



MEMORANDUM

April 30, 2021

To: Subcommittee on Health Members and Staff

Fr: Committee on Energy and Commerce Democratic Staff

Re: Hearing on “Negotiating a Better Deal: Legislation to Lower the Cost of Prescription Drugs”

On Tuesday, May 4, 2021, at 11:30 am (EDT) via Cisco Webex online video conferencing, the Subcommittee on Health will hold a topical hearing entitled, “Negotiating a Better Deal: Legislation to Lower the Cost of Prescription Drugs.”

I. BACKGROUND

A. Drug Prices and Spending in the United States

Drug prices and spending in the United States are disproportionately higher than in similarly developed countries.¹ A recent study that analyzed multiple markets and drug subsets found that prices in the United States were 256 percent higher, on average, than in 32 other countries with comparable economies.² When only comparing brand-name drugs, prices in the United States were 344 percent higher.³ Specialty drugs and treatments for severe illnesses, like hepatitis C and certain cancers, had some of the highest prices.⁴ While the United States only accounted for 24 percent of the drugs sold in the compared markets, it was responsible for 58 percent of total spending.⁵ A recent study by the U.S. Government Accountability Office (GAO) found that U.S. net prices – the price after rebates, discounts, and other price concessions – for a sample of selected drugs was on average more than two to four times higher than the publicly available retail prices and manufacturer prices in Australia, Canada (Ontario), and France.⁶

¹ The Rand Corporation, *Prescription Drug Prices in the United States Are 2.56 Times Those in Other Countries* (2021) (www.rand.org/pubs/research_reports/RR2956.html).

² *Id.*

³ *Id.*

⁴ *Id.*

⁵ *Id.*

⁶ U.S. Government Accountability Office, *U.S. Prices for Selected Brand Drugs Were Higher on Average than Prices in Australia, Canada, and France* (March 2021) (www.gao.gov/assets/gao-21-282.pdf).

This disproportionate share of spending on prescription drugs also correlates with year-over-year prescription drug price increases in the United States.⁷ For more than a decade, both list prices and net prices have increased faster than the rate of inflation, with one study noting that from 2007 to 2018, net prices increased every year by an average of 4.5 percentage points, or 3.5 times faster than inflation.⁸ This pricing trend has continued amidst the public health and economic crisis resulting from the coronavirus disease of 2019 (COVID-19) pandemic. In January 2021, the list price of over 800 brand name drugs increased by an average of 4.6 percent, over twice the rate of inflation.^{9,10} This increase in drug prices came as one in four Americans reported difficulties affording their medications.¹¹ One poll found in 2019 that the people in poor health and those with the low incomes struggled the most to afford their drugs.¹²

B. Medicare Drug Spending and Beneficiary Costs

As prescription drug prices continue to increase, so do federal spending and beneficiary cost-sharing. Since the implementation of the Medicare Part D program, annual spending for the program has nearly doubled from \$49 billion in 2007, to \$85 billion in 2019.^{13,14} In 2019, half of all drugs covered under Medicare Part D had list price increases that surpassed the rate of inflation, including 22 of the top 25 most expensive drugs – all of which were brand name

⁷ See note 1.

⁸ Inmaculada Hernandez, et al. *Changes in List Prices, Net Prices, and Discounts for Branded Drugs in the US, 2007-2018* (March 3, 2020) (jamanetwork.com/journals/jama/article-abstract/2762310).

⁹ Good Rx, *Live Updates: January 2021 Drug Price Increases* (www.goodrx.com/blog/january-drug-price-hikes-2021/) (accessed April 22, 2021).

¹⁰ Kaiser Family Foundation, *Price Increases Continue to Outpace Inflation for Many Medicare Part D Drugs* (February 4, 2021) (www.kff.org/medicare/issue-brief/price-increases-continue-to-outpace-inflation-for-many-medicare-part-d-drugs/).

¹¹ Kaiser Family Foundation, *Public Opinion on Prescription Drugs and Their Prices* (www.kff.org/slideshow/public-opinion-on-prescription-drugs-and-their-prices/) (accessed April 23, 2021).

¹² Kaiser Family Foundation, *Poll: Nearly 1 in 4 Americans Taking Prescription Drugs Say It's Difficult to Afford Their Medicines, including Larger Shares Among Those with Health Issues, with Low Incomes and Nearing Medicare Age* (March 1, 2019) (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/).

¹³ Congressional Budget Office, *CBO's March 2008 Baseline: Medicare* (www.cbo.gov/sites/default/files/recurringdata/51302-2008-03-medicare.pdf) (accessed April 27, 2021).

¹⁴ Congressional Budget Office, *Medicare – CBO's March 2020 Baseline as of March 6, 2020* (www.cbo.gov/system/files/2020-03/51302-2020-03-medicare.pdf) (accessed April 27, 2021).

drugs.¹⁵ Last year, the Congressional Budget Office (CBO) projected that Part D spending would rise to \$95 billion in 2021.¹⁶

Over 47 million Medicare beneficiaries were enrolled in a Part D plan in 2020.¹⁷ There is currently no maximum out-of-pocket limit under Part D.¹⁸ In 2021, the standard Part D benefit includes a \$445 deductible, after which beneficiaries pay a 25 percent coinsurance rate for eligible drug expenses, up to \$4,130.¹⁹ Beyond that amount, beneficiaries enter a coverage gap, also called the “donut-hole,” up to a catastrophic limit of \$6,550 for 2021.²⁰ For any expense above the catastrophic limit, there is a five percent coinsurance rate or a fixed copayment per prescription, with no cap on overall out of pocket spending.²¹ High-cost specialty drugs have the highest potential to exacerbate out-of-pocket spending and drive beneficiaries beyond the catastrophic limit.²²

Total Medicare Part B drug expenditures were \$32 billion in 2017, an increase of about 10 percent from 2016.²³ Since 2009, Part B drug spending has grown at an average rate of about 9.6 percent per year. The Medicare Payment Advisory Commission (MedPAC) estimated that more than half of the growth in Part B drug spending between 2009 and 2015 was accounted for by price growth, reflecting both increases in the prices of existing drugs and new drugs becoming available.²⁴ Biologics account for approximately 77 percent of Part B drug spending.²⁵ In

¹⁵ See note 10.

¹⁶ See note 14.

¹⁷ Centers for Medicare & Medicaid Services, *CMS Medical Populations Calendar Year 2020* (www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/CMS-Fast-Facts) (accessed April 23, 2021).

¹⁸ MEDPAC, *Part D Payment System* (October 2020) (www.medpac.gov/docs/default-source/payment-basics/medpac_payment_basics_20_partd_final_sec.pdf?sfvrsn=0).

¹⁹ *Id.*

²⁰ *Id.*

²¹ *Id.*

²² See note 11.

²³ MedPAC, *Two Medicare payment strategies to improve price competition and value for Part B drugs: reference pricing and binding arbitration* (www.medpac.gov/docs/default-source/default-document-library/part-b-drugsmarch-19-public.pdf?sfvrsn=0) (Mar. 7, 2019).

²⁴ MedPAC, *Payment Basics: Part B Drugs Payment Systems* (www.medpac.gov/docs/default-source/paymentbasics/medpac_payment_basics_18_partb_final_sec.pdf?sfvrsn=0) (October 2018).

²⁵ Assistant Secretary for Planning and Evaluation, *Medicare Part B Drugs: Trends in Spending and Utilization, 2006-2017* (aspe.hhs.gov/system/files/pdf/264416/Part-B-Drugs-Trends-Issue-Brief.pdf) (November 20, 2021).

addition, a small number of drugs account for the majority of Part B drug spending. In 2017 the top 20 drugs in terms of spending accounted for 60 percent of total Part B drug spending.²⁶

Some researchers have argued that providing the Department of Health and Human Services (HHS) Secretary with the authority to negotiate the cost of prescription drugs with drug manufacturers would significantly reduce costs and bring prices closer in line with those of other countries.^{27,28} Many other countries with similarly sized economies negotiate with drug manufacturers to establish the price for prescription drugs.²⁹ Similarly, the U.S. Department of Veterans Affairs (VA) negotiates further price discounts for drugs included on the VA formulary.³⁰ However, under current law, the HHS Secretary is prohibited from interfering “with the negotiations between drug manufacturers and pharmacies and PDP [prescription drug plan] sponsors.”³¹

II. LEGISLATION

A. H.R. 3, ELIJAH E. CUMMINGS LOWER DRUG COSTS NOW ACT

1. *Title I: Lowering Drug Prices Through Fair Drug Price Negotiation*

H.R. 3, the “Elijah E. Cummings Lower Drug Costs Now Act”, reintroduced by Chairman Pallone (D-NJ), Chairman Neal (D-MA), and Chairman Scott (D-VA) on April 22, 2021, establishes a fair price negotiation program and authorizes the Secretary of HHS to negotiate directly with prescription drug manufacturers. Under Title I, the Secretary is required to identify and publish a list of 125 negotiation-eligible drugs with the greatest total cost to Medicare and the U.S. health system, based on data used to determine aggregate costs. From the list of 125 negotiation-eligible drugs, the Secretary shall select at least 25 drugs to be subject to negotiation for the first year. Drugs selected for negotiation each year shall be prioritized according to the greatest amount of savings to the federal government or consumers, as determined by the Secretary. For each of these selected drugs, the Secretary shall enter into an agreement with the manufacturer in order to begin a voluntary negotiation process. Insulin

²⁶ *Id.*

²⁷ Kaiser Family Foundation, *What’s the Latest on Medicare Drug Price Negotiations?* (October 17, 2019) (www.kff.org/medicare/issue-brief/whats-the-latest-on-medicare-drug-price-negotiations/).

²⁸ The Journal of the American Medical Association, *The High Cost of Prescription Drugs in the United States* (August 23, 2016) (www.ncbi.nlm.nih.gov/pubmed/27552619).

²⁹ See note 6, at p. 12; James C. Robinson, et al, *Drug Price Moderation in Germany: Lessons for U.S. Reform Efforts*, Commonwealth Fund (Jan. 23, 2020) (www.commonwealthfund.org/publications/issue-briefs/2020/jan/drug-price-moderation-germany-lessons-us-reform-efforts).

³⁰ See note 6.

³¹ Sec.1860D-11(i).

products would also be subject to negotiation, in addition to the other selected drugs. Once a drug is selected for negotiation it will remain a selected drug until competition enters the market.

After entering into agreements with each manufacturer of a selected drug, the Secretary will directly negotiate with each manufacturer to establish a maximum fair price (MFP) that will be applied to the Medicare program. The negotiated price will also be made available to group health plans and health insurers offering coverage in the individual or group market. H.R. 3 establishes an upper limit for the MFP as no more than 1.2 times (or 120 percent) of the volume-weighted average price of six countries (Australia, Canada, France, Germany, Japan, and the United Kingdom), known as the average international market (AIM) price.

While negotiating a MFP, the Secretary shall take into consideration multiple factors, including research and development costs of the drug, production costs, information on alternative treatments and the extent to which the drug represents a therapeutic advance over existing alternatives, and domestic and international sales information. If a manufacturer refuses to enter into negotiations after being selected by the Secretary or if the manufacturer leaves the negotiation before a MFP is agreed to, then the manufacturer will be assessed an escalating excise tax levied on the manufacturer's sales during the period of noncompliance.

2. *Title II: Prescription Drug Inflation Rebates*

H.R. 3 establishes a mandatory rebate for drug manufacturers of all covered Part B and Part D drugs that increase in price faster than inflation. A Part B rebatable drug is defined as a drug or biological paid for under Medicare Part B, excluding certain vaccines and drugs that have average total allowed charges for a year per individual of less than \$100. For manufacturers of a Part B rebatable drug, the rebate shall be based on the percentage increase in the Average Sales Price (ASP) above the consumer price index for all urban consumers (CPI-U) from the payment amount benchmark period beginning January 1, 2016.

For Medicare Part D, a Part D rebatable drug is defined as a covered part D drug except if a drug or biological has an average total cost under a prescription drug plan (PDP) per individual per year that is less than \$100. For manufacturers of a Part D rebatable drug, the rebate is based on the percentage increase of the average manufacturer price (AMP) for the rebatable drug above CPI-U from the payment amount benchmark year which begins January 1, 2016.

3. *Title III: Part D Improvements and Maximum Out-of-Pocket Cap for Medicare Beneficiaries*

H.R. 3 would make changes to the structure of the standard benefit design for Medicare Part D and create an annual out-of-pocket maximum for Part D enrollees. Starting plan year 2024, Part D enrollees' out-of-pocket costs would be capped at \$2,000 and a new manufacturer discount program would be established to ensure manufacturers are responsible for a portion of the Part D spending in the initial coverage phase, as well as the catastrophic phase of coverage. Additionally, this provision would phase out the current coverage gap discount program to streamline the standard benefit design to include a deductible phase, an initial coverage phase, and a catastrophic coverage phase.

In the initial phase of coverage, following an enrollee's deductible phase, PDPs would be responsible for 65 percent of spending, while enrollees would be responsible for 25 percent and manufacturers would be responsible for 10 percent. Following the initial coverage phase, an enrollee's out-of-pocket drug costs will be capped at \$2,000 and in the catastrophic coverage phase the federal government will be responsible for 20 percent reinsurance payments, while PDPs will be responsible for 50 percent, and manufacturers will be responsible for 30 percent.

4. *Title IV: Drug Price Transparency*

Title IV requires certain drug manufacturers of qualifying drugs to submit a report to the Secretary prior to increasing the price of a drug in certain circumstances. If a manufacturer decides to increase the price of a drug by 10 percent or more over a 12-month period, or by 25 percent or more over a 36-month period, or if the estimated price of a qualifying drug for an applicable year per course of treatment is at least \$26,000, then the reporting requirements are triggered. A manufacturer of a qualifying drug that triggers the reporting requirements would be required to report total expenditures for manufacturing the drug, research and development expenditures for the drug, and total revenue and net profit generated by the drug, as well as other documentation as applicable. If a manufacturer of a qualifying drug fail to comply or knowingly provides false information, the manufacturer shall be subject to a civil monetary penalty of \$75,000 for each day the violation continues or \$100,000 for each item of false information.

5. *Title V: NIH, FDA, and Overdose Epidemic Funding*

H.R. 3 further invests billions of dollars into the public health system. The National Institutes of Health (NIH) would receive \$10 billion for innovation and clinical research. This investment would bolster existing efforts put forward in the 21st Century Cures Act, including over \$2 billion for efforts around precision medicine, over \$2 billion for Brain Research through Advancing Innovative Neurotechnologies® (BRAIN) Initiative, \$1.5 billion for the Cancer Moonshot, and over \$150 million for the Regenerative Medicine Innovation Project. Title V also puts forward new funds for research on antimicrobial resistance and rare disease while also providing targeted support for late-stage clinical trials and an innovation network at NIH. The Food and Drug Administration (FDA) would receive \$2 billion to enhance drug development, review, and safety, including investing further in activities authorized under the 21st Century Cures Act, information technology and data modernization, and improved adverse event reporting. Additionally, \$10 billion is targeted to combat the overdose epidemic. This includes \$7.5 billion for the Substance Abuse and Mental Health Services Administration (SAMHSA), \$600 million for the Centers for Disease Control and Prevention (CDC), \$50 million for FDA, \$1.2 billion for NIH, \$450 million for the Health Resources and Services Administration (HRSA), and \$200 million for the Administration for Children and Families (ACF).

H.R. 3 previously passed the House of Representatives on December 12, 2019.³²

³² H.R. 3, 116th Cong. (2019).

B. H.R. 19, LOWER COSTS, MORE CURES ACT OF 2021

1. Title I: Medicare Parts B and D

H.R. 19, the “Lower Costs, More Cures Act of 2021”, introduced by Ranking Member Rodgers (R-WA), includes several reforms to Medicare Parts B & D and Medicaid, among other provisions.

Reforms to Part B include expanding an online tool that allows beneficiaries to compare outpatient costs in different settings, requiring manufacturers of certain single-dose container and single-use package drugs to provide refunds for discarded product, applying variable ASP percentages based on the cost of the drug, capping maximum add-on payments for certain drugs and biologics, and requiring a site-neutral payment for the administration of a Part B drug at the lower physician fee schedule rate rather than the rate paid to hospital.

Title I also would require reporting on excessive price hikes, require public disclosure of drug discounts, initiate a study of pharmaceutical supply chain intermediaries and merger activity, make drug marketing sample information available to certain individuals and entities, and it includes a sense of Congress regarding the need to increase the availability of commercial drug price comparison platforms.

It would cap out-of-pocket expenses for Medicare Part D at \$3,100. Additionally, the legislation makes certain changes to Part D plan options and establishes a post-deductible cap for insulin and insulin supplies.

H.R. 19 also includes a technical correction to the HHS Inspector General’s authority to investigate and enforce the information blocking provisions in the 21st Century Cures Act, a provision included in Public Law No. 116–321.

2. Title II: Medicaid

Title II would make changes to certain aspects of the Medicaid program. It would amend the Social Security Act (SSA) section 1927(d)(4) to establish membership and transparency requirements for state Medicaid pharmacy and therapeutics (P&T) committees. It would require GAO to issue a report on conflicts of interest in state Medicaid program drug use review (DUR) boards and P&T committees. Another provision would require the Secretary to conduct regular audits of the price information that drug manufacturers submit as a condition of participating in the Medicaid drug rebate program. It would also require the Secretary to issue a report to Congress on the results of the audits. It would increase penalties on manufacturers for reporting information late, or for knowingly reporting false information. The bill would also prohibit spread pricing in Medicaid and require a pharmacy benefit manager (PBM) to pass any discount through to the state Medicaid program. It would also require pharmacies that participate in the Medicaid program to respond to the National Average Drug Acquisition Cost (NADAC) survey. The bill would require the Secretary to issue a report on Medicaid provider prescribing patterns for covered outpatient drugs in each state. It would authorize a state plan option for state Medicaid programs to pay for certain covered outpatient drugs through risk-sharing value-based

agreements. Finally, Title II would allow state Medicaid programs to receive rebates on covered outpatient drugs furnished by a physician’s office or in an outpatient hospital setting.

3. *Title III: Food and Drug Administration*

Title III would make unlawful the “pay-for-delay” practice whereby drug companies enter agreements with generic and biosimilar manufacturers to delay a competing drug from coming to market. This title also includes two provisions already signed into law by President Biden on April 23, 2021. Subtitle B expands education on biosimilars and provides educational materials for providers, patients, and caregivers, provisions included in Public Law No. 117–8. Subtitle C clarifies eligibility for exclusivity for certain drugs ensuring manufacturers do not receive exclusivity for previously approved products, a provision included in Public Law No. 117–9.

4. *Title IV: Revenue Provision*

Title IV targets the price of insulin for people insured by high deductible plans. This provision provides a tax incentive to health insurers offering high-deductible plans if they limit deductibles for insulin.

5. *Title V: Miscellaneous*

Title V is a series of nine provisions. They include capping reimbursement for biosimilars to the price of their reference product during their initial period, a GAO study and report on the ASP of drugs under Medicare Part B, requiring Part D and MA-PD plans to report fraud, waste, and abuse, reforming pharmacy quality measures under Part D, providing guidance for interagency coordination between the FDA and the Centers for Medicare and Medicaid Services (CMS), requiring patient consultation in local and national coverage determinations, a MedPAC report on shifting coverage of certain Medicare Part B drugs to Part D, codifying an HHS rule that requires prescription drug advertisements to include truthful and non-misleading information, and establishing a Chief Pharmaceutical Negotiator at the Office of the U.S. Trade Representative.

C. **H.R. 153, PROTECTING CONSUMER ACCESS TO GENERIC DRUGS ACT OF 2021**

H.R. 153, the “Protecting Consumer Access to Generic Drugs Act of 2021”, introduced by Rep. Rush (D-IL), would make it illegal for brand-name drug manufacturers to enter into agreements with generic and biosimilar manufacturers in which payment is exchanged for delayed entry of generic and biosimilar competition, often referred to as “pay for delay.”

D. **H.R. 2815, BOLSTERING INNOVATIVE OPTION TO SAVE IMMEDIATELY ON MEDICINES (BIOSIM) ACT**

H.R. 2815, the “Bolstering Innovative Options to Save Immediately on Medicines Act”, or “BIOSIM Act”, introduced by Reps. Schrader (D-OR) and Kinzinger (R-IL), would increase

reimbursement under Part B for certain qualifying biosimilars to the ASP of the biosimilar plus 8 percent (of the reference product's ASP) for a five-year period. Qualifying biosimilars are those with an average sales price or wholesale acquisition cost less than that of the reference biological product. Under current law, biosimilars and reference products are reimbursed based on the ASP of the product plus 6 percent of the reference product's ASP.

E. H.R. 2831, PROMPT APPROVAL OF SAFE GENERIC DRUGS ACT

H.R. 2831, the "Prompt Approval of Safe Generic Drugs Act", introduced by Rep. Barragán (D-CA), would authorize the FDA to promptly approve a follow-on generic drug if safety information protected by a brand-name drugs' exclusivity is the only thing keeping the product from coming to market. The bill would permit FDA to include any necessary safety information in the generic drug's label.

F. H.R. 2843, STOP THE OVERUSE OF PETITIONS AND GET AFFORDABLE MEDICINES TO ENTER SOON (STOP GAMES) ACT

H.R. 2843, the "Stop the Overuse of Petitions and Get Affordable Medicines to Enter Soon Act," or "STOP GAMES Act", introduced by Rep. Levin (D-MI), reforms the FDA citizen petition process to curb misuse and abuse. The citizen petition is an available means by which industry and other stakeholders can raise issues of scientific or regulatory concern related to products regulated by FDA. However, these petitions have been used by some entities to delay competing drugs from coming to market.³³ H.R. 2843 outlines the factors FDA should take into consideration when identifying whether a citizen petition has been filed with the primary purpose of delaying approval and requires companies to file a petition within 60 days of acquiring the information filed on the petition. The bill also calls for enhanced reporting regarding citizen petitions by FDA including time and resources spent on each petition, timing of petitions related to patent expiration, and any delay in approval associated with responding to a petition.

G. H.R. 2846, ENSURING ACCESS TO LOWER-COST MEDICINES FOR SENIORS ACT

H.R. 2846, the "Ensuring Access to Lower-Cost Medicines for Seniors Act", introduced by Reps. McKinley (R-WV), Kuster (D-NH), Tonko (D-NY), Carter (R-GA), Bass (D-CA), and Matsui (D-CA), would require Part D prescription drug plan (PDP) formularies to include coverage for lower-cost generic drugs and biosimilars when the wholesale acquisition cost (WAC) is less than the reference product. The bill would also require PDPs to establish specific lower cost-sharing tiers for such covered generic drugs or biosimilars as compared to the reference product and prohibits PDPs from establishing more restrictive utilization management protocols than those for the reference product.

³³ See Michael A. Carrier, *Five Actions to Stop Citizen Petition Abuse*, 118 COLUMBIA L. REV. ONLINE 82 (2018).

H. H.R. 2853, BRINGING LOW-COST OPTIONS AND COMPETITION WHILE KEEPING INCENTIVES FOR NEW GENERICS (BLOCKING) ACT OF 2021

H.R. 2853, the “Bringing Low-cost Options and Competition while Keeping Incentives for New Generics Act of 2021”, or the “BLOCKING Act of 2021”, introduced by Rep. Schrader, would discourage first generic applicants from holding onto 180-day exclusivity while blocking subsequent competition. According to FDA, approximately five times per year, generic competition is delayed because a first generic applicant delays market entry of its product while holding onto its generic exclusivity.³⁴ H.R. 2853 allows FDA to approve a subsequent generic application where a first generic applicant has certified that a brand drug’s patent is invalid or will not be infringed, and all of the following four conditions are met: (1) the subsequent generic application is ready for full approval; (2) a minimum of 30 months has passed since at least one first applicant submitted their application for the drug; (3) at least one first applicant is not precluded from being approved due to patent litigation; and (4) no first applicant has received final approval.

III. WITNESSES

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³⁴ Food and Drug Administration, *Measuring the Cost of Delayed ANDA Approvals* (2019).