



REPORT TO THE WHITE HOUSE COMPETITION COUNCIL

Comprehensive Plan for Addressing High Drug Prices

A Report in Response to the Executive Order on Competition in the American Economy

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Executive Summary

President Biden's Executive Order 14036, "Promoting Competition in the American Economy" (the Competition Executive Order), identifies a lack of competition as a key driver for problems across economic sectors. The Report presents principles for equitable drug pricing reform through competition, innovation, and transparency; describes promising legislative approaches; and summarizes actions already underway or under consideration across the Department of Health and Human Services (HHS). In the course of preparing the Report, Secretary Xavier Becerra, other HHS officials, and HHS staff held listening sessions with consumer groups, staff from the Medicare Payment Advisory Commission (MedPAC), independent experts and researchers, and stakeholders from across the health care system.

Americans spend more than \$1,500 per person on prescription drugs and pay prices that are far higher than any comparable nation. Prices for brand name drugs are rising faster than inflation. Many Americans do not take medications as prescribed because of their cost, with resulting harm to their health care and health. Lack of competition is a key factor in these high drug costs.

The report identifies three guiding principles for drug pricing reform:

1. **Make drug prices more affordable and equitable for all consumers and throughout the health care system** - Support drug price negotiation with manufacturers and stop unreasonable price increases to ensure access to drugs that can improve health for all Americans
2. **Improve and promote competition throughout the prescription drug industry** - Support market changes that strengthen supply chains, promote biosimilars and generics, and increase transparency
3. **Foster scientific innovation to promote better health care and improve health** - Support public and private research and make sure that market incentives promote discovery of valuable and accessible new treatments, not market gaming

Support for Bold Legislative Action. The report highlights potential legislative policies Congress could pursue to advance the principles described above, including:

- Drug price negotiation in Medicare Parts B and D, with those negotiated prices also available to commercial plans (including the Marketplace) and employers who want to participate
- Medicare Part D reform, including a cap on catastrophic spending to protect beneficiaries from unaffordable out-of-pocket costs
- Legislation to slow price increases over time on existing drugs
- Legislation to speed the entry of biosimilar and generic drugs, including shortening the period of exclusivity, and policies in Medicare Part B to increase the prescribing of biosimilars by clinicians
- Prohibition on "pay-for-delay" agreements and other anti-competitive practices by drug manufacturers
- Investment in basic and translational research to foster innovation, including the President's proposal to create the Advanced Research Projects Agency for Health (ARPA-H)

Administrative Levers. There are also many administrative tools HHS can use to promote competition and reduce drug pricing to advance the administration's principles, including:

- Testing models using value-based payments in Medicare Part B, in which payment for drugs is directly linked to the clinical value they provide patients
- Testing models providing additional cost-sharing support to Medicare Part D Low-Income Subsidy Beneficiaries for using biosimilars and generics

- Testing total cost of care models in Medicare to determine whether they produce changes in drug utilization, reductions in total spending, and improvements in patient outcomes
- Data collection from insurers and Pharmacy Benefit Managers (PBMs) to improve transparency about prices, rebates, and out-of-pocket spending on prescription medications
- Continuing to implement the Food and Drug Administration's Biosimilars Action Plan and Drug Competition Action Plan, and clarify the approval framework for generic drugs to make the process more transparent and efficient
- Work with states and Indian Tribes to develop drug importation programs that reduce costs to consumers without increasing risks to safety

The overall goal of the Biden-Harris Administration is to foster innovation, increase competition, and improve the market environment, all in pursuit of reduced drug spending for consumers and throughout the health care system. Most importantly, these actions will protect patients and improve their access to affordable medications, helping keep Americans healthier and more financially secure.

Summary

President Biden's Executive Order 14036, "Promoting Competition in the American Economy" (the Competition Executive Order), identifies a lack of competition as a key driver for problems across economic sectors.¹ As in the other policy areas discussed in the Competition Executive Order, solutions to high prescription drug prices necessarily involve restoring or creating competition. This Report (the Report) responds to the provision in Section 5(p)(iv) of the Competition Executive Order that the Secretary of Health and Human Services:

shall submit a report to the Assistant to the President for Domestic Policy and Director of the Domestic Policy Council and to the Chair of the White House Competition Council, with a plan to continue the effort to combat excessive pricing of prescription drugs and enhance domestic pharmaceutical supply chains, to reduce the prices paid by the Federal Government for such drugs, and to address the recurrent problem of price gouging.²

The Report presents principles for equitable drug pricing reform through competition, innovation, and transparency; describes promising legislative approaches; and summarizes actions already underway or under consideration across the Department of Health and Human Services (HHS).

In the course of preparing the Report, Secretary Becerra, other HHS officials, and HHS staff held listening sessions with consumer groups, staff from the Medicare Payment Advisory Commission (MedPAC), independent experts and researchers, and stakeholders from across the health care system. We thank the participants for their time and for their shared commitment to lowering drug prices for all Americans. We have incorporated many of the ideas they shared into the Report.

I. Introduction

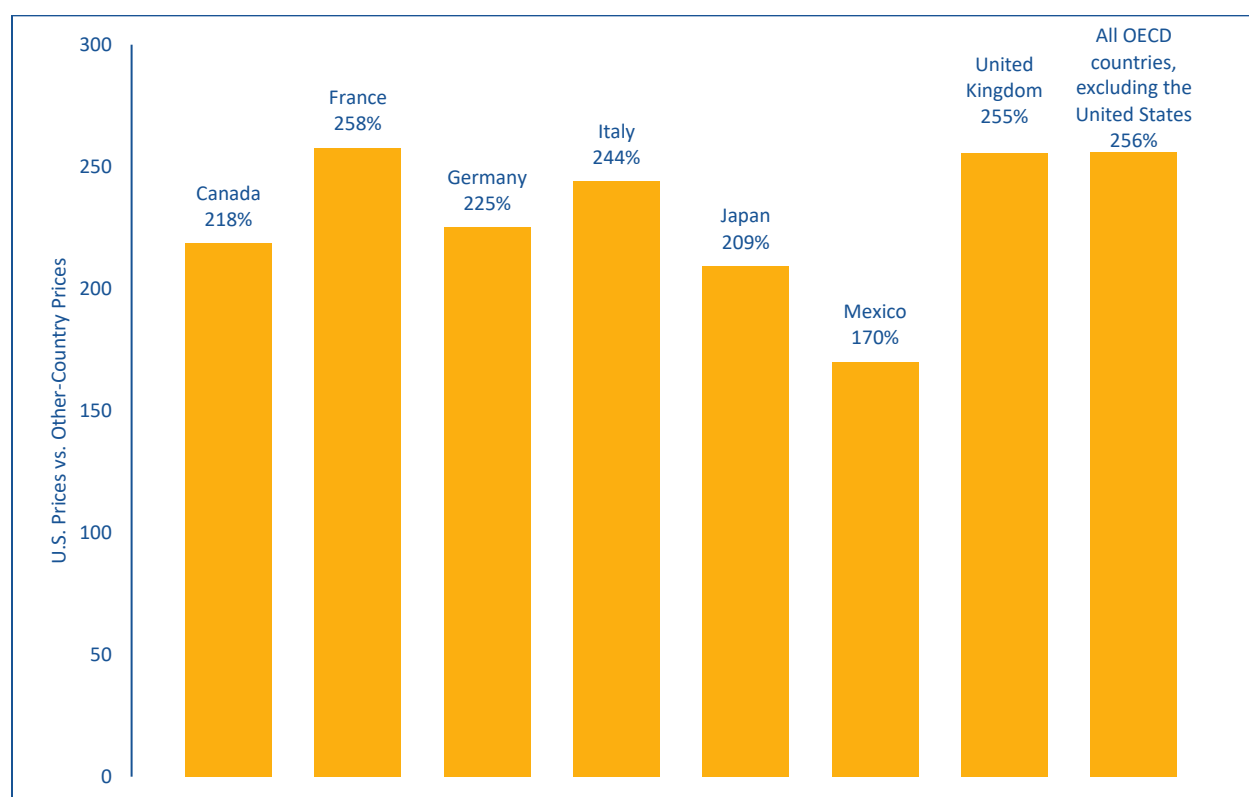
Americans pay too much for prescription drugs. We pay the highest prices in the world, which leads to higher spending. Higher spending puts pressure on private and government payers to raise premiums or make benefits less generous. Lack of affordable access to prescription drugs and other health care services leads to worse health outcomes.

Drug prices in the U.S. are too high because multiple factors stifle competition. The prescription drug industry is characterized by multiple market failures including lack of new entrants; incentives for list price inflation to increase rebates and fees; price hikes on single-source generics; research and development spending that goes toward me-too drugs instead of new treatments and cures; and other monopolistic or oligopolistic behavior. The system also fails to lower prices because of legal abuses including pay-for-delay; patent thickets; product hopping; and exploitation of Risk Evaluation and Mitigation Strategy (REMS) provisions.³

Patients in other comparable countries regularly pay substantially less for prescription drugs than Americans. U.S. prescription drug prices are more than double (2.56 times as high) those in other countries that are members of the Organisation for Economic Co-operation and Development (OECD) – see Figure 1. Even after taking rebates and other discounts into account, the U.S. pays at least 1.9 times as much.⁴ The price gap between the U.S. and other nations is even larger for some critical medications.

U.S. insulin prices, for example, are about four times higher than prices in other comparable countries, even after rebates.⁵

Figure 1. U.S. Prescription Drug Prices as a Percentage of Prices in Selected Other Countries, All Drugs, 2018



Source: Andrew W. Mulcahy, Christopher Whaley, Mahlet G. Tebeka, Daniel Schwam, Nathaniel Edenfield, and Alejandro U. Becerra-Ornelas, “International Prescription Drug Price Comparisons: Current Empirical Estimates and Comparisons with Previous Studies,” RAND Research Report RR-2956-ASPEC, 2021 (https://www.rand.org/content/dam/rand/pubs/research_reports/RR2900/RR2956/RAND_RR2956.pdf), p. xi.

High drug prices result in access and affordability challenges for many Americans. Twenty-four percent of adults taking prescription drugs say they are hard to afford,⁶ and nearly 10 percent of adults report not taking medication as prescribed in order to save money.⁷ Some have died as a result.⁸ Additionally, racial and income-based disparities in medication access are pervasive across numerous health conditions.⁹ As President Biden stated, high drug prices “have put the squeeze on too many families and stripped them of their dignity,” forcing them to choose whether to maintain their health, pay the rent or mortgage, or put food on the table.¹⁰

The uninsured and underinsured suffer most from high list prices. Increased spending on drugs makes it harder to afford insurance and puts pressure on payers to offer less generous benefits. Spending on retail prescription drugs (that is, drugs obtained at pharmacies) reached \$369.7 billion in 2019 (\$1,128 per person on average), and individuals covered \$53.7 billion of that total themselves as out-of-pocket spending (\$164 per person on average, including both people with health coverage and the uninsured).¹¹ This spending represented 10 percent of national health spending, and 13 percent of out-of-pocket spending in 2019.¹² Some Americans spend much more than average on prescription drugs,

even with health insurance coverage. For example, among Americans over 65 with Medicare Part D coverage, the top five percent in spending had an average of \$1,490 in out-of-pocket prescription drug costs in 2019.¹³ Total retail prescription drug spending, net of rebates and other discounts, rose 5.7 percent from 2018 to 2019 (the most recent data available), and out-of-pocket spending rose 3.5 percent.¹⁴ Retail prices for widely used brand drugs have been increasing faster than inflation.¹⁵

Drugs administered in hospitals or physician offices, which are not included in the retail totals above, accounted for 28 percent of all drug spending in 2015.¹⁶ This suggests current spending of about \$144 billion (\$439 per person on average, including both people with health coverage and the uninsured) on non-retail drugs, for an overall total of \$1,567 per person spent on prescription drugs every year. These figures may be underestimates, as spending on non-retail drugs has increased more sharply than spending on retail drugs and the data on such spending is not as well reported.¹⁷

Not only are U.S drug prices too high, but for brand name drugs, they often rise far faster than inflation. Under the current system, prescription drug manufacturers are able to raise the prices of their products over time, with no relation to the clinical value of the medication and often far outstripping inflation. In many cases involving older drugs, even though the patents might have expired, incentives to establish competing products are weak, and manufacturers face little to no competition from biosimilars, generics, or branded alternatives. In such cases, the lack of competition allows the few manufacturers to command far higher prices and enact further price increases at will.¹⁸

Monopolistic market conditions have also contributed to exorbitant price increases, far exceeding the rate of inflation, for some prescription drugs. Pyrimethamine, for example, entered the market under the brand name Daraprim in 1953 as a treatment for toxoplasmosis. Though the Food and Drug Administration (FDA) had approved many generic versions of the drug, by 2015 all but one of the U.S. manufacturers had exited the pyrimethamine market. This gave a monopoly to Turing Pharmaceuticals, then led by Martin Shkreli, and in 2015, the price went from \$13.50 to \$750.00 per pill.¹⁹ Significant price increases occur in Medicare Part B as well; for instance, the average spending per claim on Humalog administered through an insulin pump increased from \$274.53 in 2015 to \$1,130.77 in 2019.²⁰

All Americans pay for higher drug spending through insurance premiums and taxes to pay for drug costs in programs including Medicare, Medicaid, the Children's Health Insurance Program (CHIP), the Veterans Health Administration (VA), and the Indian Health Service. Medicare spending on drugs is growing faster than Medicare spending on other services: 5.9 percent annually on Part B Fee-for-Service drugs and Part D, compared to 5.3 percent for the program as a whole.²¹ Drug spending per beneficiary on Medicare Part B, which covers drugs administered in physician offices and hospital outpatient departments, has increased roughly eight percent each year since 2006, and nearly 10 percent from 2017-2018, compared to about six percent annually for overall Part B spending.²² Medicare Part B drug spending has been growing even more sharply in recent years.²³ With no cap on out-of-pocket spending in Medicare Part D, beneficiaries who need expensive drugs or many different drugs to treat chronic conditions can be hit particularly hard: in 2019, nearly 1.5 million beneficiaries had out-of-pocket spending above the catastrophic threshold that is currently set at \$6,550, with 3.6 million beneficiaries having had out-of-pocket spending above the catastrophic threshold in at least one year over the ten year period from 2010-2019.²⁴

People with low incomes, people with disabilities, and the communities in which they live, bear the brunt of high drug prices resulting from lack of competition in the pharmaceutical supply chain. Low-income individuals are more likely to be uninsured than other Americans.²⁵ Communities of color may

be more likely to face geographic barriers as well as affordability barriers to prescription drug access. They are more likely, for example, to live in “pharmacy deserts” from which they must travel far to obtain needed medications.²⁶ Fostering equity across Medicare, Medicaid, CHIP, and the private insurance market, including the Marketplace, is critical.

A multitude of players claim a share of the nation’s drug spending in a complex prescription drug supply chain.²⁷ More specifically, manufacturers produce prescription drugs, physicians prescribe those drugs, and patients buy them from pharmacies; wholesalers move drugs between manufacturers and pharmacies; health insurers, PBMs, and other intermediaries arrange and finance coverage. Anti-competitive conduct and oligopolies, in which a few companies dominate a market, are present throughout the pharmaceutical sector. For instance, the three companies that control the sale of most insulin products worldwide have increased their U.S. prices more than 1,200 percent since the 1990s.²⁸ Brand drug manufacturers sometimes exploit the patents and exclusivities that are intended to promote innovation with “patent thickets,” “product hopping,” “pay-for-delay,” and other anti-competitive practices to keep cheaper generics and biosimilars off the market. They also pay PBMs rebates to cover their drugs, with no guarantee that the savings will be passed on to patients. PBMs use their market power to collect fees from independent pharmacies. The three PBMs that manage 77 percent of prescription claims have consolidated with major health insurance companies, and one of them is also the largest pharmacy/mail-order chain.²⁹ Firms in the pharmaceutical supply chain currently have limited or no incentives to reduce drug costs and challenge anti-competitive actions.

While this Report focuses on federal approaches to lowering drug prices, many state efforts are consistent with the principles stated in this Report, including prescription drug importation programs; copayment caps for insulin and other vital drugs; drug price transparency requirements; laws on PBM reimbursement to pharmacies; tough anti-price gouging laws; and prescription drug affordability boards.³⁰ Neither the Employee Retirement Income Security Act (ERISA)³¹ nor the so-called “dormant Commerce Clause”³² prevent states from taking action on drug prices. But strong federal leadership is also needed to catalyze and coordinate change in the health care system in areas beyond the purview of state powers.

II. Guiding Principles for the Biden-Harris Administration Drug Pricing Plan

This report discusses an approach to lowering drug prices that is based on three principles summarized in Figure 2 and explained in greater detail below.

Figure 2. Three Guiding Principles for Drug Pricing Reform

- 1) Make drug prices more affordable and equitable for all consumers and throughout the health care system**
 - *Support drug price negotiation with manufacturers and stop unreasonable price increases to ensure access to drugs that can improve health for all Americans*
- 2) Improve and promote competition throughout the prescription drug industry**
 - *Support market changes that strengthen supply chains, promote biosimilars and generics, and increase transparency*
- 3) Foster scientific innovation to promote better health care and improve health**
 - *Support public and private research and make sure that market incentives promote discovery of valuable and accessible new treatments, not market gaming*

1) Make drug prices more affordable and equitable for all consumers and throughout the health care system

High drug prices result in higher out-of-pocket costs for consumers, and larger premiums and government and private sector expenditures. The burden of these costs falls most heavily on those who are uninsured, who are more likely to have lower incomes; people with disabilities and chronic conditions, who often face higher prescription drug costs; and communities of color, which experience economic and geographic barriers to medication access.

President Biden’s Competition Executive Order stated, “It is also the policy of my Administration to support aggressive legislative reforms that would lower prescription drug prices, including by allowing Medicare to negotiate drug prices.”³³ Lowering drug prices through negotiation is key to lowering out-of-pocket costs for consumers, governments, and total drug spending. Otherwise, market failures resulting from the lack of competition mean high drug prices are simply shifted to workers, employers, and taxpayers, who pay premiums and fund public insurance programs. Allowing the Secretary of HHS to negotiate Medicare prices will achieve fair prices for beneficiaries when markets fail to do so. Allowing commercial payers, including employer and Marketplace plans, to access those prices will extend savings to additional consumers. An effective negotiation policy must establish criteria for market failure, define a fair price, provide the Secretary with tools and guidelines to negotiate a fair price, and incentivize pharmaceutical companies to participate in the negotiation process.³⁴

In the absence of adequate competition, manufacturers of brand-name drugs in Medicare Part D have raised their prices more than twice the overall rate of inflation over the past 20 years.³⁵ To rein in this pricing behavior, the Biden-Harris Administration supports bipartisan congressional efforts to impose an excise tax when manufacturers raise the price of their products faster than the rate of inflation.

Actions to reduce drug prices through negotiation, inflation rebates, and other methods that enhance competition will be fully consistent with Executive Order 13985, “Advancing Racial Equity and Support for Underserved Communities Through the Federal Government.”³⁶ As defined in that Executive Order, equity means:

the consistent and systematic fair, just, and impartial treatment of all individuals, including individuals who belong to underserved communities that have been denied such treatment, such as Black, Latino, and Indigenous and Native American persons, Asian Americans and Pacific Islanders and other persons of color; members of religious minorities; lesbian, gay, bisexual, transgender, and queer (LGBTQ+) persons; persons with disabilities; persons who live in rural areas; and persons otherwise adversely affected by persistent poverty or inequality.³⁷

The same Executive Order defines underserved communities as “populations sharing a particular characteristic, as well as geographic communities, that have been systematically denied a full opportunity to participate in aspects of economic, social, and civic life.”³⁸ As noted in the introduction of the Report, current high drug prices disproportionately create affordability burdens for underserved communities, and remedying these inequities is a central priority.

Policies that cap out-of-pocket costs, as President Biden is proposing for Medicare Part D,³⁹ are already in place for the employer and individual market, including Marketplace plans, under the Affordable Care Act (ACA). These caps are of particular benefit to those with expensive chronic conditions. Other policies to maintain or increase pharmacy competition will help low-income and rural individuals obtain the medicines they need, close to where they live.

Consistent with the commitment to equity, HHS will support efforts to improve the Medicaid Drug Rebate Program. This approach is also consistent with President Biden’s Executive Order 14009, “Strengthening Medicaid and the Affordable Care Act,” which commits the Administration to these vital programs.⁴⁰

Finally, there are important concerns about the equity implications of certain methodologies, such as Quality Adjusted Life Years (QALYs), for people of all ages with disabilities and chronic conditions.⁴¹ Drug pricing reforms should avoid utilization of methodologies that adversely impact access to needed medications for vulnerable populations.

2) Improve and promote competition throughout the prescription drug industry

To facilitate competition, it is important to reduce regulatory challenges to approving new products. Reforms should address industry tactics and regulatory challenges that delay or discourage competition by slowing down the approval of competing generics and biosimilar products. Improving competition through these methods will result in a more resilient and transparent prescription drug industry than we have today, which in turn should lower prices.

Improving competition in the prescription drug industry requires promoting the development and availability of biosimilar and interchangeable biosimilar products,⁴² as well as generic drugs. Ensuring clarity in FDA processes can expedite the approval and increase the availability of biosimilars, including interchangeable biosimilars, and generics. Because licensure of biosimilars and approval of generics can result in greater direct competition, regulatory barriers to the approval of these products should be reduced. For biosimilars, more than a decade has passed since the creation of a pathway to license biosimilar products. We are committed to re-examining the regulatory environment and using the decade of experience to streamline the licensure process. Some drug products have become more complex in their active ingredients, formulation, route of delivery, or dosage form compared to when the approval process for generic drugs was enacted nearly 40 years ago. It is also important to ensure

that the process for approving generic versions of complex drugs is streamlined and addresses the unique challenges FDA faces when assessing these products.

It is also important to promote the use of biosimilars, interchangeable biosimilars, and generics once they are approved. Greater use of these lower-cost products will not only save money but will also promote future development of such products. Reforms should promote use of biosimilars, interchangeable biosimilars, and generics within Medicare, Medicaid, CHIP, and the Marketplace.

Policies should prevent manufacturers from using strategies to game the regulatory process. These strategies reduce competition and retain market power, as has been observed in the context of medications to treat opioid use disorder.⁴³ Policies should reduce gaming by brand manufacturers to ensure that biosimilar and generic entrants have access to the market. As directed in the Competition Executive Order, FDA will work with the Chair of the Federal Trade Commission (FTC) to identify and address any efforts to impede generic drug and biosimilar competition, including but not limited to false, misleading, or otherwise deceptive statements about the safety or effectiveness of generic drug and biosimilar products.⁴⁴

Having multiple competing brand products on the market is a key part of fostering competition before the entry of generic and biosimilar products. When the incentives are aligned properly, multiple brand products can compete with each other to lower prices. However, manufacturers may have difficulty incentivizing new clinical trials to develop a second-in-market drug, when there is already a therapy available. This results in first-in-class products remaining on the market without any competition. We must explore ways to improve the process to get additional products to the market while continuing to ensure rigorous standards for safety and efficacy.

The patent system also affects prescription drug costs. The number of patents on pharmaceutical products has grown over time, resulting in the development of patent thickets surrounding a given product. For example, among the 100 best-selling drugs from 2005 to 2015, more than 70 percent had their patent protection extended at least once, with almost 50 percent having patent protection extended more than once.⁴⁵ Over this time period, 78 percent of the drugs associated with new patents were existing drugs already on the market.⁴⁵ These groups of patents make it harder to introduce biosimilars and generics into the market, even if the patents are ultimately deemed invalid, unenforceable, or are not infringed upon by the competitor. At the extreme, manufacturers can “evergreen” their patents, in which their originator drugs obtain patent protection for each subsequent, minor change, helping to continuously avoid facing competition. For patents challenged in court, anti-competitive behavior such as “pay-for-delay” agreements—in which brand manufacturers pay generic competitors *not* to enter a market—further reduces timely market entry of follow-on products. The Biden-Harris Administration supports action to ensure that drug manufacturers cannot unfairly use the patent system to discourage competition. The FDA and the U.S. Patent and Trademark Office (USPTO) will work together to develop solutions as requested in the Competition Executive Order.⁴⁶ An important component of this collaboration is FDA’s transmission of a letter to the Under Secretary of Commerce for Intellectual Property and Director of the USPTO regarding ways in which the patent system can continue to incentivize innovation and more rapid availability of biosimilars and generic drugs. Increased engagement between FDA and USPTO can facilitate greater awareness of their complementary work and introduce efficiency into their respective workstreams.

Competition throughout the supply chain is critical for lowering the cost of products and ensuring that drugs are available when patients need them. A resilient drug supply chain is diverse (relies on

manufacturers that vary in size, geographic concentration, or the types of products offered), redundant (there are multiple manufacturers for each product), and produces high-quality drugs. Promoting resiliency thus enhances competition as well. Over the last decades, however, pharmaceutical manufacturing has become an increasingly global enterprise that has resulted in decreased supply chain resilience. President Biden's Executive Orders 14001 "A Sustainable Public Health Supply Chain" and 14017, "America's Supply Chains," commit the Administration to promoting resilient, diverse, and secure supply chains to ensure economic prosperity and national security.⁴⁷ Less robust supply chains, combined with increased consolidation in drug markets, result in higher costs to consumers and potentially life-threatening delays in treatment. This can occur when affordable drugs are unavailable and consumers must switch to higher-cost drugs. Conversely, when the market rewards investments in quality manufacturing that strengthens the supply chain, we further ensure the availability of safe, effective, and high-quality drug products. Thus, efforts should improve supply chain transparency and incentivize resilience; revitalize and rebuild domestic capability and the availability of critical drugs; and maintain U.S. leadership in research and development capacity by promoting investments in breakthrough medicines.

Well-functioning competitive markets are also transparent, meaning that all parties know and understand the prices of the products and services changing hands. Lack of transparency can contribute to market failures: for example, when a doctor prescribes an off-patent medicine assuming it will be priced reasonably and does not realize the price has been raised. Across the U.S. health care system, the Biden-Harris Administration is working vigorously to implement the No Surprises Act, which protects patients enrolled in group health plans and individual health insurance coverage from surprise billing for emergency out-of-network medical and air ambulance services, and non-emergency services by out-of-network providers without advance notice.⁴⁸ The Competition Executive Order requires the Secretary of HHS to "support existing price transparency initiatives for hospitals, other providers, and insurers along with any new price transparency initiatives."⁴⁹

This commitment to price transparency includes prescription drugs. At the pharmacy counter, physician's office, or hospital outpatient department, patients should know what they have to pay out-of-pocket for a prescription; whether they could get it at a lower price by going outside their insurance coverage, or through other means; and what transfers among other parties are triggered by their transactions. Payers, including employer plans and state Medicaid agencies, should know what the drugs they purchase really cost them. Just as in other markets where consumers can compare the price and value of products before purchase, drug pricing should be transparent.

3) Foster scientific innovation to promote better health care and improve health

New pharmaceutical products are a critical part of improving the health of Americans. To address the need for cures for cancer, Alzheimer's, and other conditions that affect millions of Americans, policies should create incentives for innovations that improve the lives of Americans. Too often pharmaceutical companies invest in product development aimed at extending the monopolies of already-approved products. These investments typically result in little or no improvements in health but translate into increased costs for patients and the health system. These "product hops" also have the effect of reducing the incentives for generic manufacturers to seek approval of safe and effective prior formulations of the product. This type of gaming reduces the incentives to invest in *real* innovation by increasing the opportunity cost of such investments. We are committed to better aligning incentives for companies to focus on innovations with the greatest health impact. Drug pricing reform can realign

these incentives so that companies are rewarded for investments in innovation that will have the largest impact on health.

We can also reduce the costs of bringing new innovations to market by bolstering government investment in the research needed to create new breakthrough drugs. As part of this commitment, the Biden-Harris Administration has proposed the creation of the Advanced Research Projects Agency for Health (ARPA-H).⁵⁰ ARPA-H would be tasked with building high-risk, high-reward capabilities to drive biomedical breakthroughs, providing transformative solutions to patients. Just as existing government programs, such as the Defense Advanced Research Projects Agency (DARPA) and the Biomedical Advanced Research and Development Authority (BARDA), have fostered key medical innovations as part of their missions, and investments in the National Aeronautics and Space Administration (NASA) led to technological discoveries that ultimately spurred private innovation, ARPA-H will help bring more new cures and treatments to patients. The initial focus of ARPA-H will be on cancer and other diseases such as diabetes and Alzheimer's.⁵¹ ARPA-H will thus continue the collaboration of public and private sectors that accelerated the availability of COVID-19 vaccines, developed by manufacturers building on previous research by NIH, DARPA, and BARDA. The COVID-19 vaccines were purchased with federal funding and made available to all Americans without patient cost-sharing.

A recent analysis shows NIH contributed to 100 percent of FDA-approved New Molecular Entities (NMEs) by funding research on NME targets or, to a lesser extent, the NMEs themselves.⁵² Consumers will benefit as ARPA-H and other government programs continue to draw upon these fundamental investments.

III. Support for Bold Legislative Action

The rising cost of prescription drugs is a pressing concern for many Americans who rely on being able to afford their medicines to survive or maintain quality of life, and there is broad support across the political spectrum for action. The Biden-Harris Administration is eager to work with Congress to enact robust and transformative proposals to reform the American pharmaceutical market and bring much needed relief from high drug prices to all Americans.

Legislation to Lower Out-of-Pocket Drug Costs and Reduce Overall Drug Spending

Skyrocketing list prices are fueling greater out-of-pocket costs for patients and driving increases in overall drug spending. Novel pharmaceutical products are entering the market at unprecedented prices. For some drugs, these prices might be justified by the significant clinical benefit they offer to patients. For others, the high price tag far exceeds what could be considered reasonable based on the clinical benefits they offer. The trend toward development and marketing of blockbuster drugs is a primary driver of recent surges in pharmaceutical spending.^{53,54} Innovative drug development provides tremendous benefits, but the unabated movement toward higher list prices is unsustainable. The Biden-Harris Administration supports legislation that will lower out-of-pocket costs and reduce overall prescription drug spending by enabling direct price negotiation by Medicare, allowing commercial payers to access those prices, redesigning Medicare benefits, and reducing incentives that encourage overutilization of high-cost drugs.

Under the current Medicare Part D system, Medicare contracts with private plan sponsors to provide a prescription drug benefit and entrusts plan sponsors with authority to negotiate drug prices with

pharmaceutical companies. A provision in the law that established the Medicare Part D program specifically prohibits the HHS Secretary from interfering with the negotiations between drug manufacturers and pharmacies and plan sponsors, requiring a particular formulary, or instituting a price structure for the reimbursement of covered Part D drugs. This restriction is unique to Part D and contrasts with how drug prices are determined in other federal programs, such as the use of ceiling prices in the VA and mandatory rebates in Medicaid—both of which result in lower brand drug prices than in Medicare Part D.⁵⁵ The restriction also contrasts how Medicare pays for other services, such as those provided by hospitals and physicians.

Medicare Part B is also constrained in how it pays practitioners, hospital outpatient departments, and other providers for the cost of separately paid prescription drugs. For physician-administered drugs, Part B is a price-taker, in most cases paying 106 percent of the Average Sales Price (ASP), which is the average manufacturer sales price to all purchasers in the U.S. (with limited exceptions), inclusive of rebates and other discounts. The current percentage-based system creates perverse incentives for manufacturers to raise their prices and for providers to use higher cost drugs and/or more drugs. Negotiation of prices for Part B drugs, combined with enhanced incentives for hospitals and physicians to administer biosimilars or other lower cost drugs when they are available, would produce cost savings for beneficiaries and the government.⁵⁶ Part B drugs can also create shocking out-of-pocket expenditures.⁵⁷ For example, average annual 2017 Medicare Part B Fee-for-Service cost-sharing per user for Eculizumab, used to treat rare forms of blood, kidney and muscle diseases, was over \$31,500.⁵⁸ In addition to lowering out-of-pocket costs, authorizing the Secretary of HHS to negotiate fair prices on behalf of Medicare could lead to hundreds of billions of dollars in savings for the federal government.⁵⁹ The authority to negotiate directly with drug manufacturers would enable the Secretary to leverage the purchasing power of these programs more effectively, particularly for high-priced drugs for which there are no competitors, and where private plans or providers may be less able to negotiate lower prices. The lower prices obtained in these negotiations will translate into lower costs for patients at the doctor's office (Part B) and the retail pharmacy counter (Part D), and lower premiums.⁶⁰

The benefits of price negotiation under this plan would not be limited to Medicare. These lower and fairer prices could also be available to patients with employer coverage, ACA Marketplace coverage, and other individual market coverage if the plan sponsors choose to participate. As President Biden has said, "If Medicare prices are available to private insurance companies, then it would reduce the price of employer-based health insurance coverage."⁶¹

To ensure that Medicare beneficiaries have access to affordable medications, the Biden-Harris Administration supports a cap on out-of-pocket costs and other reductions in cost-sharing for Medicare Part D beneficiaries. The Biden-Harris Administration supports a redesign of the Part D prescription drug benefit to establish a beneficiary out-of-pocket cap, increase overall levels of liability of Part D plans and drug manufacturers, and decrease Medicare liability in the catastrophic phase. Redesign efforts that better share liability for catastrophic costs can strengthen incentives for plans to negotiate more aggressively and for manufacturers to offer lower prices. In addition, Part D plans would have greater incentive to promote drugs that offer the most value at the lowest cost.

Other changes could reduce Medicaid prescription drug costs for the federal government and the states while maintaining patients' access to medicines. Some proposals would authorize HHS to negotiate Medicaid supplemental rebates on behalf of states that voluntarily choose to participate in such a program to achieve greater leverage than they could have on their own or in existing state pools. Other proposals would ban spread pricing, under which PBMs receive more for drugs than they pay the

pharmacies that dispense them, in Medicaid contracts. Legislation could also be considered to allow states to apply the Medicaid Drug Rebate Program requirements to bundled drugs provided as part of outpatient hospital and physician services.

Last year, Congress made sure that COVID-19 vaccines would be available to everyone with no patient cost-sharing. Under the ACA, this is also true for other vaccines recommended by the Centers for Disease Control and Prevention (CDC) for enrollees in non-grandfathered employer and individual market plans, and for adults in the Medicaid expansion eligibility group in states that have expanded Medicaid. Congress acted years ago to ensure that all children should have access to vaccines regardless of insurance status. Similarly, Congress could provide all adults access to all CDC-recommended vaccines without cost-sharing. Doing so will prevent needless suffering, hospitalizations, and deaths from conditions including influenza, shingles, and pneumonia.

Legislation to Slow Price Increases

In conjunction with negotiation, the Administration encourages Congress to address situations in which manufacturers increase pharmaceutical prices faster than the rate of inflation. As discussed in the Introduction, price increases for existing drugs are sometimes exorbitant, in some cases doubling in just a few years – or even faster – with no clinical reason for an underlying price change. Restructuring the Part D catastrophic benefit as proposed above would better align incentives for plan sponsors and drug manufacturers to slow the growth of Part D drug spending.

Legislation to Improve Competition by Promoting Biosimilars and Generics

Legislative efforts that take aim directly at high drug prices are a critical first step and the foundation for any reform. Building on that foundation, congressional efforts can also improve competition by promoting the development and availability of lower cost biosimilar and generic drugs for all Americans. This includes actions that promote the prompt approval of generic drugs and provide federal support for the development of nonprofit generic drug manufacturers that increase the availability of generic drugs. Congress can also consider reassessing the optimal period of exclusivity for biological products. This in turn will reduce the likelihood of drug shortages and may lower drug costs. Congress can pursue proposals that would promote competition by expediting market entry of lower cost biosimilars and generics. These efforts include clarifying regulatory standards and processes to incentivize the rapid submission of interchangeable products and ensuring exclusivity periods are not abused.

Because Medicare is the largest payer in the U.S., accounting for 34 percent of U.S. net drug spending when Part B and Part D are combined,⁶² Medicare payment policy can play a large role in promoting biosimilar and generic drug availability. The Competition Executive Order recognizes this by requiring CMS to “prepare for Medicare and Medicaid coverage of interchangeable biological products, and for payment models to support increased utilization of generic drugs and biosimilars.”⁶³ In 2016, Medicare Part D could have saved as much as \$3 billion if generics were substituted for all brand-name drugs for which they were available.⁶⁴ Steps to encourage utilization of biosimilars and generics could also be pursued for Marketplace plans.

Congress could consider other efforts to promote the use of biosimilars and generics. For example, Congress could encourage providers to use biosimilars and interchangeable biosimilars by eliminating the separate calculation of the Medicare Part B payment limit for reference biological products. To date,

setting the provider add-on for a biosimilar to match that for its reference product has not provided sufficient incentive for providers to change prescribing patterns and generate maximum Medicare Part B savings. A single payment limit applicable to the reference biological product and the biosimilar product(s) of that reference biological product could spur price competition and drive down average sales prices for all products included in the payment limit calculation, resulting in savings for Medicare and supplemental insurers. Other proposals include modifying payments to providers to increase their incentives to prescribe biosimilars and generics, as opposed to higher cost alternatives, in Part B. Finally, policymakers can consider the use of a least costly alternative and value pricing, including outcomes-based arrangements in Part B. Beneficiaries could see lower cost-sharing that addresses equity concerns about access to high cost Part B drugs. As more biosimilars become available over time, the potential for savings from this proposal would expand.

Legislation to Enhance Regulatory Environment and Market Structure

Similarly, there are several ways that legislative action can enhance the regulatory environment and market structure of the pharmaceutical and biotech industries, which provide critical medications to Americans.

Congress could take additional legislative action to prohibit reverse patent settlements, also known as “pay-for-delay” agreements, which have been estimated to cost consumers as much as \$36 billion a year.⁶⁵ In many cases, it is profitable for a company that has an on-patent brand-name drug to financially compensate the first-to-file generic challenger in return for the generic manufacturer’s agreement to delay its own market entry. This effectively forestalls all other generic entry by delaying the start of the 180-day exclusivity period. Congress could address this behavior through bipartisan proposals that would designate as “anti-competitive” any agreements between branded and generic drug manufacturers in which Abbreviated New Drug Application (ANDA) holders commit to forgo research and development activities, manufacturing, marketing, or sales in exchange for economic compensation. Other proposals would make technical changes to the structure of the 180-day exclusivity period awarded to the first-to-file generic to reduce the ability and the incentive to delay the entry of other generic firms into the marketplace. Such proposals may include specifying that exclusivity does not block approval of subsequent applications until a first applicant begins commercial marketing of the drug, or expanding the circumstances in which the 180-day exclusivity period may be forfeited by first applicants who fail to market their products within specified timeframes. These proposals also address pay-for-delay agreements between reference product sponsors and applicants for biosimilar and interchangeable biosimilar products.

Legislative action can also enhance regulatory flexibility and market competitiveness by increasing the speed and flexibility of the review process for biosimilars and generics, which will ultimately lead to faster approvals for safe and effective products and a more competitive marketplace. Such proposals would eliminate unnecessary regulatory requirements that slow the approval process. For example, Congress could exempt biological products from the U.S. Pharmacopeia (USP) monograph standards for drugs, as these standards are thought to cause delay in the licensure of biosimilars; and Congress could enhance efficiency in biosimilar development by providing greater flexibility and clarity in regards to the inclusion of data from animal studies. Another proposal designed to facilitate the development of generics would amend the law to require drug manufacturers to disclose full information about their product’s inactive ingredients in their product labeling. This proposal would also clarify that it is not an improper disclosure by the FDA to provide a potential generic drug sponsor with the names and

amounts of inactive ingredients used in the formulation of a reference listed drug when a generic drug is required to have the same formulation to obtain approval. Congress can also facilitate the development of complex generic drug-device combination products by amending the law to provide enhanced scientific and regulatory clarity to generic drug developers of these products, as well as reduce their product development time, uncertainty, and cost.

Other legislative changes would make it harder for brand manufacturers to abuse the regulatory process to prevent the introduction of biosimilar and generic products. Congress could make it more difficult for manufacturers to try to slow FDA's ability to make decisions on generic and biosimilar products by submitting sham citizen petitions, or prevent manufacturers from exploiting REMS to stifle the development of biosimilar and generic products.

It is also important to foster innovation in the antimicrobial market by developing novel payment mechanisms that delink volume of sales from revenue for selected products. This is especially true for therapies aimed at drug resistant pathogens for which there is a critical unmet societal need as a direct result of large externalities from infection transmission and evolved resistance. Creating such a delinked payment mechanism has the ability to simultaneously restore a robust pipeline and supply chain of new antimicrobial therapies, as well as maintain and enhance stewardship efforts to limit the rate of evolved resistance.

IV. Administrative Actions

In addition to working with Congress on marquee legislative approaches that take aim directly at high drug prices, administrative levers can promote competition and reduce drug prices. Actions across HHS and other Departments and Offices, such as the USPTO, can lower prices and promote competition. Important efforts can also address pay-for-delay agreements as explicitly mentioned in the Competition Executive Order.⁶⁶

The Centers for Medicare & Medicaid Services (CMS)

The Centers for Medicare & Medicaid Services (CMS) develops and implements a broad set of policies for drugs that are covered under Medicare, Medicaid, CHIP, and Marketplace coverage. CMS will continue to use its authority to combat excessive prescription drug pricing, reduce the prices paid by the federal government for such drugs, address the recurrent problem of price gouging, and achieve greater equity in drug access and affordability for all Americans. The CMS Innovation Center was established to test innovative payment and service delivery models to reduce program expenditures while preserving or enhancing the quality of care furnished to individuals under Medicare, Medicaid, and CHIP. CMS will continue prioritizing payment and service delivery models that test ways to reduce program and beneficiary spending on prescription drugs, support increased utilization of biosimilars and generic drugs, and lower overall spending while improving quality and beneficiary health.

Medicare Part B

As the CMS Innovation Center enters its second decade, it has laid out an ambitious vision that focuses on advancing health equity, improving quality, and reducing costs.⁶⁷ The goal is a transformed health care system that pays for value instead of volume and provides patient-centered care.⁶⁸ Models that work to reduce the high price of Part B drugs and redress the distortionary reimbursement structures of

the program are consistent with these areas of focus and remain a priority for CMS. The Innovation Center is exploring an array of potential models:

Innovative payments within Medicare Part B: The Innovation Center can consider small-scale mandatory models that link payment for prescription drugs and biologics to factors such as improved patient outcomes, reductions in health disparities, patient affordability, and lower overall costs. The models could include incentives for use of high-value therapies, such as biosimilars and generic drugs, and could also include outcome-based arrangements with manufacturers. The models could be made available to other payers, including employer and Marketplace plans, and state Medicaid and CHIP agencies. This approach has the potential to reduce public and private sector costs, expand utilization of biosimilars and generics, and encourage manufacturers to develop innovative new drugs—all without reducing anyone’s access to needed medicines. As CMS indicated in its August 10, 2021 proposed rulemaking, the agency is also reviewing comments on the Most Favored Nation model for selected Medicare Part B drugs.⁶⁹

Shared savings: The CMS Innovation Center is interested in models in which Medicare Part B savings from utilization of biosimilars, generics, or other high-value products are shared between prescribing providers and the government. Beneficiaries who have wrap-around supplemental coverage would benefit from lower premiums for that coverage, while patients who do not have supplemental coverage would benefit from lower out-of-pocket costs for medicines.

Bundled payment for treatment episodes: These models could focus on episodes of care that include drugs and biologics accounting for a large proportion of Medicare Part B drug spending along with the drug administration services, devices, and related services furnished to a beneficiary over a period of time. The models could include incentives for use of biosimilars, generic drugs, and high-value single source products.

Medicare Part D

The CMS Innovation Center continues to test the impact of the Part D Senior Savings Model, a voluntary Medicare Part D model that offers beneficiaries an increased choice of enhanced alternative Part D plan options that offer predictable out-of-pocket costs for a broad set of formulary insulins.⁷⁰ This model could be updated to include additional drug classes that are associated with high out-of-pocket costs for beneficiaries and have high prevalence and/or utilization within the Medicare population. Doing so would provide additional opportunities to test whether the changes to enhanced alternative Part D plan options improve affordability, access, and adherence for beneficiaries taking certain medications. The CMS Innovation Center is also considering models that provide additional Medicare Part D cost-sharing support to Low-income Subsidy Beneficiaries for using biosimilars and generics, with the potential to increase utilization and affordability of biosimilars and generics.

Another area of focus is Direct and Indirect Remuneration (DIR). DIR payments include concessions that are typically based on pharmacy metrics such as generic dispensing rates and medication adherence rates. Changes to DIR can also lower costs for Medicare Part D beneficiaries. Between 2013 and 2020, these negotiated price concessions that Part D sponsors receive from pharmacies after the point of sale grew from \$0.2 to \$11.2 billion per year.⁷¹ Although the savings from these price concessions are ultimately reported to CMS at the end of the yearly cycle, the savings typically do not get incorporated into the reported “negotiated prices” of drugs at the point of sale that are used to determine beneficiary cost-sharing. When price concessions are not reported in the “negotiated prices,” the patient does not

benefit from them at the point of sale and pays more out-of-pocket. In late 2018, CMS sought comment on a policy that would require Part D sponsors to apply all price concessions they receive from network pharmacies to the price of a drug to the negotiated price upon which beneficiary cost-sharing and benefit adjudication is based. CMS is analyzing these comments to inform future action in this area.

Accountability for Total Cost of Care within Medicare Part B and Medicare Part D

The CMS Innovation Center is considering models to test whether comprehensive payment and service delivery reform focusing on whole person care results in changes to drug utilization, spending, and patient outcomes. Models that test innovative bundled payments for a broad set of services could include incentives for care redesign to support patient engagement, enhanced care coordination, and improved quality. A model could test holding prescribers accountable for a reduction in total cost of care over time, including drugs under Medicare Part B and Medicare Part D, and could include incentives for use of high-value therapies, biosimilars, and generics. Such a model would build on the CMS Innovation Center's experience with total cost of care models, including the Oncology Care Model and Accountable Care Organizations (ACOs), though ACOs do not include Part D spending in calculating spending targets. The models could address conditions such as hepatitis C, HIV/AIDS, opioid use disorder, and diabetes. They would take advantage of the lower drug prices achieved through negotiation while addressing important public health goals.

Drug Price Transparency

CMS will use information from two data collections to improve transparency in the prescription drug industry, including a better understanding of which drugs are driving the increase in U.S. prescription drug spending, the impact of prescription drug rebates, trends in prescription drug utilization, and the impact of prescription drug rebates on premiums and out-of-pocket costs.

CMS is implementing the provisions of Section 204 of Title II (Transparency) of Division BB of the Consolidated Appropriations Act, 2021.⁷² This legislation requires group health plans and health insurance issuers in the group and individual markets to annually report information about prescription drug and other medical costs to the Departments of HHS, Labor, and the Treasury (collectively, the Departments). The Departments and the Office of Personnel Management (OPM) received public comments through a Request for Information, which was published in June 2021,⁷³ and are actively working on related rulemaking. The Departments and OPM anticipate providing guidance on timelines for the collection of data from plans and issuers shortly. The Departments and OPM will publish a biannual report to Congress on prescription drug reimbursements under group health plans and group and individual health insurance coverage, prescription drug pricing trends, and the role of prescription drug costs in contributing to premium changes under such plans or coverage.

CMS is also implementing ACA provisions that require issuers of Marketplace plans or their PBMs to provide drug, rebate, and spread pricing information.⁷⁴ On January 28, 2020, and September 11, 2020, HHS published notices in the Federal Register soliciting public comment on the collection of information requirements, which detailed the proposed data collection.⁷⁵ HHS has completed development of the data collection portal and is currently developing mechanisms to provide technical assistance to issuers and PBMs. Data collection from PBMs is expected to begin in 2022.

The Food and Drug Administration (FDA)

FDA is working to address potential barriers to biosimilar and generic drug development and market entry to spur competition so that consumers can access the medicines they need at affordable prices. FDA is also working with states and Tribes to implement safe prescription drug importation programs to significantly reduce costs for consumers.⁷⁶

Biosimilar Competition

Competitive markets for biological products, including biosimilars and interchangeable biosimilars, are essential for improving patient access to medicines and facilitating the reduction of health care costs. In July 2018, FDA released the Biosimilars Action Plan (BAP), which applies many of the lessons learned from FDA's experience with generic drugs to facilitate biosimilar competition.⁷⁷ The BAP is based on four key strategies: improving the efficiency of the product development and approval process; maximizing scientific and regulatory clarity for the product development community; developing effective communications to improve understanding among interested parties; and supporting market competition by reducing gaming of FDA requirements or other attempts to unfairly delay market entry to follow-on versions of biological products.

To facilitate the development and approval of biosimilar and interchangeable biological products and to make the process more transparent, efficient, and predictable, FDA has finalized guidance documents on a range of foundational issues in biosimilar and interchangeable development; has modernized the Lists of Licensed Biological Products with Reference Product Exclusivity and Biosimilarity or Interchangeability Evaluations, commonly known as the Purple Book, into a user-friendly source of information about approved biological products; and is actively working on modernizing biological product regulations. These regulations were primarily drafted in the 1970s, before passage of the Biologics Price Competition and Innovation Act of 2009 (BPCI Act), and need to be updated and modernized to account for the existence of biosimilar and interchangeable biological products. In addition, FDA is conducting research to support more efficient biosimilar development programs. Consistent with the Advancing Education on Biosimilars Act of 2021 (Public Law 117-8), FDA is also working to establish new education initiatives to develop curricula for use in medical, nursing, and pharmacy schools, to expand the availability of continuing education for health care providers, and to better inform patients about biosimilars and interchangeables.

We are also exploring ways to provide greater flexibility regarding the data and information needed to support licensure of a proposed biosimilar or interchangeable biosimilar. Such flexibility can expedite the development and approval process for these lower cost products without compromising safety or efficacy. To inform product developers who intend to seek the FDA's approval of proposed insulin products that are biosimilar to, or interchangeable with, an approved insulin product, FDA issued a draft guidance for industry, "Clinical Immunogenicity Considerations for Biosimilar and Interchangeable Insulin Products."⁷⁸ Significantly, FDA recommends in the draft guidance that, under certain circumstances, a comparative clinical immunogenicity study would not be necessary for approval of certain proposed biosimilar and interchangeable insulin products.

Since releasing that draft guidance, FDA announced approval of the first interchangeable biosimilar product on July 28, 2021, for a long-acting insulin that did not include a clinical immunogenicity study.⁷⁹ FDA determined that Semglee (insulin glargine-yfgn), a long-acting insulin analog, is biosimilar to, and

interchangeable with, its reference product (Lantus). Approval of additional safe, high-quality products for treating diabetes facilitates access to cost-effective options for patients. States may permit a pharmacist to substitute an interchangeable product for the reference product without consulting the prescriber—a practice commonly called “pharmacy-level substitution”—and this may result in further savings for patients, the federal government, and other payers including commercial insurance plans.

FDA will continue its work to build robust and competitive markets for biosimilar and interchangeable biosimilar products, for patients with diabetes and other conditions. We will continue to engage with stakeholders, conduct research, and pursue the development of guidance and other policies to promote the efficient development of biosimilar and interchangeable biosimilar products, as well as to support their uptake.

Generic Competition

FDA is committed to addressing the high cost of medicines by encouraging robust and timely market competition for generic drugs through various initiatives, one of which is the Drug Competition Action Plan.⁸⁰ Through this plan, FDA continues to clarify and improve the approval framework for generic drugs to make approval more transparent, efficient, and predictable. These targeted efforts to clarify FDA’s regulatory expectations support generic drug development and improve the overall quality of generic drug applications submitted for approval. At the same time, FDA is making its own review process more efficient, improving the speed and predictability of the generic drug review process while maintaining rigorous scientific standards. Bringing greater transparency to the generic drug review and approval process, as well as removing barriers to generic drug development and market entry, supports patients’ access to the medicines they need at affordable prices.

Many of these efforts focus on the development and approval of complex generic drug products, a category that includes generics with complex active ingredients, complex formulations, or complex routes of delivery, as well as complex drug-device combination products. These complex generic drug products are typically harder to develop than other generic drugs, which means that many complex brand products face less competition than other brand products and can therefore be more expensive and less accessible to the patients who need them. FDA’s ongoing initiatives in this area, such as forthcoming product-specific guidance to support the development and approval of safe and effective complex generic drug products,⁸¹ are aimed at ensuring that regulatory requirements for complex generic drugs are clear, predictable, and science based. Reducing the time, uncertainty, and cost of drug development in this way will improve patients’ access to affordable medicines.

Across these efforts, FDA is committed to ensuring its policies bolster a strong and sustained generic drug supply chain, as discussed earlier in the Report.

Labeling Carve-Outs

Both the biosimilar and generic drug marketing pathways created by Congress provide important flexibility for biosimilars and generic drugs to seek approval for fewer than all of the brand product's conditions of use, and, accordingly, to exclude or "carve-out" certain uses from their labeling, including those that are protected by patents for the brand product. Biosimilar and generic drug manufacturers can thus seek timely approval of and market their products for non-protected uses, even when other uses of the brand product remain patent protected. This practice, sometimes described as "skinny labeling," may result in decreased costs to patients and to the federal government, including reducing spending on Medicare and Medicaid.

Recent litigation has raised some questions about the practice of carving out patent-protected indications for generic drugs, which may discourage the use of carve-outs and thus delay the approval of some generic drugs. We are committed to taking steps as appropriate to ensure these critical practices remain available for generic drugs and biosimilars.

Access to Product Samples

The Creating and Restoring Equal Access to Equivalent Samples Act of 2019, widely known as the CREATES Act,⁸² makes available an important new pathway for developers of potential drug and biological products to obtain samples of brand products that they need to support their applications. Under this new law, FDA promotes competition by providing Covered Product Authorizations (CPAs) to developers of follow-on products, including biosimilars, generics, and 505(b)(2) drugs. The CPAs provide an important mechanism for these developers to obtain timely access to the samples of certain brand products they need to support their applications. FDA is developing guidance for industry to provide additional information about CPAs, which it expects to release this winter.

Importation

The Competition Executive Order calls for FDA to work with states and Indian Tribes that propose to develop prescription drug importation programs, in accordance with section 804 of the federal Food, Drug, and Cosmetic Act and FDA's implementing regulations. Congress created this statutory pathway for FDA to allow the importation of certain prescription drugs from Canada in order to reduce the cost of these drugs without imposing additional risk to public health and safety. In October 2020, FDA and the Department of Health and Human Services announced a final rule pursuant to section 804.⁸³ The rule allows FDA-authorized programs to import certain prescription drugs from Canada under specific conditions that ensure, as required by section 804, that the importation poses no additional risk to the public's health and safety while achieving a significant reduction in the cost of covered products to American consumers. FDA is working with states and Indian Tribes that propose to develop Section 804 Importation Programs and has recently invited states that are interested in such programs to partner with the agency throughout the process.

Other Programs

340B Drug Pricing Program

HHS reiterates its strong support for the 340B Drug Pricing Program. Congress created the 340B Program in 1992 to increase safety net provider resources so these safety net providers could reach more eligible patients and provide more comprehensive services.⁸⁴ These additional resources are generated by discounts provided by manufacturers for drugs purchased by such providers. Under the 340B Program, drug manufacturers participating in the Medicaid drug rebate program must agree to provide outpatient drugs to eligible safety net providers (referred to as “covered entities”) at significantly reduced prices. Such drugs are purchased by covered entities and dispensed through the entities’ own in-house pharmacies or through contract arrangements with commercial pharmacies to eligible patients.

Currently, more than 600 manufacturers and approximately 13,000 covered entities participate in the 340B Program. These safety net providers purchased \$38 billion in covered outpatient drugs in 2020, saving on average between 25 to 50 percent. Covered entities are defined in statute and include Community Health Centers, Ryan White grantees, hemophilia treatment centers, qualifying hospitals, and Title X Family Planning Clinics. These providers serve a diverse cross-section of the nation’s safety net population and utilize the 340B Program to address health equity by expanding the provision of under-reimbursed and often scarce services, such as behavioral health, HIV/AIDS treatment, and addiction services for otherwise underserved populations.

March-In Rights and Government Use

The Bayh-Dole Act was designed to address the absence of incentives to commercialize government-funded inventions by allowing small businesses or nonprofit organizations, such as universities, to claim title to inventions generated during performance of a federal grant or contract. Before the Bayh-Dole Act became law in 1980, the federal government owned any inventions it funded and none of them were used to develop therapeutics or vaccines; since then, 245 therapeutics and vaccines have been brought to market using university and federal laboratory patents.⁸⁵ The federal government may grant a license to use the intellectual property arising from government funding without the permission of the rights-holder under certain circumstances, including when “action is necessary to alleviate health and safety needs which are not reasonably satisfied” or when the benefits of the patented product are not “available to the public on reasonable terms.”⁸⁶

HHS, NIH, and other agencies have been petitioned to take action under these provisions, and HHS will continue to give such petitions due consideration.* HHS will also engage other government agencies to address barriers to accessing government-funded inventions as emphasized in the Competition Executive Order, which directs the Director of the National Institute for Standards and Technology to consider not finalizing any provisions on march-in rights and product pricing in the proposed rule, “Rights to Federally Funded Inventions and Licensing of Government Owned Inventions.”⁸⁷

* Another provision, 28 U.S.C. § 1498, allows the federal government to “use or manufacture” technologies protected under current U.S. patents, while giving the patent owner “recovery of his reasonable and entire compensation for such use and manufacture”; <https://uscode.house.gov/view.xhtml?req=granuleid:USC-prelim-title28-section1498&num=0&edition=prelim>

Pay-for-Delay

As discussed above, pay-for-delay agreements occur when follow-on product manufacturers agree to delay market entry in exchange for monetary payment (or payment-in-kind) from brand-name firms. The FTC has authorities to investigate some forms of anti-competitive agreements and has made substantial progress challenging these practices in court. This includes the landmark 2013 Supreme Court decision in *Federal Trade Commission v. Actavis, Inc., et al.*,⁸⁸ which allowed the government and private parties to proceed with antitrust lawsuits against drug companies. However, certain challenges remain, as patent settlements increasingly favor non-cash business transactions that continue to serve as pay-for-delay agreements. HHS supports the FTC in its mission to ensure that any settlements do not infringe on competition and will remain vigilant to combat all forms of anti-competitive behavior by working with federal and state partners on enforcement.

While patent rights, which are granted by the USPTO, are intended to encourage innovation, pay-for-delay agreements allow weak or ineffective patents to remain unchallenged. Coupled with the 180-day exclusivity period provided to the first generic challenger under the Food, Drug, and Cosmetic Act, this has the effect of extending the brand-name manufacturer's monopoly by blocking all competitors. FDA is mindful of its obligations under the "Hatch-Waxman Amendments" to the Federal Food, Drug, and Cosmetic Act to ensure a balance between innovation and access to lower cost follow-on products, and of the impact patent listing procedures can have in delaying access to follow-on products. FDA is working to enhance the patent information listed in FDA's *Approved Drug Products With Therapeutic Equivalence Evaluations* (commonly known as the Orange Book), and has issued guidance on Orange Book processes, held related public educational events, and sought public comment on future changes. These efforts are discussed further in FDA's letter to the USPTO and can help promote the availability of lower-cost generic drugs by providing additional clarity on what patents should be listed in the Orange Book and can potentially lead to a 30-month stay of FDA approval.

V. Conclusion

This Report responds to the request in the Competition Executive Order for "a plan to continue the effort to combat excessive pricing of prescription drugs and enhance domestic pharmaceutical supply chains, to reduce the prices paid by the federal government for such drugs, and to address the recurrent problem of price gouging."⁸⁹ The Report presents principles for equitable drug pricing reform through competition, describes the promising congressional initiatives that are underway in both the House and the Senate, and summarizes administrative actions and proposals across HHS.

Our overall goals are to foster innovation, harness market forces, and improve the market environment, all in pursuit of reduced drug spending for consumers and the health care system. This goal can be achieved by implementing real, equitable solutions. One of the key policies in this effort is legislation that would allow the Secretary of HHS to negotiate drug prices directly with pharmaceutical companies, an approach that is projected to generate reductions in patient cost-sharing and large savings for both government and commercial payers.

Legislative and administrative actions consistent with the guiding principles presented in this Report would reduce prices paid by the federal government for prescription drugs, curb brand drug manufacturers' abuse of patents and exclusivities to avoid competition, increase transparency for

patients and across the drug industry, enhance domestic pharmaceutical supply chains, and address price gouging. Most importantly, these levers will protect American patients and improve their access and adherence to medications by lowering drug prices through increased competition throughout the health care system.

Notes

¹ <https://www.govinfo.gov/content/pkg/FR-2021-07-14/pdf/2021-15069.pdf>

² <https://www.govinfo.gov/content/pkg/FR-2021-07-14/pdf/2021-15069.pdf>, p. 36997.

³ Under “pay-for-delay” agreements, brand manufacturers pay potential generic and biosimilar competitors to keep their products off the market (see <https://www.judiciary.senate.gov/imo/media/doc/Kades%20Written%20Testimony--Final%20July%2012%202021.pdf>). “Patent thickets” are dense webs of overlapping intellectual property rights that generic or biosimilar manufacturers must navigate in order to commercialize generic drugs and biosimilar products (see https://www.judiciary.senate.gov/imo/media/doc/Testimony%20-%20July%2013%202021_Rachel_Moodie.pdf). “Product hopping” occurs when a brand manufacturer makes a minor change to its product before a generic competitor enters, and may even withdraw the original product from the market (see <https://www.judiciary.senate.gov/imo/media/doc/Kades%20Written%20Testimony--Final%20July%2012%202021.pdf>). A Risk Evaluation and Mitigation Strategy (REMS) is a drug safety program that the U.S. Food and Drug Administration (FDA) can require for certain medications with serious safety concerns to help ensure the benefits of the medication outweigh its risks. REMS are designed to reinforce medication use behaviors and actions that support the safe use of that medication. While all medications have labeling that informs health care stakeholders about medication risks, only a few medications require a REMS. FDA may also require that a REMS contain certain Elements To Assure Safe Use (ETASU) when such elements are necessary to mitigate specific serious risks associated with a drug. Brand and generic versions of drug are required by law to have a single-shared system for ETASU unless FDA issues a waiver.

⁴ https://www.rand.org/content/dam/rand/pubs/research_reports/RR2900/RR2956/RAND_RR2956.pdf

⁵ https://aspe.hhs.gov/sites/default/files/migrated_legacy_files/196281/Comparing-Insulin-Prices.pdf

⁶ <https://www.kff.org/health-costs/press-release/poll-nearly-1-in-4-americans-taking-prescription-drugs-say-its-difficult-to-afford-medicines-including-larger-shares-with-low-incomes/>

⁷ https://wwwn.cdc.gov/NHISDataQueryTool/SHS_adult/index.html

⁸ <https://www.washingtonpost.com/news/magazine/wp/2019/01/07/feature/insulin-is-a-lifesaving-drug-but-it-has-become-intolerably-expensive-and-the-consequences-can-be-tragic/>

⁹ <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC8060916/pdf/nihms-1688075.pdf>

¹⁰ <https://www.whitehouse.gov/briefing-room/speeches-remarks/2021/08/12/remarks-by-president-biden-on-how-his-build-back-better-agenda-will-lower-prescription-drug-prices/>

¹¹ See Tables 1 and 16 in NHEA Tables (ZIP) link at <https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/NationalHealthExpendData/NationalHealthAccountsHistorical>.

¹² See Tables 1 and 16 in NHEA Tables (ZIP) link at <https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/NationalHealthExpendData/NationalHealthAccountsHistorical>.

¹³ https://meps.ahrq.gov/data_files/publications/st532/stat532.pdf

¹⁴ See Table 16 in NHEA Tables (ZIP) link at <https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/NationalHealthExpendData/NationalHealthAccountsHistorical>.

¹⁵ <https://www.aarp.org/content/dam/aarp/ppi/2021/06/trends-in-retail-prices-of-brand-name-prescription-drugs-widely-used-by-older-americans.10.26419-2Fppi.00143.001.pdf>

¹⁶ <https://aspe.hhs.gov/sites/default/files/private/pdf/187586/Drugspending.pdf>

¹⁷ <https://aspe.hhs.gov/system/files/pdf/264416/Part-B-Drugs-Trends-Issue-Brief.pdf>

¹⁸ https://aspe.hhs.gov/sites/default/files/migrated_legacy_files/198346/medicare-part-d-generic-comp.pdf

¹⁹ <https://www.nytimes.com/2015/09/21/business/a-huge-overnight-increase-in-a-drugs-price-raises-protests.html>

²⁰ ASPE analysis of CMS Medicare Part B dashboard data available at <https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/Information-on-Prescription-Drugs/MedicarePartB>.

²¹ Office of the Assistant Secretary for Planning and Evaluation (ASPE) calculations of program spending for drugs based on Fee-for-Service claims data for Part B drugs, Medicare Trustees Report 2020 for Part D drugs, and the National Health Expenditure Accounts for total Medicare spending.

²² <https://aspe.hhs.gov/system/files/pdf/264416/Part-B-Drugs-Trends-Issue-Brief.pdf>

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Office of the Assistant Secretary for Planning and Evaluation

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