are negotiated with others in the supply chain, such as pharmacy benefit managers (PBMs), wholesalers and pharmacies.

Once the exclusivity period expires and the brand-name drug is off-patent, generic manufacturers and the newly developing biosimilars market are provided with an opportunity to make the same medicine, with the same clinical benefit, for patients. The introduction of competition into the market significantly reduces the price of medicine, and patients benefit from greater, more affordable access to FDA-approved drugs. Experience shows prescription drug prices decline by more than half the first year generics enter the market.⁴

Generic drugs consequently play an integral role in health care. The expiration of patents and the introduction of multiple generic manufacturers competing against each other on price results in significant savings for the health care system. Over the last 10 years, generic manufacturers delivered savings of nearly \$1.8 trillion – including \$265 billion in 2017 – to patients and the health care system.⁵

But the manner in which the generic drug market operates differs in meaningful ways from the one for brand-name drugs. These differences between brand-name drugs and generics drugs lead to different financial incentives for other stakeholders in the supply chain.

While brand-name drugs operate in a market where there is no direct price competition due to government-awarded exclusivities and patent protections, generic drugs compete within a multi-competitor model with drug prices decreasing as more competitors enter the market. In

⁴ IMS Institute for Healthcare Informatics, Price Declines after Branded Medicines Lose Exclusivity in the U.S., January 2016.

⁵ Ibid., AAM.



fact, today there are more than 200 manufacturers supplying generic drugs to the U.S. market.

While brand-name drug companies maximize revenue through price rather than volume and negotiate discounts or rebates with other stakeholders in the supply chain, generic drug manufacturers compete solely on the basis of price and the ability to supply. As a result, brand-name drug companies retain 76 percent of all revenue, while other stakeholders in the supply chain for generic drugs capture 64 percent of all revenue.⁶

In the brand-name drug market, brand-name drug companies use their leverage in the supply chain to negotiate formulary placement through rebate agreements with PBMs and health insurers. There is little room for wholesalers and pharmacies to capture large margins due to their relative lack of negotiating power. And pharmacy reimbursement for brand-name drugs is tied to the reported price and there is only one product available.

For generic drugs, wholesalers, through collaborative purchasing agreements with pharmacies across the country, and group purchasing organizations exert leverage through their purchasing power and the robust competition between multiple generic manufacturers who are making identical products. Generic drug manufacturers now compete for the business of three consolidated wholesaler-pharmacy groups who now control more than 90 percent of all generic drug sales.⁷ This competition results in significant savings for patients but leaves generic drugs vulnerable to drug shortages and easily impacted by increased operational costs.

Brand-Name Drugs Increase Costs, Generic Medicines Drive Savings

The differences between the brand-name drug and the generic drug markets lead to different results for patients. Patients thrive with access to generic medicines, both in terms of health outcomes and financial savings. Insured patients benefit from an average copay for generics of only \$6.06, while paying more than \$40 for brand-name drugs.⁸ In fact, over 90 percent of generic prescriptions are filled for \$20 or less out-of-pocket.⁹ That is in comparison to just 39 percent for brand-name drugs at that price.¹⁰

⁶ USC Schaeffer, "The Flow of Money Through the Pharmaceutical Distribution System," June 2017.

⁷ Fein, Adam, "The 2018-19 Economic Report on Pharmaceutical Wholesalers and Specialty Distributors," October 2018.

⁸ Ibid., AAM.

⁹ Ibid.

¹⁰ Ibid.



Experience also shows that patients are far less likely to fill a prescription for a high-priced brand-name drug. Brand-name drugs account for 40 percent of all abandoned claims for new patients, while constituting only 20 percent of approved claims.¹¹ In contrast, new patient abandonment rates for generics are three times lower than those for brand-name drugs.¹² Prescription drug abandonment has a serious effect on patient health – leading to hospitalizations, death, and extensive health care costs.

With brand-name drugs now accounting for 77 percent of total spending on prescription drugs in 2017, the high cost of many prescriptions is often out of reach for patients.¹³ One of out every 10 prescriptions filled in the U.S. is for brand-name drugs.¹⁴ In other words, 10 percent of prescriptions comprise 77 percent of the costs. And specialty medicines (including brand biologics) are rapidly approaching half of all spending although they are used by fewer than 3 percent of patients.¹⁵

Annual price increases of less than 10 percent on brand-name drugs and the cumulative impact of such price increases translates into hundreds, if not thousands, of dollars in higher prescription drug spending. AARP, for example, found 94 percent (133 of 142) of brand-name drugs more than doubled in price between 2005 and 2017.¹⁶ And the Office of Inspector General at the Department of Health and Human Services (HHS) found that “reimbursement for brand-name drugs in Part D still increased 62 percent from 2011 to 2015” after accounting for rebates.¹⁷

Higher spending on prescription drugs impacts everyone – directly in the form of higher premiums and out-of-pocket costs and as taxpayers to cover the costs of Medicare, Medicaid, and other federal health care programs. Prescription drugs now account for \$0.23 out of every premium dollar and the average co-pay for brand-name drugs was \$40.30 in 2017.^{18 19} Moreover, in the latest National Health Expenditures report from the Centers for Medicare and Medicaid Services, Medicare spending on prescription drugs increased 36 percent, Medicaid spending increased 50 percent, and CHIP spending increased 35 percent over the last five years.²⁰

¹¹ Ibid.

¹² Ibid.

¹³ Ibid.

¹⁴ Ibid.

¹⁵ IQVIA, “Medicine Use and Spending in the U.S.,” April 2018.

¹⁶ AARP, “Trends in Retail Prices of Brand Name Prescription Drugs,” September 2018.

¹⁷ HHS OIG, “Increases in Reimbursement for Brand-Name Drugs in Part D,” June 2018.

¹⁸ America’s Health Insurance Plans (AHIP), “Where Does Your Health Care Dollar Go?,” May 2018.

¹⁹ Ibid., AAM.

²⁰ CMS, National Health Expenditure Data 2017, December 2018.





In contrast, nine out of every 10 prescriptions filled in the U.S. are for generic drugs and spending on generic drugs accounted for only 23 percent of total prescription drug spending.²¹ Continued growth in the use of generic drugs and declining generic drug prices led to savings of \$265 billion in 2017 – an average of \$1,952 for every Medicare and \$568 for every Medicaid enrollee.²²

Savings, however, often go unrealized. HHS found “incompletely aligned incentives for generic substitution leave significant savings uncaptured.”²³ Seniors and the Medicare Part D program would have saved \$3 billion in 2016 if generics had been dispensed rather than the brand-name drug.²⁴ Last year, the FDA reported that patients could have saved “more than \$4.5 billion in 2017” if they had the ability to purchase FDA-approved biosimilars.²⁵

In recent years, the Assistant Secretary for Planning and Evaluation (ASPE) at HHS and the Government Accountability Office (GAO) examined trends in the prices of generic drugs. Due to the relatively-low cost of generic medicines, minor price changes can result in significant percentage increases. GAO, for example, cited the price of hydrocortisone increasing from \$0.16 per tablet in 2012 to \$0.41 per tablet in 2013 – an increase of 160 percent.²⁶ Correspondingly, the HHS ASPE report concluded, “Our review of the evidence strongly supports the conclusion that generic drug prices are not an important part of the drug cost problem facing the nation.”²⁷

Nowhere is the need for lower-priced alternatives, and the challenges facing them, more real than among high-price brand biologics. Biologics, many of which are specialty medicines, are the most rapidly growing segment of increasing brand-name prescription drug costs in the U.S. Many brand biologics cost tens of thousands of dollars per year per patient – some more than \$200,000.

Biosimilar medicines represent a key step forward in reducing high drug prices. Biosimilars are safe, effective and more affordable versions of costly brand biologics. By the year 2025, over 70 percent of drug approvals are expected to be biological products.²⁸ Experts estimate that FDA-approved biosimilars could save more than \$54 billion over the next 10 years.²⁹ In

²¹ Ibid., AAM.

²² Ibid.

²³ HHS, “Savings Available Under Full Generic Substitution of Multiple Source Brand Drugs in Medicare Part D,” January 2018.

²⁴ Ibid.

²⁵ FDA, Remarks from FDA Commissioner Scott Gottlieb, M.D., FDA’s Biosimilars Action Plan, September 2018.

²⁶ GAO, “Generic Drugs Under Medicare,” August 2016.

²⁷ HHS, “Understanding Recent Trends in Generic Drug Prices,” January 2016.

²⁸ U.S. Pharmacist, “Biosimilars: Current Approvals and Pipeline Agents,” October 2016.

²⁹ RAND, “Biosimilars Cost Savings in the United States,” October 2017.





doing so, biosimilars will mean greater access to lifesaving cures for an estimated 1.2 million patients.³⁰ Research shows women, low-income families, and elderly patients would particularly benefit from access to biosimilar medicines.³¹

Unfortunately, the ability of biosimilars to fulfill their potential is threatened by market abuses by brand-name drug companies and misguided policies that block access to lower-cost medicines. Seventeen biosimilars are now approved in the U.S., yet only seven are on the market and available to patients.³² In comparison, more than 50 biosimilars are available to patients in Europe.

It is sobering to consider what America's patients would face if there no FDA-approved generic or biosimilar medicines to provide reliable access to affordable treatments. Generics do not only deliver the most medicine at the lowest cost and the greatest savings; generic medicines cushion the significant impact dealt to patients and the health care system by high brand-name drug prices every day.

Put another way, the availability of low-cost generics offsets the impact of high brand-name drug prices.

Conclusion

Understanding the differences between brand-name drug, brand-name biologics, generic drugs, and biosimilars; how each market functions; and, the different incentives stakeholders have throughout the supply chain is essential when considering solutions to address the rising costs of prescription drugs and to ensuring that the policies that are adopted result in meaningful savings to patients at the pharmacy counter.

AAM is available to help explain how the prescription drug markets work, to help identify opportunities for improvement, and to discuss solutions that lower the cost of prescriptions for patients. We appreciate the Oversight Committee's hearing today and look forward to working with the Chairman, Ranking Member, and members of the Committee to address this public health challenge.

³⁰ The Biosimilars Council, "Biosimilars in the United States: Providing More Patients Greater Access to Lifesaving Medicines," August 2017.

³¹ Ibid.

³² FDA, FDA-Approved Biosimilar Products, January 2019.