Statement before the Senate Committee on Health, Education, Labor and Pensions
Subcommittee on Primary Health and Retirement Security:
"Why Does the US Pay the Highest Prices in the World for Prescription Drugs?"

Foster Competition to Realize Additional Pharmaceutical Cost Savings

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Chairman Sanders, Ranking Member Collins, and Members of the Subcommittee,

Thank you for the opportunity to testify on this important topic. My name is Alex Brill, and I am a resident fellow at the American Enterprise Institute, a public policy think tank here in Washington, DC. The views and opinions I offer today are mine alone and do not represent those of my employer or necessarily those of my colleagues at AEI.

In my testimony today, I will make three broad points:

1. The United States is a large market that offers substantial rewards to successful innovators. This structure encourages the development of valuable medicines.
2. Lowering the cost of medicines to the US healthcare system can be achieved by promoting robust competition, but policymakers should be careful to ensure that adequate incentives remain in place to bring new products to market.
3. There are multiple existing barriers to robust pharmaceutical competition, and lower drug prices can be achieved by removing these barriers.

I would like to begin with a brief observation about the current pandemic, economic recession, and ongoing recovery.

The coronavirus pandemic, which hit the US one year ago, has resulted in more than 540,000 confirmed deaths, more than 130 million probable and confirmed cases[1], and tremendous economic upheaval and harm. The US suffered a dramatic economic contraction in the second quarter of 2020. Though the economy has recovered significantly, total employment is down by more than 9 million compared to a year ago. Employment in the leisure and hospitality sector is 20 percent lower than it was a year ago; nearly 3.5 million jobs in that sector were lost.

The first coronavirus vaccine was deployed in December 2020, less than a year after the pandemic began. Today, three approved COVID-19 vaccines are being distributed in the US, and these products are quite literally saving not only our economy but our country. The vaccination rate is now near 2.5 million doses per day, and daily new cases are down nearly 80 percent from the peak.

The biopharmaceutical industry, including talent and capital from around the globe, has accomplished a stunning feat, and I look forward to receiving my vaccine as soon as possible. We should be thankful not only to those involved in the development and deployment of the vaccines but to all who have worked on vaccine development, including those whose projects did not yield successful products. Clearly, the ability to bring to market these highly effective vaccines is not only the result of work that began in 2020 but also the result of decades of research supported by both public and private investment.

1. US Drug Spending Overview

To set the stage for policy recommendations to address drug costs in the United States, it is worthwhile to put in context the size and scale of drug spending at present. In 2019, the most recent year for which government statistics are available, US prescription drug expenditures were $367.9 billion, 9.7 percent of national health expenditures, and $1,128 per capita. Growth in 2019 expenditures (5.7 percent) was driven by an increase in volume, not prices (CMS, 2020). An increasing share of this burden is borne by

[1] This estimate is based on 28.9 million confirmed cases and a CDC estimate (CDC, 2021) that approximately 1 in 4.6 total COVID-19 infections were reported.

health insurers, though of course their higher costs are reflected in higher premiums. Notably, out-of-pocket spending on retail prescription drugs as a share of total prescription drug spending has declined significantly over the last two decades, from 28.5 percent in 2000 to 14.5 percent in 2019 (CMS, 2020).

There are, of course, important exceptions to these aggregate trends for individual patients who have experienced significant hardship. However, on average, out-of-pocket spending for households with the highest overall healthcare costs (those in the 95th percentile) declined for households below the federal poverty line (FPL) and for households below 200 percent of the FPL from 2006 to 2017 (Glied and Zhu, 2020). For higher-income households with very high out-of-pocket costs, those costs have increased (Ibid.). Among those with the highest out-of-pocket medical costs across all income groups, average out-of-pocket drug costs have declined from near $2,300 in 2006 to $1,000 in 2017 (Ibid.). Among Medicare Part D beneficiaries, 90 percent had out-of-pocket pharmacy costs less than $500 (IQVIA, 2020a).

It is important to note that biologic drug spending is the driver behind overall rising drug spending in the United States in recent years. Biologics, which are highly complex drugs made from living cells, are among the most expensive pharmaceutical products. In inflation-adjusted terms, biologic drug spending increased from $291 to $435 per capita from 2014 to 2018 while small-molecule drug spending fell from $689 to $610 per capita during this period (IQVIA, 2019).

2. Balancing Innovation and Competition

The US pharmaceutical market, with a relatively high level of prescription drug spending overall as well as a high generic utilization rate, reflects the outcome of two complementary policy objectives: a system that both offers financial rewards to innovator drug companies who launch new drugs and encourages a robust competitive marketplace for generic drug manufacturers to sell at dramatic price discounts. This is the result of a dual mandate embodied in landmark legislation widely known as Hatch-Waxman, which was intended to foster both innovation and competition in the prescription drug industry. Broadly speaking, this system has worked well for traditional small-molecule drugs.

According to research by IQVIA published by the Association for Accessible Medicines, 90 percent of retail drug prescriptions are filled with a generic, and generics represent 20 percent of total prescription drug spending. The average generic prescription copay is approximately $7, and 92 percent of all generic prescriptions are filled for $20 or less (AAM, 2020). The utilization of generic drugs in the United States far exceeds most peer nations. According to the OECD, generic drugs are, on average, just 52 percent of the total pharmaceutical market in 2017 by volume. Generic utilization varies considerably across the OECD. In Canada, generics are reported to be 76 percent, by volume but in Italy only 25 percent (OECD, 2019).

Inherent in the broad policy framework in the United States that incentivizes both critical new pharmaceutical innovation and a robust generic market are several distinct forms of drug competition.

Brand-Brand Competition. Within a drug class, brand drugs can compete with other brand drugs that treat the same condition or disease, and this can result in lower prices for all competing products. In practice, the mechanism by which this form of competition yields price discounts is through rebates – that is, discounts paid to pharmacy benefit managers – not through reductions in list prices.

Generic-Brand Competition. As chemical copies of their brand counterparts, generics provide direct competition to brands. While research has shown that brand prices do not typically fall when facing generic competition, the first generic competitor is, on average, 30 percent lower than the brand price (Conrad and Lutter, 2019).

Generic-Generic Competition. The largest price effect arises when multiple generics for a product are on the market. Conrad and Lutter (2019) find that the generic price discount rises from 30 percent with one generic on the market to 55 percent with three generics and 85 percent with five generics.

Biosimilar Competition. A fourth type of pharmaceutical competition, a hybrid of the three above, is emerging in the US biosimilars market. Since the passage and enactment of the Biologics Price Competition and Innovation Act (BPCIA), part of the Affordable Care Act, an additional regulatory pathway has existed to permit competition for biologics. This abbreviated pathway allows for the approval of what are known as biosimilars, more affordable versions of brand biologic drugs. While this market was somewhat slow to develop at first, today there are 29 biosimilars approved by the Food and Drug Administration (FDA) and 18 biosimilars available on the US market. One favorable but unexpected pricing dynamic in this nascent market is that when a biosimilar competes with a reference biologic, we see a net price decline of the innovator product (Brill and Ippolito, 2019).

3. Promoting Drug Competition and Lowering Prices

In debates about US drug spending, two competing policy frameworks exist. In the first, government controls are necessary to set drug prices because market failures are causing "wrong" prices to be paid by public programs, commercial insurance, and individuals. In the second, policymakers observe imperfections in the prescription drug market (some of which are policy-induced) and seek to adopt reforms to improve and strengthen the existing framework established by Hatch-Waxman and the BPCIA – that is, adequate incentives for innovation in a costly and risky industry combined with appropriate incentives and relatively little friction for generics and biosimilars to ensure robust competition.

Having spent the last decade studying competition in the US pharmaceutical market, I can tell you that several incremental changes to our existing framework could make drug competition more robust. These changes could yield more small-molecule generics, more complex generics, more biosimilars, and more of the savings that competition induces.

Ways That Drug Competition Is Stymied in the US

There are a variety of reasons why there is room for improvement in the competitiveness of the US pharmaceutical market, some systemic and some due to strategies of drug manufacturers to create excessive delays in the market entry of competitors.

Complex Generics. On delays arising in the system, consider the situation around complex generics. These are products with a complex molecular base, route of delivery, formulation, dosage form, or approval requirement. In Europe and Canada, some complex generics have already been approved and launched while applications for these same products are delayed at the FDA. By my estimation, generic competition for seven complex generics approved in Europe and/or Canada but not in the United States would yield annual US savings of between $600 million and $1.7 billion, with a median savings estimate of $1.3 billion.

When Congress reauthorizes the Generic Drug User Fee Amendments (GDUFA), it is my hope that the FDA commits to further prioritize the approval of complex generics, with objectives focused on outcomes rather than process metrics. The delay in the approval of some complex generics has already attracted bipartisan interest and concern among members of the House Energy and Commerce Committee in a letter to the FDA (Energy and Commerce Committee, 2020). Current acting FDA Administrator Janet

Woodcock has also acknowledged complex generics' "outsized potential to increase patient access and lower drug spending" (Woodcock, 2019).

On strategies intended to delay generic entry, there are various tactics that brand drug manufacturers employ to limit or delay the availability of lower-cost drugs. These include product hopping, misuse of "orphan" drug exclusivity and citizen petitions, patent thickets, and other tactics that effectively suppress competition. (Below, I describe four of these tactics.) There is evidence that the average period a brand drug is on the market before generic entry increased by more than two years between 1995 and 2014 (Grabowski et al., 2016). From my own work, I estimate that if generic entry were to be accelerated to pre-1995 rates, the US healthcare system would save nearly $32 billion.

Product Hopping. Product hopping describes the established brand strategy of making an inconsequential change to a drug and moving patients to this version before the original faces competition. The Alzheimer's drug Namenda IR represents a notorious example of product hopping. In 2013, before Namenda IR went generic, the manufacturer launched an extended-release version that could be taken once a day instead of twice a day. In 2014, the manufacturer removed Namenda IR from the market entirely. This is what is called a "hard switch." In a "soft switch," a manufacturer will leave the original product on the market but work to move patients to the slightly altered product, even at times intentionally undermining confidence in their original product. I have estimated that five instances of specific product hops cost the US healthcare system $4.7 billion annually.

Misuse of Orphan Drug Exclusivity. Orphan drugs, defined as drugs treating conditions that fewer than 200,000 people in the United States suffer from, are eligible for six extra months of exclusivity from the FDA. This creates an incentive for drug manufacturers to develop products to treat rare diseases. But brand manufacturers have been obtaining orphan drug designations for products that treat much larger populations. Daniel et al. (2016) find that 7 of the 10 bestselling drugs in the world in 2015 were approved by the FDA as orphan drugs.

Misuse of Citizen Petitions. Citizen petitions are an important safety mechanism created to raise concerns with the FDA about a drug whose application is under review. But brand drug manufacturers have taken to using this mechanism, often right before facing generic competition, to delay generic entry while the FDA reviews the petition. A recent study showed that brand manufacturers filed more than 90 percent of petitions and less than 10 percent were eventually granted (Carrier and Shadowen, 2017).

Patent Thickets. Especially pernicious is a tactic known as a patent thicket. Brand manufacturers obtain as many overlapping patents as possible on a single product in order to create an impenetrable web for potential competitors. These patents are frequently broad and weak and often filed after the drug is on the market. Consider the blockbuster drug Humira® – 89 percent of AbbVie's nearly 250 patent applications were filed after launch (I-MAK, 2020). While patenting strategies of this drug have attracted the most attention, the policy concern is much broader as these tactics may serve as a future playbook for other drug manufacturers to unduly delay generic entry.

A Word about Biosimilars

As I mentioned earlier, biosimilars represent a relatively new arena of drug competition in the United States, as the regulatory pathway for these products was established in 2010. According to IQVIA (2020b), biosimilar savings in the United States have reached $37 billion through 2019 and could exceed $100

billion through 2024. Despite their enormous cost savings opportunity, biosimilars face hurdles in realizing their full potential. These hurdles range from lack of education among physicians and patients to contracting practices by originator companies to keep competitors from gaining an edge. Patent thickets, described above, are very problematic for biosimilars because biologics tend to be very lucrative, and originators have learned that they can build these thickets in the United States largely unchecked.

It is worth noting that Europe, which preceded the United States by nearly a decade in the launch of its first biosimilar, has done well in many regards. Many European countries have proactively engaged in education campaigns to familiarize patients and healthcare providers with biosimilars and have shared the savings from biosimilars with patients and providers. But not all European practices should be emulated. Some countries have established price controls or held winner-take-all tenders. These may have negative effects on the long-term sustainability of biosimilars.

Achieving greater uptake of biosimilars in the US market would, in the near term, produce lower average spending on biologic medicines. In the medium and longer-term, policies that facilitate a larger biosimilars market in the US will encourage more biosimilar manufacturers to pursue product launches in the United States. Broadly speaking, a robust biosimilars market would include both multiple competitors to a single reference biologic and more biosimilar entry to compete with smaller-market biologics. The approval of interchangeable biosimilars may also contribute to the realization of additional pharmaceutical cost savings, for biosimilars covered in the pharmacy benefit as opposed to the medical benefit.

To accelerate the adoption of biosimilars, policymakers should consider policies to align the incentives of prescribers with the cost savings objectives of payers, namely Medicare. Existing legislative proposals that could achieve this goal include ASP+8 reimbursement for Part B biosimilars or a demonstration run by the Center for Medicare and Medicaid Innovation that could establish an incentive to prescribers whose patients utilize lower-cost biosimilars. Either approach offers the opportunity to achieve cost savings by incentivizing the utilization of lower-cost biosimilars.

4. Conclusion

Any inquiry into the cost of medicines in the United States should be related closely to a careful review of the quality and quantity of pharmaceutical innovation also underway. As a large and prosperous market, the United States effectively entices significant investment in the private research and development of drugs and publicly funds significant amounts of related research. The United States is also a global leader with respect to its robust generic drug market, a testament to a successful commitment to a competitive marketplace. Nevertheless, opportunities to foster competition and realize additional cost savings do exist.

Congress should protect the intent of existing law but pursue improvements to facilitate more competition, curtail overly long monopolistic periods for brand drugs, and promote the approval of new innovative medicines to compete with existing brand drugs. Finally, biosimilars have shown initial success and cost savings in the US market, and a larger and more robust biosimilars market should be encouraged.

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