The Administration's FDA Reforms and Reduced Biopharmaceutical Drug Prices

The Council of Economic Advisers
October 2018

Executive Summary

October 2018

Many Americans face excessively high prices for pharmaceutical drugs, making them either unaffordable or taking up a large share of household budgets. The Trump Administration has responded to this problem with several actions undertaken by the Department of Health and Human Services (HHS) and the Food and Drug Administration (FDA). In most industries, free market entry and robust competition provide a pathway to lower prices. However, FDA regulations intended to guarantee safety and efficacy can constitute barriers to price competition for drugs. In few other industries do firms spend a decade and over $2 billion to enter the market—which is the current state of affairs for new, innovative drugs going through the FDA's safety and efficacy review process.

As part of the Trump Administration's overall deregulatory agenda, HHS and the FDA have launched a series of reforms to better facilitate price competition by streamlining the drug application and review process in a way that effectively lowers barriers to entry while ensuring a supply of safe and effective drugs. This deregulatory effort will enhance competition and may already be contributing to the faster flow of newly approved generic drugs seen since January 2017. We find that relative annual price growth for prescription drugs has slowed since January 2017, and estimate that lower prices from new generic drug products saved consumers $26 billion through July 2018. We also argue that the influx of new brand name drugs should be viewed as implicitly lowering the price of improved health, even though the methods currently being used to estimate changes in drug prices do not reflect this. Implicit price reductions from new, brand name drugs since January 2017 are providing an estimated $43 billion in annual benefits to consumers.

In May 2018, the Administration introduced the American Patients First Blueprint to bring down pharmaceutical drug prices.[1] The Blueprint offers several strategies to help patients address rising drug costs, including enhancing price competition. The Blueprint's many actions will further enhance this goal.

---

[1] See https://www.hhs.gov/sites/default/files/AmericanPatientsFirst.pdf.

Introduction

Americans report major concerns about the affordability of healthcare. In August this year, 81 percent of registered voters indicated that healthcare was the most important or a very important political issue for candidates to discuss (Kirzinger et al. 2018).[2] In particular, high pharmaceutical drug prices remain a problem for Americans, making drug pricing a major policy issue.

In most industries, market entry and competition lead to lower prices. The market for pharmaceutical drugs, however, involves barriers to entry resulting from government regulations (CEA 2018). In few other industries does it take about a decade and an estimated $2.6 billion to enter the market—which is the current state of affairs for innovator drugs going through the FDA safety and efficacy review process (DiMasi, Grabowski, and Hansen 2016). The regulatory challenge is to ensure both the safety of the drug supply and greater competition through the timeliness of market entry for valuable drugs. Although past review regulations were intended to ensure the safety and effectiveness of marketed drugs, a major side effect has been slower market entry, which hinders price competition. The evidence suggests that the value of a faster FDA regulatory process outweighs potential harmful effects on drug safety, in the sense that patients' improved health and savings resulting from faster access to drugs exceed any additional safety risks (Philipson and Sun 2008; Philipson et al. 2008).
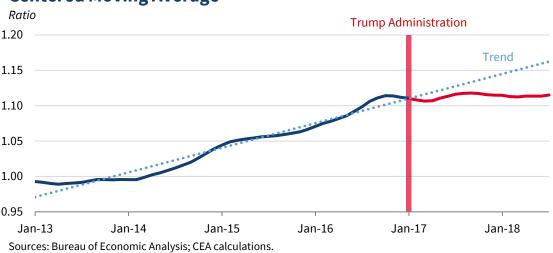
As part of the Trump Administration's overall deregulatory agenda, the FDA launched a series of reforms to facilitate new pharmaceutical drug entry while ensuring the security of the drug supply. Those reforms, which will foster price competition in the future, may already be helping consumers. We find that growth in relative drug prices has slowed since January 2017, that generic drugs are being approved at a particularly rapid pace, and that savings from new generic entrants totaled about $26 billion as of July 2018.

We first find that price inflation for prescription drugs has slowed down. Figure 1 shows that the price of drugs relative to other goods decreased during the Trump Administration compared with the trend of the previous Administration (dotted line).[1] Indeed, after 20 months of zero or slightly negative relative inflation, as of August 2018 the relative price of prescription drugs was lower than it was in December 2016. In addition, due to the way price inflation for drugs is measured, the actual reduction in inflation after January 2017 may be larger.[3] As of

---

[2] Measured by the ratio of the Personal Consumption Expenditure Chain Price Index (seasonally adjusted, 2012 = 100) for pharmaceutical drugs versus all personal consumption expenditures.

[3] Two factors contribute to this. First, the Bureau of Labor Statistics (BLS) has a six-month lag for incorporating generics, so any generic entry after March 2018 is not included. Second, in 2016 the BLS changed its index from geometric to Laspeyres, the latter having larger inflation.

August 2018, the slower price inflation for prescription drugs under President Trump implies annual savings of $20.1 billion.[4] Even if the relative price inflation of prescription drugs were to return to its original higher trend prior to this Administration, the 2017–18 level effect would yield savings of $170 to $191 billion over 10 years.[5] Although many factors affect prices in the large and complex market for drugs, it is also plausible that the Administration's vocal advocacy concerning the challenges of high drug prices could have played a role in the observed slowdown of drug price growth.

Figure 1. Price of Prescription Drugs Relative to PCE, 3–Month Centered Moving Average

Sources: Bureau of Economic Analysis; CEA calculations.
Note: The relative price of prescription drugs is computed as the index for prescription drugs relative to the index of overall consumption prices as measured in the national income and product accounts for personal consumption expenditures (PCE). Trendline is calculated based on the second term of the Obama Administration.

Current FDA reforms are lowering entry barriers for new pharmaceutical drugs, and this partly accounts for the slower growth of drug prices. We focus primarily on generic drugs, which the FDA approves on the basis of a determination that they are bioequivalent to an approved innovator drug for which exclusive sales rights have expired. Generic drug entry is quicker to respond to regulatory changes than brand name drug entry—which, as discussed, involves a longer review and development process. Figure 2 reports the 12-month moving average number of generic drug approvals starting in January 2013. The dotted blue line represents an estimated time trend from January 2013 through December 2016 projected through August

---

[4] Calculated by multiplying actual nominal personal consumption expenditures on prescription drugs (at a seasonally adjusted annual rate) in August 2018 by the percent difference between the actual three-month centered moving average relative price ratio in August 2018 and that projected by the linear trend estimated over January 2013 through December 2016.

[5] Dependent on a real discount rate between 0.9 and 3.2 percent. The lower bound is implied by the rate on 20-year TIPS and the upper bound by Shiller's cyclically adjusted earnings-to-price ratio for the Standard & Poor's 500, respectively.

2018, the most recent observation available. Since December 2016, the number of generic drug approvals has outpaced the trend. We find that 17 percent more generic drugs have been approved each month, on average, since January 2017 than were approved during the previous 20-month period. Furthermore, we find that this increase in approvals has taken place despite the fact that the number of brand name drug patent expirations—necessary precursors for generic entry—has declined during this period.
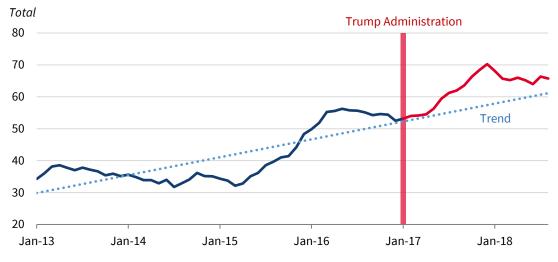
Figure 2. New Generic Drug Approvals, 12–Month Moving Average

Sources: Food and Drug Administration; CEA calculations.
Note: Data includes final generic drug approvals. Prior to October 2013 the data is a truncated moving average, with data beginning in October 2012. Trendline is calculated based on the second term of the Obama Administration.

We corroborate and extend these overall findings by estimating the value to consumers of each drug that has been newly approved and marketed since January 2017. Analyzing the price declines induced by the generics that have entered since January 2017, we find that they have generated savings of about $26 billion through July 2018.

For new, innovator pharmaceutical drugs, we argue that the traditional measures of price growth overstate price growth. This is because before a new drug enters the market, it is unavailable at any price, making such a drug equivalent to one with a price so high that there is no demand for it. Economists generally interpret innovations as price reductions from the price at which the product would not sell at all due to its observed price when marketed. Before the development of drugs to treat HIV in the mid-1990s, the price of a longer life for an HIV-positive individual was inaccessibly high, and was thus reduced by these innovations. Using the appropriate empirical methodology to measure such price declines for new drugs marketed since January 2017, we find that they have generated annualized gains to consumers of $43 billion in 2018, though lower-bound estimates of the price elasticity of demand for brand name drugs suggest the gains could be much larger.

The report is briefly outlined as follows. The first section discusses the Administration's FDA reforms. The second section discusses our results on increased price competition from faster generic drug market entry. And the third section discusses the value of increased entry of new, innovative drugs.

The Administration's Efforts to Enhance Generic and Innovator Competition

The Trump Administration's overall deregulatory agenda includes streamlining and efficiency improvements in the FDA's review process that facilitate price competition by reducing market entry barriers while securing a supply of safe and effective drugs. In August 2017, the President signed into law the Food and Drug Administration Reauthorization Act (FDARA), reauthorizing the Generic Drug User Fee Amendments (GDUFA) for another five years, to authorize the FDA to collect user fees for generic drug applications and to process applications in a timely manner. In fiscal year (FY) 2018, the FDA approved a record 971 generic drug approvals and tentative approvals—exceeding 937 in FY 2017 and 835 in FY 2016 (FDA 2016, 2017a, 2018a). The Trump Administration has prioritized the approval of more generic drugs to bring down the cost of pharmaceuticals (FDA 2018b). Last year, the FDA announced the Drug Competition Action Plan to expand access to safe and effective generic drugs. The efforts focus on three key priorities to encourage generic drug competition: (1) preventing branded companies from keeping generics out of the market, (2) mitigating scientific and regulatory obstacles to approval, and (3) streamlining the generic review process. The FDA has already released guidance for companies and FDA staff members that outlines the specific steps to reduce the number of review cycles and shorten the approval process.

In 2018, the FDA took expanded action as part of its 2018 Strategic Policy Roadmap to maintain balance across the spectrum of FDA-regulated pharmaceutical products—from small molecules to complex products and biologics—given each of their critical roles in advancing the health of patients (FDA 2018b). The Roadmap includes the launch of the Medical Innovation Access Plan, Drug Competition Action Plan, Biosimilars Action Plan, and Advanced Manufacturing Strategy Roadmap. These plans are designed to

- Modernize the FDA's programs and increase administrative efficiencies for reviewing applications for brand name and generic products.
- Provide product and technology-specific guidance to increase regulatory and scientific clarity for sponsors to ensure efficient product development programs.
- Reduce anticompetitive behavior by firms attempting to game FDA regulations or statutory authorities to delay competition from generic or biosimilar products.

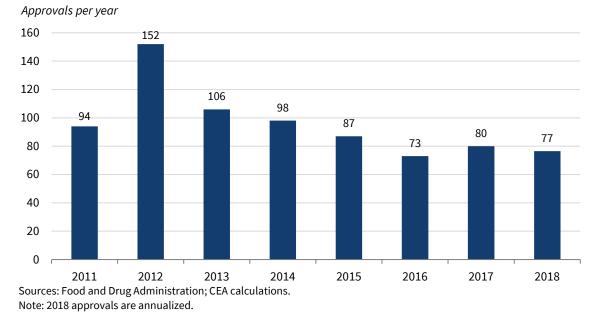# The Value of Lower Prices from Increased Generic Competition

A major source of relief from rising pharmaceutical drug costs has been the increased availability and utilization of lower-cost generic versions of brand name, innovator drugs. We find that there has been an increase in the number of generic drug approvals above the trend before January 2017.

Brand name drugs can frequently command high prices because the drugmaker's exclusive sales right confers market power over prices. Once the brand name drug's patent expires, however, generic versions of the drug can enter the market, and the resulting competition drives down market prices and leads to substantial savings for patients and the healthcare system. Roughly nine out of every ten prescriptions are for generic drugs, but because they are so much cheaper than their brand name counterparts, they constitute only about 23 percent of prescription drug spending (AAM 2018), reflecting the enormous savings made available to consumers.

Data on Increased Generic Drug Approvals

Since the beginning of 2017, the FDA has approved generic pharmaceutical drugs at a rapid pace. A total of 1,617 final and tentative approvals have been made in the 20 months of the Trump Administration, a monthly average of 81 approvals. This represents an 18 percent increase over the preceding 20-month period, which saw a total of 1,376 generic approvals and a monthly average of 69. The FDA has continued to aggressively address the backlog of generic drug applications pending decisions.
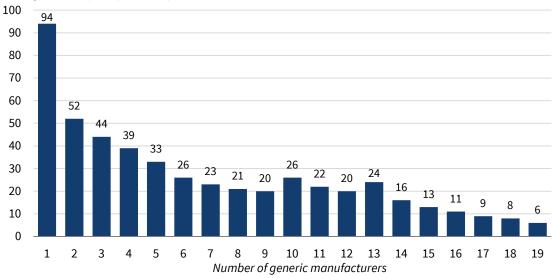
The increased volume of generic drug approvals does not appear to be the simple result of an increased volume of applications due to more patents expiring. As reported in figure 3, first-time generic drug approvals, which are an indication of expiring patents, were trending down after 2012. Indeed, between 2011 and 2016, first-time approvals averaged 8.5 per month; since January 2017, they have averaged only 6.5 per month. This suggests that the increase in generic drug approvals has occurred despite, not because of, fewer patents of brand name drugs expiring.

Figure 3. First-Time Generic Drug Approvals, 2011–18

Approvals per year

Sources: Food and Drug Administration; CEA calculations.
Note: 2018 approvals are annualized.

Estimated Reductions in Pharmaceutical Drug Costs from Generic Drug Entry

Economic theory predicts that increased competition will lower prices, and substantial evidence shows that pharmaceutical drug prices fall dramatically when a generic drug enters the market, offering great savings to consumers (Aitken et al. 2013; Berndt, McGuire, and Newhouse 2011; Caves et al. 1991). Prices continue to decline substantially as the number of generic competitors increases. One analysis of the effect of generic entry on drug prices in the 1980s found that generic drug prices were 70 percent of brand name drug prices after the first generic entrant, 50 percent of the brand name price when four generic drugs were on the market, and 30 percent of the brand name price with 12 generic drugs (Frank and Salkever 1997). A more recent analysis using data from 2005 to 2009 found price reductions following a similar pattern (Berndt and Aitken 2011). Other analyses have confirmed this general finding. The estimates shown in figure 4 illustrate prices declining substantially as the number of generic market competitors increases (For further discussion, see HHS 2010). Brand name drug market share, in addition to prices, falls dramatically with generic competition.

Figure 4. Generic Drug Price Relative to Brand Name Price

Average relative price per dose (percent)

Sources: Food and Drug Administration; IMS Health; Morton and Kyle (2012).

However, the effects of increased competition through patent expirations and generic drug entry reflect not just a fall in market prices but also a drop in overall quantity consumed, because brand name drug manufacturers often stop advertising their product, which reduces overall demand for the chemical entity (Lakdawalla and Philipson 2012). Therefore, the change in consumer welfare resulting from a patent expiration does not just involve a movement downward along a demand curve, but also an inward shift in the demand curve. The analysis that follows represents a lower bound on the value of generic entry focusing on savings alone.

We estimate the savings made available to consumers from generic drugs entering the market from January 2017 through June 2018. The analysis represents an update of a similar analysis published by the FDA (Conrad et al. 2018). The estimated savings presented here represent sales of those generic drugs in the period from January 2017 through July 2018.[6]

The baseline price before an entry (P^{Before}) used in this analysis is determined for each compound by aggregating sales across all drug products with the same active ingredient and dosage form for up to six months before the 2017 approval of abbreviated new drug applications, and dividing by the quantity of all drug products with the same active ingredient and dosage form that were sold (Q^{Before}). In some cases, a generic entrant is the first to compete
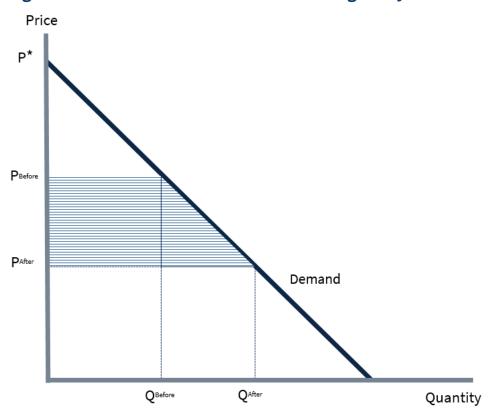
---

[6] Data on generic drug approvals represent the period from January 2017 through June 2018, the most recent approvals data available. Estimates of savings from that set of generic entrants represent sales through July 2018, based on the most recent available sales data.

with its brand name counterpart; in others, a generic entrant follows one or more other generic entrants. Determination of baseline prices addresses this as follows: When a brand name drug is facing its first generic entrant, the baseline price is determined using solely the brand name drug's sales; when a brand name drug already faces one or more generic competitors, the baseline price reflects both brand name and generic sales, weighted accordingly. The market price following entry of the generic drug (P^{After}) is estimated by dividing the aggregate sales volume in the market by the aggregate quantity sold, per month. Monthly savings from generic entry are then estimated for the period as

$$\textit{Monthly Savings} = (P^{\text{Before}} - P^{\text{After}}) * Q^{\text{Before}}$$

Total savings are the sum of all monthly savings estimates.

Figure 5 shows the consumer benefit from the lower prices enabled by generic entry. Note that the savings estimate does not reflect the full trapezoid shown in figure 5. This is because the onset of generic competition, as mentioned above, is often accompanied by a cessation of marketing by the innovator drugmaker, which causes the demand curve to shift inward. We therefore limit the savings estimated to the preentry quantities observed.

Figure 5. Price Decline Due to Generic Drug Entry

We estimate that the total savings from the generic drugs that entered the market from January 2017 through June 2018 was $26 billion, in January 2018 dollars. We expect consumers to benefit further from lower drug prices in the years to come as more generic drugs are approved for sale and price competition becomes even more robust.

The Value of the Lower Price of Health Generated by New Drugs

This section estimates the increase in new drugs since January 2017 and finds 11 drug approvals per month, on average, compared to 8.5 drug approvals per month during the preceding period. New drugs reduce the price of better health from prohibitive levels to patented price levels. For the new drugs approved since January 2017, we find that the price reductions have generated annualized gains to consumers of $43 billion in 2018.

The Increase in Approvals of New Drug Applications and Biologic License Applications
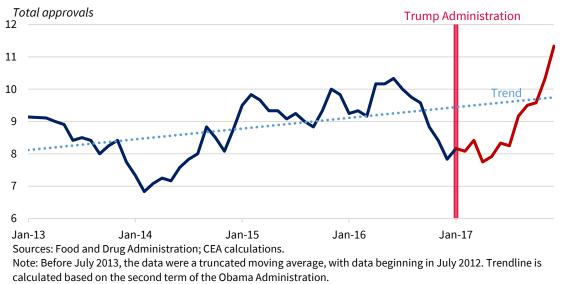
A new, brand name drug can be marketed only after its New Drug Application (NDA) has been approved; for biologic drug products, the corresponding approval is for a Biologic License Application (BLA). Figure 6 shows the number of approved NDAs and BLAs since January 2013, reported as a 12-month moving average to smooth intermonth volatility. Notably, the 12-month average line shows a substantial and sustained rise in approvals starting in about January 2017. These new approvals reflect the emergence of many valuable new drug therapies that will add to competitive market pressures on prices for existing drugs and bring new benefits to patients.

During the sample period from January 2013 through December 2016, we estimate a linear time trend for the 12-month, moving-average sum of NDAs and BLAs approved. We then project this trend through December 2017, the most recent observation available. As reported in figure 6, after falling below the trend in 2016, in 2017 actual applications approved climbed above the trend, and by the end of 2017 were 15 percent above the trend projection.[7]

Although the FDA approves a wide array of biological products and new drugs, only some are novel, innovative products that are being introduced in clinical practice for the first time. Novel drugs can be classified as new molecular entities (NMEs), an active molecule with no prior FDA approval, or novel biologics. These new entities are the most meaningful NDAs and BLAs approved because they provide previously unavailable options to patients seeking therapies.

---

[7] To test whether this outperformance of the trend was statistically significant, we regress NDAs and BLAs approved on a linear time trend fully interacted with a post–December 2016 binary variable. The estimated coefficient on the interaction term is positive and significant at the 0.01 level, meaning that we can reject the null hypothesis of no trend break with 99 percent confidence.

Approvals of new molecular entities and novel biologics, meanwhile, have more than doubled in 2017–18, relative to 2015–16. In 2015 and 2016, NMEs and novel biologics approvals averaged just 1.8 per month. From January 2017 through October 2018, approvals averaged 4.1 per month, with 9 approved in August 2018 alone. Given the lengthy clinical development process for new drugs, these trends do not reflect solely the actions of the Administration, but they are nevertheless influenced by a faster NDA and BLA process.

Figure 6. New Drug Applications and Biologic License Applications Approved, 12–Month Moving Average

Sources: Food and Drug Administration; CEA calculations.
Note: Before July 2013, the data were a truncated moving average, with data beginning in July 2012. Trendline is calculated based on the second term of the Obama Administration.

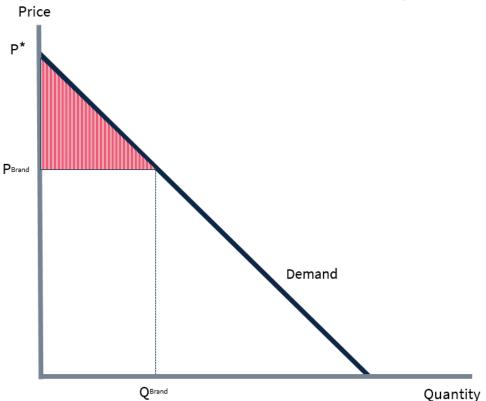## Estimates of the Value of Price Reductions from New Drugs

The price of improved health today is much lower than it was a generation ago, even though many of today's new drug products are more costly than those in the past. Consider the example of a patient diagnosed with HIV in the early 1990s.[8] Before the emergence of new breakthrough therapies for HIV, the price of a longer, better quality of life was prohibitively high; specifically, it could not be bought at any price anywhere in the world. But once new HIV drugs were developed and marketed starting in 1996, the price of a longer and healthier life for HIV-positive individuals decreased dramatically, falling from prohibitively expensive to the finite market price of the new, brand name, patented drugs.

Generally, prices fall further when these brand name drugs face therapeutic competitors; eventually, prices fall much further as brand name drugs lose their sales exclusivity and face generic competition. The example of innovative HIV drugs illustrates the essential point that

---

[8] Multiple government agencies helped in efforts to establish the HIV therapies.

even though the price of a new, innovator drug might be considerable and lead to higher overall drug spending, the effective price of improved health declines over time, greatly benefiting patients. In other words, it is important to separate the price of healthcare, such as drugs, from the effective price of better health.

More precisely, one may generally view a new innovation as simply involving a price change in this way. This is illustrated in figure 7. The price, P^*, is the prohibitively high price at which there is zero demand for the drug because it is too expensive. However, if no one is buying the drug, it is equivalent to it not being discovered yet; in both cases, no one uses it. An innovation can be interpreted as simply reducing the price from this high level to the price at which it is marketed, P^{Brand} in the figure, resulting in quantity Q^{Brand} of drugs being bought. Therefore, the value of the new innovation to patients is simply the consumer surplus generated when lowering the price from P^* to P^{Brand}, indicated by the red area in figure 7.

Figure 7. Price Reductions from Brand Name Drug Entry

We rely on two methods for calculating this consumer surplus. The first is to apply empirical estimates of producer surplus (profits) as a share of social surplus arising from new drugs to the NDAs and BLAs approved since January 2017. Grabowski and others (2012), Goldman and others (2010), Jena and Philipson (2008), and Philipson and Jena (2006) estimate that producer

surplus is generally between 5 and 25 percent of social surplus, with Jena and Philipson (2008) observing a median level of 15 percent, which implies that consumer surplus is about 5.7 times producer surplus. We can then apply these estimates to 2018 revenue data for new NDAs and BLAs approved by netting out the variable costs of production from sales. These costs are assumed to be 16 percent of sales for brand name drugs based on estimated differences in drug prices before and after patent expiration (Caves et al. 1991; Grabowski and Vernon 1992; Berndt and Aitken 2011; CEA 2018).

The second approach is to use price and quantity data along with empirical estimates of the price elasticity of demand for pharmaceutical drug products to generate a demand schedule and to calculate the consumer surplus that arises from lowering the price from P^* to P^{Brand}, as shown in figure 7—in other words, calculating the red area of the figure as the integral of the demand curve above P^{Brand} from $Q = 0$ to $Q = Q^{Brand}$. Across 150 common drugs, Einav, Finkelstein, and Polyakova (2018) estimate an average elasticity of demand of –0.24, and across 100 common therapeutic classes an average elasticity of –0.15. Goldman and others (2010) and Goldman and others (2006), meanwhile, estimate elasticities of between –0.01 and –0.21.

For price and quantity in both methods, we use IQVIA National Sales Perspectives data on pharmacy and hospital acquisition costs, based on invoice prices, for new molecule entities and novel biologics approved from January 2017 through July 2018. We then average the estimated consumer surplus gain calculated, first, assuming the median estimate of producer appropriation from Jena and Philipson (2008) and, second, assuming the mean elasticity of demand for common therapeutic classes of –0.15 from Einav, Finkelstein, and Polyakova (2018).[9] Averaging the results of the two approaches indicates that the price reductions induced by the new drugs approved since January 2017 have increased the total consumer surplus in 2018 by $43 billion.

The Additional Value of Increased Price Competition from New Innovations

The analysis given above ignores the value of new innovations in reducing the prices of other innovations through increased price competition. In many cases, a particular condition is treatable with several different brand name drugs, which are partial but not perfect substitutes for one another, and are known as a therapeutic class. When the market evolves from a monopoly with one unique brand name product to a new stage of therapeutic competition, or oligopoly, market pricing improves with one or more brand name competitors. This form of competition is analogous to the direct price competition resulting from new generic products that are closer, almost perfect, substitutes than brands in a given therapeutic class. The

---

[9] Because the Goldman et al. (2006) upper-bound estimated elasticity of –0.01 generates implausibly large consumer surplus gains when applied to all newly approved drugs, for the second method we assume an upper bound of –0.15.

evidence suggests that therapeutic competition between brand name drugs affects innovative drugmakers' returns at least as much as competition from generic entry (Lichtenberg and Philipson 2002).

There are numerous therapeutic classes in which new brand name drugs have led to vigorous price competition, although the literature is more limited on the systematic effect that therapeutic competition has on price. One recent notable example is treatment for hepatitis C. A major breakthrough brand name drug was approved for sale in the United States in 2013. Unlike previously available therapies, it essentially offered a cure for many hepatitis C patients and was therefore able to command a substantial price. In subsequent years, however, new products in the same broad class of hepatitis C drugs entered the market, creating price competition. Data on transactions prices (net of rebates provided by the drugmaker) were not available for this analysis, but examples strongly suggest that the first-on-the-market drugmaker was forced to slash prices in response to the enhanced price competition from the new products.[10]

Another example of price competition within a therapeutic class is the case of the cholesterol-lowering drugs known as statins. At one point in the 1990s, the brand name version of simvastatin enjoyed a larger market share than other highly similar drugs in the market, including pravastatin and lovastatin. However, a new competitor, the brand name version of atorvastatin, was introduced in 1996, and this led to vigorous market competition. Today, all these drugs are available quite cheaply in generic form (Aitken, Berndt, and Cutler 2008).

Conclusion

The Trump Administration's deregulatory agenda includes measures that allow more rapid market entry for generic pharmaceutical drugs. These efforts are designed to facilitate vigorous price competition in the drug market and yield savings, and we argue that they may already be paying off for consumers. The rate of increase in drug prices, as measured in the personal consumption expenditures price index, has evidently slowed since January 2017 relative to preceding years, and this may partly reflect the Administration's outspoken advocacy concerning high drug prices. Consumers have benefited from estimated savings of $26 billion due to the lower prices of new generic drug products from January 2017 through July 2018, and they will continue to benefit from these generic drug products and others in the future. New, innovative brand name drugs effectively lower the price of improving a patient's health by offering new clinical benefits that were previously unattainable. This type of benefit is not reflected in existing price indexes, but we estimate that new brand name drugs have increased consumer welfare by $43 billion since January 2017.

---

[10] For a brief discussion of recent price competition in this market, see Walker (2018).

References

AAM (Association for Accessible Medicines). 2018. "Generic Drug Access & Savings in the U.S.: Access in Jeopardy." https://accessiblemeds.org/sites/default/files/2018_aam_generic_drug_access_and_savings_report.pdf.

Aitken, M., E. Berndt, B. Bosworth, I. Cockburn, R. Frank, M. Kleinrock, and B. Shapiro. 2013. *The Regulation of Prescription Drug Competition and Market Responses: Patterns in Prices and Sales Following Loss of Exclusivity*. NBER Working Paper 19487. Cambridge, MA: National Bureau of Economic Research.

Aitken, M., E. Berndt, and D. Cutler. 2008. "Prescription Drug Spending Trends in the United States: Looking Beyond the Turning Point." *Health Affairs* 28, no. 1: w151–w160.

Berndt, E., and M. Aitken. 2011. "Brand Loyalty, Generic Entry and Price Competition in Pharmaceuticals in the Quarter Century after the 1984 Waxman-Hatch Legislation." *International Journal of the Economics of Business* 18, no. 2: 177–201.

Berndt, E., T. McGuire, and J. Newhouse. 2011. "A Primer on the Economics of Prescription Pharmaceutical Pricing in Health Insurance Markets." *Forum for Health Economics & Policy* 14, no. 2.

Caves, R., M. Whinston, M. Hurwitz, A. Pakes, and P. Temin. 1991. "Patent Expiration, Entry, and Competition in the U.S. Pharmaceutical Industry." *Brookings Papers on Economic Activity: Microeconomics*, 1–66.

CEA (Council of Economic Advisers). 2018. "Reforming Biopharmaceutical Pricing at Home and Abroad." https://www.whitehouse.gov/wp-content/uploads/2017/11/CEA-Rx-White-Paper-Final2.pdf.

Conrad, R., W. Liu, Z. Tillman, A. So, A. Schick, C. Nardinelli, and R. Lutter. 2018. "Estimating Cost Savings from Generic Drug Approvals in 2017." https://www.fda.gov/downloads/Drugs/ResourcesForYou/Consumers/BuyingUsingMedicineSafely/GenericDrugs/UCM609808.pdf.

DiMasi, J., H. Grabowski, and R. Hansen. 2016. "Innovation in the Pharmaceutical Industry: New Estimates of R&D Costs." *Journal of Health Economics* 47: 20–33.

Einav, L., A. Finkelstein, and M. Polyakova. 2018. "Private Provision of Social Insurance: Drug-Specific Price Elasticities and Cost Sharing in Medicare Part D." *American Economic Journal: Economic Policy* 10, no. 3: 122–53.

FDA (U.S. Food and Drug Administration). 2016. "Activities Report of the Generic Drugs Program (FY 2016) Monthly Performance."

———. 2017a. "Activities Report of the Generic Drugs Program (FY 2017) Monthly Performance." https://www.fda.gov/Drugs/DevelopmentApprovalProcess/HowDrugsareDevelopedandApproved/ApprovalApplications/AbbreviatedNewDrugApplicationANDAGenerics/ucm584749.htm.

———. 2017b. "Number of New Drug Applications (NDAs) and Biologics License Applications (BLAs) Approved." https://www.accessdata.fda.gov/scripts/fdatrack/view/track.cfm?program=cder&status=public&id=CDER-RRDS-Number-of-NDA-and-BLAs-submitted-and-approved&fy=All.

———. 2018a. "Activities Report of the Generic Drugs Program (FY 2018) Monthly Performance." https://www.fda.gov/drugs/developmentapprovalprocess/howdrugsaredevelopedandapproved/approvalapplications/abbreviatednewdrugapplicationandagenerics/ucm375079.htm.

———. 2018b. "Healthy Innovation, Safer Families: FDA's 2018 Strategic Policy Roadmap. Summary of Strategic Policy Areas." https://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Reports/UCM592001.pdf.

Frank, R., and D. Salkever. 1997. "Generic Entry and the Price of Pharmaceuticals." *Journal of Economics and Management Strategy* 6, no. 1: 75–90.

Grabowski, D., D. Lakdawalla, D. Goldman, M. Eber, L. Liu, T. Abdelgawad, A. Kuznik, M. Chernew, and T. Philipson. 2012. "The Large Social Value Resulting from Use of Statins Warrants Steps to Improve Adherence and Broaden Treatment." *Health Affairs* 31, no. 10: 2276–85.

Grabowski, H., and J. Vernon. 1992. "Brand Loyalty, Entry and Price Competition in Pharmaceuticals after the 1984 Drug Act." *Journal of Law and Economics* 35: 331–50.

Goldman, D., A. Jena, D. Lakdawalla, J. Malin, J. Malkin, and E. Sun. 2010. "The Value of Specialty Oncology Drugs." *Health Services Research* 45, no. 1: 115–32.

Goldman, D., G. Joyce, G. Lawless, W. Crown, and V. Willey. 2006. "Benefit Design and Specialty Drug Use." *Health Affairs* 25, no. 5: 1319–31.

HHS (U.S. Department of Health and Human Services). 2010. "Expanding the Use of Generic Drugs." Assistant Secretary for Planning and Evaluation Issue Brief. https://aspe.hhs.gov/system/files/pdf/76151/ib.pdf.

Jena, A., and T. Philipson. 2008. "Cost-Effectiveness Analysis and Innovation." *Journal of Health Economics* 27, no. 5: 1224–36.

Kirzinger, A., B. Wu, C. Muñana, and M. Brodie. 2018. "Kaiser Health Tracking Poll: Late Summer 2018—The Election, Pre-existing Conditions, and Surprises on Medical Bills." Henry J. Kaiser Family Foundation.

Lakdawalla, D., and T. Philipson. 2012. "Does Intellectual Property Restrict Output? An Analysis of Pharmaceutical Markets." *Journal of Law and Economics* 55, no. 1: 151–87.

Lichtenberg, F., and T. Philipson. 2002. "The Dual Role of Intellectual Property Regulations: Within- and Between-Patent Competition in the U.S. Pharmaceuticals Industry." *Journal of Law and Economics* 45, no. S2: 643–72.

Morton, F., and M. Kyle. 2012. "Markets for Pharmaceutical Products." In *Handbook of Health Economics*, vol. 2, edited by M. Pauly et al. Amsterdam: Elsevier.

Philipson, T., E. Berndt, A. Gottschalk, and E. Sun. 2008. "Cost-Benefit Analysis of the FDA: The Case of the Prescription Drug User Fee Acts." *Journal of Public Economics* 92, nos. 5–6: 1306–25.

Philipson, T., and A. Jena. 2006. "Who Benefits from New Medical Technologies? Estimates of Consumer and Producer Surpluses for HIV/AIDS Drugs." *Forum for Health Economics & Policy* 9, no 2: 1–33.

Philipson, T., and E. Sun. 2008. "Is the Food and Drug Administration Safe and Effective?" *Journal of Economic Perspectives* 22, no. 1: 85-102.

Walker, J. 2018. "Gilead to Slice List Prices of Liver Drugs." *Wall Street Journal*, September 24. https://www.wsj.com/articles/gilead-to-slice-list-prices-of-liver-drugs-1537818060.

ABOUT THE COUNCIL OF ECONOMIC ADVISERS

The Council of Economic Advisers, an agency within the Executive Office of the President, is charged with offering the President objective economic advice on the formulation of both domestic and international economic policy. The Council bases its recommendations and analysis on economic research and empirical evidence, using the best data available to support the President in setting our nation's economic policy.

www.whitehouse.gov/cea

October 2018