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Before the

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Committee on Energy & Commerce
Health Subcommittee

Negotiating a Better Deal: Legislation to Lower the Cost of Prescription Drugs

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Chairwoman Eshoo, Ranking Member Guthrie, and other distinguished members of the Health Subcommittee of the House Committee on Energy & Commerce, my name is Rachel Sachs and I am an Associate Professor of Law at Washington University in St. Louis, where my research focuses on innovation into new healthcare technologies, primarily pharmaceuticals, and access to those same technologies. I also serve as a Faculty Scholar with the University's Institute for Public Health and a Faculty Fellow with the University's Cordell Institute for Policy in Medicine and Law. Thank you for the opportunity to testify before you today about the high prices of prescription drugs and how this Committee might take steps toward solving these problems. The opinions I offer today are my own.

In this testimony, I will explain why comprehensive prescription drug pricing reform should include three particular types of policy solutions — and why drug pricing reforms that only include some of these policies may even exacerbate the problems of our current system. First, comprehensive prescription drug pricing reform should seek to lower patients' out-of-pocket costs. Second, reform should strive to fix the misaligned incentives in our existing pharmaceutical pricing and payment system. Third, reform should aim to address the underlying problem of the high prices of prescription drugs. There is no single way to accomplish each of these three goals, and different countries have chosen different answers to each of them. But H.R. 3, the Elijah E. Cummings Lower Drug Costs Now Act, works to pull all three of these policy levers to lower drug prices. Other Congressional proposals do not.

I. THE HIGH PRICE OF PRESCRIPTION DRUGS

Prescription drug prices and spending in the United States are high, and they are often rising. Between 2018 and 2019, pharmaceutical companies raised the list prices of half of all covered drugs in Medicare Part D at a rate that exceeded inflation, including the list prices of 22 of the top 25 drugs by total Part D spending.¹ To be sure, the pharmaceutical industry commonly pushes back on criticisms of price hikes like these by noting that *list* prices are not representative of the *net* prices that insurers will negotiate for these products, although those net prices remain largely confidential. But net spending for public payers is also rising. Between 2007 and 2017, the federal government's Medicare Part D spending rose from \$46.2 billion to \$79.9 billion, increasing an average of 5.6% per year.² Medicare Part B prescription drug spending is rising even more quickly, increasing from \$15.4 billion in 2009 to \$35.0 billion in 2018, with a 9% increase from 2017 to 2018 alone.³

These dynamics have created challenges for patients, as well as payers. Nearly one in four (24%) people report difficulty affording their prescription medications, and 29% report not taking their

¹ Juliette Cubanski & Tricia Neuman, *Price Increases Continue to Outpace Inflation for Many Medicare Part D Drugs*, KAISER FAMILY FOUND. (Feb. 4, 2021), <https://www.kff.org/medicare/issue-brief/price-increases-continue-to-outpace-inflation-for-many-medicare-part-d-drugs/>.

² MEDICARE PAYMENT ADVISORY COMM'N (hereinafter MEDPAC), REPORT TO THE CONGRESS: MEDICARE PAYMENT POLICY 409 (March 2019), http://www.medpac.gov/docs/default-source/reports/mar19_medpac_entirereport_sec.pdf.

³ MEDPAC, A DATA BOOK: HEALTH CARE SPENDING AND THE MEDICARE PROGRAM 139 (July 2020), http://medpac.gov/docs/default-source/data-book/july2020_databook_entirereport_sec.pdf?sfvrsn=0.

medication as prescribed because of the cost.⁴ Importantly, these dynamics are not limited to the under-65 population, where many Americans have more precarious access to health insurance: 23% of seniors still report that it is difficult to afford their prescription medications.⁵ Patients may respond by delaying filling their prescriptions, cutting their pills in half, or skipping doses.⁶ Patients have died in the face of these impossible choices.⁷ A large bipartisan majority of Americans — 79% — believes that prescription drug costs are “unreasonable.”⁸

The United States is an outlier when it comes to our drug prices, as compared to other countries. A recent Committee on Ways and Means report found that United States drug prices are far higher than those in other countries, even after accounting for confidential rebates.⁹ As one example, the Committee report notes that the average net price in the United States of Humira, the best-selling prescription drug in the world, is \$2,346.02 per dose — compared to \$787.10 in Denmark, the next highest price. The combined mean price for Humira in 11 other countries was just \$450.60, far lower than the American price.¹⁰

II. LEGAL DRIVERS OF THIS PROBLEM

Our existing legal system for 1) providing exclusive rights to pharmaceutical manufacturers and 2) guaranteeing insurance reimbursement for those products underlies manufacturers’ ability to set and maintain these high prices. The United States Patent & Trademark Office grants exclusive rights to companies for their new, nonobvious, and useful innovations. Pharmaceutical companies whose products receive Food & Drug Administration (FDA) approval typically have effective patent lives for their products that are approximately 12 years,¹¹ or 14-15 years for first-in-class drugs.¹² Approved drugs are also legally entitled to an exclusivity period overseen by the FDA. Depending on the type of drug, companies may receive either five years (for small-molecule drugs without a Paragraph IV filing), seven years (under the Orphan Drug Act), or twelve years (for biologic drugs) of exclusivity for their product.¹³ These exclusivity periods run in parallel with an

⁴ Ashley Kirzinger et al., *Kaiser Health Tracking Poll – February 2019: Prescription Drugs*, KAISER FAMILY FOUND. (March 1, 2019), <https://www.kff.org/health-reform/poll-finding/kff-health-tracking-poll-february-2019-prescription-drugs/>.

⁵ *Id.*

⁶ *Id.*

⁷ Bram Sable-Smith, *Insulin’s High Cost Leads to Lethal Rationing*, NPR (Sept. 1, 2018), <https://www.npr.org/sections/health-shots/2018/09/01/641615877/insulins-high-cost-leads-to-lethal-rationing>.

⁸ Kirzinger et al., *supra* note 4.

⁹ U.S. HOUSE OF REPRESENTATIVES COMM. ON WAYS & MEANS, *A PAINFUL PILL TO SWALLOW: U.S. VS. INTERNATIONAL PRESCRIPTION DRUG PRICES 4* (Sept. 2019), https://waysandmeans.house.gov/sites/democrats.waysandmeans.house.gov/files/documents/U.S.%20vs.%20International%20Prescription%20Drug%20Prices_0.pdf.

¹⁰ *Id.* at 18.

¹¹ C. Scott Hemphill & Bhaven N. Sampat, *Evergreening, Patent Challenges, and Effective Market Life in Pharmaceuticals*, 31 J. HEALTH ECON. 327, 336 (2012).

¹² Bo Wang et al., *Variations in Time of Market Exclusivity Among Top-Selling Prescription Drugs in the United States*, 175 JAMA INTERNAL MED. 635, 636 (2015).

¹³ 21 U.S.C. § 355(j)(5)(F)(ii) (2012) (Hatch-Waxman Act, conferring five years of data exclusivity for small-molecule drugs); 21 U.S.C. § 360cc(a) (2012) (Orphan Drug Act, conferring seven years of market exclusivity for Orphan Drugs); 42 U.S.C. § 262(k)(7)(A) (2012) (Biologics Price Competition and Innovation Act, conferring twelve years of data exclusivity for biologics). These exclusivity periods do differ formally in terms of the type of exclusivity conferred and how that exclusivity functions. Hatch-Waxman exclusivity runs from the approval of the innovator

approved drug’s patent life,¹⁴ and in some ways they offer even stronger protection against competitors than do patents. Patents typically require their holders to invest resources in enforcing them against potential competitors, while FDA exclusivity periods are automatically enforced against other companies by the agency itself, as competitors need FDA approval before coming to market. FDA exclusivity periods are also not meaningfully subject to challenge and invalidation in the courts or administrative bodies, unlike patents.¹⁵

Embedded within these laws, including the Hatch-Waxman Act and Biologics Price Competition and Innovation Act, is a social bargain: the government will provide pharmaceutical companies with lengthy periods of market exclusivity, to enable them to recoup their research investments and plan for future innovation, after which the public expects generic or biosimilar competitors will be able to enter, driving down prices and improving patient access and affordability. But too often, pharmaceutical companies have violated this social bargain. Professor Michael Carrier’s work, for instance, has identified a broad range of anticompetitive practices engaged in by brand pharmaceutical companies.¹⁶ Through the use of “pay for delay” settlements or “product hopping,” the filing of frivolous citizen petitions, strategies to prevent generic companies from completing FDA-required bioequivalence testing either through FDA-required Risk Evaluation and Mitigation Strategy protocols or more generally, and manipulation of the rebate process, pharmaceutical companies have worked to extend their monopoly periods beyond what the drafters of these programs envisioned.¹⁷

A number of bills have been proposed that would address several of these practices,¹⁸ and Congress has recently passed others, including the Creating and Restoring Equal Access to Equivalent Samples (CREATES) Act.¹⁹ Although it is important for Congress to pass laws like these to restore the social bargain between monopoly pricing in the short term and generic competition in the long term, industry’s ability to invent new forms of extending their monopolies means that more action will be needed to assist both patients and payers.

At the same time that we have given the pharmaceutical industry lengthy exclusive rights over their products, we have limited our public payers’ ability to negotiate fair prices for those products.²⁰ Medicare Part B must cover all prescription drugs which are “reasonable and necessary

product until the *filing* of the generic application, 21 U.S.C. § 355(j)(5)(F)(ii), while the Biologics Act exclusivity runs from the approval of the innovator product until the *approval* of the follow-on biosimilar. 42 U.S.C. § 262(k)(7)(A); *see also id.* § 262(k)(7)(B) (noting that an application may not be filed for four years). But in practice, they often behave interchangeably.

¹⁴ Hemphill & Sampat, *supra* note 11, at 330.

¹⁵ Yaniv Heled, *Patents vs. Statutory Exclusivities in Biological Pharmaceuticals—Do We Really Need Both?*, 18 MICH. TELECOMM. & TECH. L. REV. 419, 431–32 (2012).

¹⁶ Michael A. Carrier, *High Prices & No Excuses: 6 Anticompetitive Games (Presentation Slides), Testimony for FTC Workshop on “Understanding Competition in Prescription Drug Markets”* (Nov. 8, 2017), <https://ssrn.com/abstract=3066514>.

¹⁷ *Id.*

¹⁸ *See, e.g.*, The Protecting Consumer Access to Generic Drugs Act of 2021, H.R. 153, 117th Cong. (2021); the Stop the Overuse of Petitions and Get Affordable Medicines to Enter Soon Act of 2021, H.R. 2843, 117th Cong. (2021).

¹⁹ U.S. Food & Drug Admin, *Access to Product Samples: The CREATES Act* (March 13, 2020), <https://www.fda.gov/drugs/guidance-compliance-regulatory-information/access-product-samples-creates-act>.

²⁰ Rachel E. Sachs, *Delinking Reimbursement*, 102 MINN. L. REV. 2307, 2308–09 (2018).

for the diagnosis or treatment of illness or injury,”²¹ and the Centers for Medicare and Medicaid Services (CMS) cannot decline to cover an effective FDA-approved drug simply because it is expensive.²² Medicare Part D plans must cover at least two FDA-approved drugs per therapeutic class,²³ and for six protected classes of drugs — anticonvulsants, antidepressants, antineoplastics, antipsychotics, antiretrovirals, and immunosuppressants — Part D must cover essentially all FDA-approved drugs.²⁴ Similarly, state Medicaid programs choosing to cover outpatient prescription drugs must provide reimbursement for all FDA-approved drugs with a few classes of exceptions, such as drugs used for cosmetic purposes.²⁵

To be clear, there are very important reasons why both our intellectual property laws and our system of reimbursement have been structured in the way that they have. The process of bringing a new drug to market is expensive,²⁶ lengthy,²⁷ and risky.²⁸ Particularly coupled with the low costs of imitation (especially for small-molecule generics),²⁹ it is not a surprise to see scholars,³⁰ policymakers³¹ and industry³² agreeing that strong patent rights are important to encourage pharmaceutical innovation. Medicare and Medicaid’s coverage requirements (particularly Part D’s protected class rules) also serve important purposes. CMS’ goal was to prevent discrimination against beneficiaries with these conditions, as might be expected for patients with high-cost preexisting conditions.³³

And yet, the combination of the two systems — exclusive rights plus guaranteed reimbursement — has driven our problem of high drug prices. If our public payers, when seated at the negotiating table, must accept the price a branded company with exclusive rights is demanding, it will be difficult for them to obtain fair prices on these products. Other countries often have similar intellectual property and regulatory exclusivity systems to our own, but they have used a variety of tools to strengthen the hands of their payers in the negotiating process in a way that can drive

²¹ 42 U.S.C. § 1395y(a)(1)(A) (2012).

²² 42 U.S.C. § 1395y(a)(1)(A) (2012).

²³ 42 C.F.R. § 423.120(b)(2)(i) (2012).

²⁴ 42 U.S.C. § 1395w-104(b)(3)(G)(iv) (2012).

²⁵ 42 U.S.C. § 1396r-8(k)(2), § 1396r-8(d)(2)(C) (2012).

²⁶ The cost of pharmaceutical development is a topic of intense debate, but most estimates put the cost at well over a billion dollars. *See, e.g.*, Joseph A. DiMasi et al., *Innovation in the Pharmaceutical Industry: New Estimates of R&D Costs*, 47 J. HEALTH ECON. 20, 20 (2016).

²⁷ C. Scott Hemphill, *Paying for Delay: Pharmaceutical Patent Settlement as a Regulatory Design Problem*, 81 N.Y.U. L. REV. 1553, 1564 (2006).

²⁸ Michael Hay et al., *Clinical Development Success Rates for Investigational Drugs*, 32 NATURE BIOTECHNOLOGY 40, 47 (2014).

²⁹ Henry Grabowski et al., *Does Generic Entry Always Increase Consumer Welfare?*, 67 FOOD & DRUG L.J. 373, 390 (2012).

³⁰ Dan L. Burk & Mark A. Lemley, *Policy Levers in Patent Law*, 89 VA. L. REV. 1575, 1617 (2003); *see also, e.g.*, Rebecca S. Eisenberg, *The Problem of New Uses*, 2 YALE J. HEALTH POL’Y L. & ETHICS 717, 720–21 (2005).

³¹ FED. TRADE COMM’N, *TO PROMOTE INNOVATION: THE PROPER BALANCE OF COMPETITION AND PATENT LAW AND POLICY* ch. 3, at 14 (2003).

³² *See, e.g.*, Stuart J.H. Graham et al., *High Technology Entrepreneurs and the Patent System: Results of the 2008 Berkeley Patent Survey*, 24 BERKELEY TECH. L.J. 1255, 1286 (2009); Wesley M. Cohen et al., *Protecting Their Intellectual Assets: Appropriability Conditions and Why U.S. Manufacturing Firms Patent (or Not)* 2, 12 (Nat’l Bureau of Econ. Research, Working Paper No. 7552, 2000), <http://www.nber.org/papers/w7552>.

³³ *See* CTRS. FOR MEDICARE & MEDICAID SERVS., DEP’T OF HEALTH & HUMAN SERVS., *MEDICARE PRESCRIPTION DRUG BENEFIT MANUAL* ch. 6, § 30.2.5 (2016), <https://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovContra/Downloads/Part-D-Benefits-Manual-Chapter-6.pdf>.

down prices, including (though not limited to) international reference pricing, reference pricing within a class of drugs, and pricing based on the clinical value of the product.

III. STRUCTURING EFFECTIVE POLICY SOLUTIONS

This Committee has the jurisdictional authority to reform our prescription drug approval and reimbursement systems to respond to the problem of high prescription drug prices. This Committee should also consider working with other Committees to identify solutions that might be based in areas outside of its jurisdiction, such as patent law. Comprehensive reform will be most effective at addressing these problems in the long term.

It is important for this Committee to make change in at least three areas: limiting patients' out-of-pocket costs, fixing misaligned incentives, and reducing overall pharmaceutical prices and spending. Many existing proposals have both costs and benefits, and combining reform proposals from each of these categories may help maximize these benefits and minimize these costs.

A. Limiting Patients' Out-of-Pocket Costs

Reforms that limit patients' out-of-pocket costs are necessary both to relieve the financial pressures facing many patients and to mitigate the negative health consequences of those financial pressures. As the CBO has concluded, increasing patients' adherence to their medications may improve their health outcomes and even create partially offsetting savings elsewhere in the healthcare system.³⁴ Yet today, there is no cap on Medicare Part D beneficiaries' out-of-pocket costs, and 1.1 million Part D beneficiaries have out-of-pocket spending above the existing catastrophic threshold.³⁵

H.R. 3 directly addresses this problem, for the first time imposing a cap on Part D out-of-pocket costs, to be set initially at \$2,000 per year.³⁶ This amount is far lower than the \$6,550 a Part D patient would spend out-of-pocket today before even reaching the catastrophic phase. H.R. 3 also follows on from important expert recommendations that such a cap be created, including from the Medicare Payment Advisory Commission (MedPAC).³⁷

This Committee might also consider additional policy reforms that would accomplish this goal. For instance, this Committee might consider building on the spirit of the Affordable Care Act's requirement that private insurance plans cover preventive interventions without cost-sharing. In that vein, the National Academies recommended Congress authorize CMS to limit patients' cost-sharing for particular classes of drugs, "when there is clear evidence that treatment adherence for a particular indication can reduce the total cost of care."³⁸

³⁴ CONG BUDGET OFFICE, OFFSETTING EFFECTS OF PRESCRIPTION DRUG USE ON MEDICARE'S SPENDING FOR MEDICAL SERVICES 4–6 (2012).

³⁵ MEDPAC, REPORT TO THE CONGRESS: MEDICARE AND THE HEALTH CARE DELIVERY SYSTEM 132 (June 2020), http://www.medpac.gov/docs/default-source/reports/jun20_reporttocongress_sec.pdf?sfvrsn=0 ("In 2018, 3.9 million, or 8.3 percent, of Part D enrollees reached Part D's OOP threshold. Among those individuals, 2.7 million (70 percent) received the LIS and 1.1 million did not.")

³⁶ Elijah E. Cummings Lower Drug Costs Now Act, H.R. 3, 117th Cong., § 301 (2021).

³⁷ MedPAC, *supra* note 35, at 132.

³⁸ NAT'L ACAD. SCI., ENG'G, MED., MAKING MEDICINES AFFORDABLE: A NATIONAL IMPERATIVE 129–30 (2017).

H.R. 3's Part D out-of-pocket cap and other proposals in this category would provide critical assistance for millions of Medicare beneficiaries who have difficulty affording their medications due to high out-of-pocket costs. They also allow Part D to more effectively serve its intended purpose — as an insurance program, it ought to pool risk among beneficiaries and safeguard enrollees against catastrophic expenses. However, these proposals do not directly address drug prices. As Professor Stacie Dusetzina and colleagues have noted, these proposals “merely shift costs between stakeholders. Moreover, capping out-of-pocket spending could reduce price sensitivity for patients and thus lessen public scrutiny of drug companies’ pricing strategies.”³⁹ MedPAC has noted that lowering patients’ out-of-pocket costs in isolation could be expected to increase overall premiums, though slightly, and increase Medicare spending, through its premium subsidy systems.⁴⁰ As a result, these reforms ought to be paired with reforms in the below categories, which would directly address prescription drug prices.

B. Fixing Misaligned Incentives

Our existing system for approving and paying for prescription drugs creates incentives for many different institutional stakeholders to drive drug prices and costs up, rather than down, over time. Fixing these misaligned incentives could help slow the increase of prescription drug prices and spending over time, and could also help promote competition in the market.

H.R. 3 includes two key elements that would help fix misaligned incentives in our current system. First, it takes aim at *prescription drug manufacturers* who raise their prices over time without new supporting evidence in an attempt to increase their revenues, by requiring manufacturers of drugs in both Medicare Part B and Part D who have raised the relevant prices of their drugs more rapidly than inflation to pay the above-inflation amount back to the government as a rebate.⁴¹ These rebates could be broadly applicable, as a recent Kaiser Family Foundation analysis found that half of all drugs covered by Part D had list price increases between 2018 and 2019 that outpaced inflation, including 22 of the top 25 drugs by total spending.⁴²

Importantly, inflation-based rebates are not a new concept: Medicaid has long required the manufacturers of brand-name drugs whose prices rise more quickly than inflation to pay similar rebates.⁴³ The U.S. Department of Health and Human Services Office of Inspector General has concluded that more than half of Medicaid rebates were attributable to these inflation-based rebates, and suggested that extending these rebates to Part D could help control costs in that program.⁴⁴

Second, H.R. 3's Medicare Part D benefit redesign (explained above) attempts to address the role of both *manufacturers* and *Part D plans* in increasing spending over time. Currently, once Part D beneficiaries enter the catastrophic phase of their benefits, the beneficiary is responsible for 5% of

³⁹ Stacie B. Dusetzina, Nancy L. Keating, & Haiden A. Huskamp, *Proposals to Redesign Medicare Part D – Easing the Burden of Rising Drug Prices*, 381 N. ENG. J. MED. 1401, 1403 (2019).

⁴⁰ MedPAC, *supra* note 35, at 133.

⁴¹ Elijah E. Cummings Lower Drug Costs Now Act, H.R. 3, 117th Cong., §§ 201, 202 (2021).

⁴² Cubanski & Neuman, *supra* note 1.

⁴³ 42 U.S.C. § 1396r-8(c)(2)(A).

⁴⁴ DEP'T OF HEALTH & HUMAN SERVS., OFFICE OF INSPECTOR GEN., OEI-03-13-00650, MEDICAID REBATES FOR BRAND-NAME DRUGS EXCEEDED PART D REBATES BY A SUBSTANTIAL MARGIN 8–9 (2015).

costs, without limit. Manufacturers have no responsibility in the catastrophic phase, even though a single prescription of a costly drug can launch a beneficiary directly into that phase. Plans are responsible for 15% of the costs, down from 75% in the initial coverage phase (though up from 5% in the coverage gap phase), and Medicare itself is responsible for 80% of the costs.⁴⁵

Under H.R. 3's redesign, Medicare would be responsible for just 20% of the costs in the catastrophic phase, with both manufacturers and plans assuming greater responsibility than currently (30% and 50%, respectively).⁴⁶ As MedPAC notes, some analysts argue that creating a manufacturer discount in the catastrophic phase "could make the prospect of raising prices less attractive for manufacturers."⁴⁷ Similarly, increasing plan responsibility is expected to "give plan sponsors stronger incentives to manage benefits, which could improve their formulary design decisions."⁴⁸

Although H.R. 3's proposals do address important misaligned incentives in our current system, there are many other examples of such incentives this Committee should consider addressing. To give just one example, this Committee might examine the business practices of pharmacy benefit managers (PBMs), aiming to remove existing incentives for PBMs to award preferred formulary placements to drugs with high list prices and large rebates, relative to drugs with lower net prices but smaller list-to-net spreads. Several Part D plans offer more favorable formulary placements to branded drugs than they do to lower-priced generics, which may not only harm patients (whose out-of-pocket costs are typically based on the list price), but also overall spending.⁴⁹

Although H.R. 3's attempts to address misaligned incentives are likely to be impactful, they have tradeoffs as well. For instance, there is some concern that extending inflationary rebates into the Medicare program might encourage companies to set even higher prices than they otherwise would.⁵⁰ These strategies would not fundamentally address the underlying high prices of these drugs and the government's lack of negotiating leverage.

C. Addressing Overall Pharmaceutical Prices

Reforms like the above are unlikely to assist Medicare in obtaining lower prices on many products, particularly specialty drugs with little or no competition. It will be important for this Committee to consider reforms that would strengthen Medicare's negotiating authority and increase the likelihood that our public payers can obtain fair prices for these products.

⁴⁵ Juliette Cubanski & Tricia Neuman, *How Will the Medicare Part D Benefit Change Under Current Law and Leading Proposals?*, KAISER FAMILY FOUND. (Oct. 11, 2019), <https://www.kff.org/medicare/issue-brief/how-will-the-medicare-part-d-benefit-change-under-current-law-and-leading-proposals/>.

⁴⁶ Elijah E. Cummings Lower Drug Costs Now Act, H.R. 3, 117th Cong., § 301 (2021).

⁴⁷ MedPAC, *supra* note 35, at 134.

⁴⁸ *Id.* at 135; *see also* Dusetzina, Keating, & Huskamp, *supra* note 39, at 1403.

⁴⁹ Testimony of Dr. Gerard Anderson before United States House of Representatives Committee on Oversight and Government Reform 12 (Jan. 29, 2019), <https://docs.house.gov/meetings/GO/GO00/20190129/108817/HHRG-116-GO00-Wstate-AndersonG-20190129.pdf>.

⁵⁰ CONG. BUDGET OFFICE, A COMPARISON OF BRAND-NAME DRUG PRICES AMONG SELECTED FEDERAL PROGRAMS 14 (Feb. 2021), <https://www.cbo.gov/publication/57007>.

H.R. 3 aims to address this issue by providing the Secretary of Health and Human Services (HHS) the authority to negotiate with the manufacturers of select high-priced, single-sourced drugs, aiming to target limited resources at the drugs where there is likely to be the most important need. To facilitate this negotiation, H.R. 3 uses international reference pricing, creating an average international market price across six countries (Australia, Canada, France, Germany, Japan, and the United Kingdom) as the target fair price in negotiations.⁵¹ H.R. 3 also includes an enforcement mechanism: if a manufacturer will not agree to a fair price on these terms, H.R. 3 assesses a significant non-compliance tax.⁵²

Given the large scale of the Medicare program and the novelty of these negotiations in the United States context, it may be difficult for the Secretary to negotiate for each drug in the program individually. H.R. 3 envisions that the Secretary will begin in the first year of the program by negotiating for the price of “at least 25” such single-sourced drugs, negotiating for “at least 50” drugs in subsequent years.⁵³ H.R. 3 intends for the Secretary to draw these drugs from particular categories, including the 125 highest-spend drugs in Part D, 125 highest-spend drugs in the United States more generally (not focusing specifically on Part D), and insulin.⁵⁴ Targeting even a small number of products is likely to yield substantial savings, as a recent Kaiser Family Foundation analysis showed that relatively few drugs are responsible for a large percentage of Medicare drug spending. Specifically, the 50 top-selling Part B drugs account for 80% of Part B spending, and the 10 top-selling Part D drugs account for 16% of net Part D spending.⁵⁵

There are many different ways of constructing an effective drug price negotiation system, and H.R. 3 offers just one potential example. Several of the countries included in H.R. 3’s market basket provide examples of this or other approaches, as well. Canada employs a system based on external, international reference pricing similar to H.R. 3’s approach.⁵⁶ Germany’s model uses *internal* reference pricing, in which they compare and assess the price of new drugs relative to existing treatments for the same condition. In the event a negotiated price cannot be reached, the government and pharmaceutical manufacturer submit to an arbitration process, in which neutral arbiters assess the parties’ positions and reach a decision.⁵⁷ The United Kingdom’s model gives primacy to a health technology assessment conducted by the National Institute for Health and Care Excellence, which then makes recommendations about a drug’s clinical and cost effectiveness to the National Health Service.⁵⁸

⁵¹ Elijah E. Cummings Lower Drug Costs Now Act, H.R. 3, 117th Cong., § 101 (2021).

⁵² *Id.* at § 102.

⁵³ *Id.* at § 101.

⁵⁴ *Id.*

⁵⁵ Juliette Cubanski & Tricia Neuman, *Relatively Few Drugs Account for a Large Share of Medicare Prescription Drug Spending*, KAISER FAMILY FOUND. (April 19, 2021), <https://www.kff.org/medicare/issue-brief/relatively-few-drugs-account-for-a-large-share-of-medicare-prescription-drug-spending/>.

⁵⁶ Joel Lexchin, *Drug Prices: How Do We Get to a Better Place?*, 189 CANADIAN MED. ASS’N J. E792 (2017).

⁵⁷ James C. Robinson, Dimitra Panteli, & Patricia Ex, *Reference Pricing in Germany: Implications for U.S. Pharmaceutical Purchasing*, COMMONWEALTH FOUNDATION (Feb. 4, 2019), <https://www.commonwealthfund.org/publications/issue-briefs/2019/jan/reference-pricing-germany-implications>.

⁵⁸ NAT’L INST. FOR HEALTH & CARE EXCELLENCE, *GUIDE TO THE PROCESS OF TECHNOLOGY APPRAISAL 6* (2018), <https://www.nice.org.uk/process/pmg19/resources/guide-to-the-processes-of-technology-appraisal-pdf-72286663351237>.

CBO estimated that the negotiation provisions of H.R. 3 would lower government spending by approximately \$456 billion over a decade, much more than the reforms in either of the above categories.⁵⁹ Drug price negotiation reforms are likely to have the largest potential impact on lowering spending system-wide, helping to preserve or even expand these programs in the future.

IV. PRESERVING THE IMPORTANCE OF INNOVATION

Opponents of drug pricing reform have long argued that it would threaten future pharmaceutical innovation. As the argument goes, because the goal of these drug pricing reforms would be to pay less for existing medications, pharmaceutical firms will be unwilling or unable to maintain their existing levels of research investments in the future, and they may bring fewer drugs to market going forward. These arguments are certainly not unfounded, and CBO has estimated that H.R. 3 would result in 8 fewer drugs coming to market in the decade after its passage (compared to approximately 300 drugs CBO would otherwise expect them to approve).⁶⁰ H.R. 3 acknowledges these dynamics, which is why the bill seeks to direct a portion of its savings to the National Institutes of Health.⁶¹ But these arguments — which have been made by opponents without regard to the size of the pricing reform, without regard to when in a product’s life cycle it would take effect, and without regard for which products it would impact — cannot be permitted to bar any possible change within the system.

First, the *kind* of innovation, not only the *amount* of innovation, matters. Economists studying the creation of Medicare Part D found that it provided a large new subsidy for pharmaceutical firms, encouraging them to invest more in the development of products with particularly high market share among senior citizens.⁶² However, they also found that most of this impact was concentrated in disease classes with multiple existing treatments.⁶³ Allowing Part D to negotiate lower prices for its highest-cost medications might be expected to discourage the development primarily of me-too drugs, with more limited impact on first-in-class products.

Second, the *age* of the drugs at issue matters as well. As discussed above, the social bargain enshrined in law envisions providing pharmaceutical companies with market exclusivity, after which we expect generic or biosimilar competitors can enter, driving down prices. But this social bargain has often failed. As one specific example, Humira first launched in 2002, yet nearly twenty years later it remains one of the ten top-selling drugs in Medicare Part D, and it will not face competition in the United States until 2023⁶⁴ due to the extensive patent thicket (of over 100 patents) created by its manufacturer.⁶⁵ Over time, Humira’s manufacturer managed to increase its

⁵⁹ CONG. BUDGET OFFICE, BUDGETARY EFFECTS OF H.R. 3, THE ELIJAH E. CUMMINGS LOWER DRUG COSTS NOW ACT 2 (Dec. 10, 2019), https://www.cbo.gov/system/files/2019-12/hr3_complete.pdf.

⁶⁰ *Id.* at 6.

⁶¹ Elijah E. Cummings Lower Drug Costs Now Act, H.R. 3, 117th Cong., § 501 (2021).

⁶² Margaret E. Blume-Kohout & Neeraj Sood, *Market Size and Innovation: Effects of Medicare Part D on Pharmaceutical Research and Development*, 97 J. PUB. ECON. 327, 327 (2013).

⁶³ David Dranove et al., *Pharmaceutical Profits and the Social Value of Innovation* 2–3, 6–7 (Nat’l Bureau of Econ. Research, Working Paper No. 20212, 2014).

⁶⁴ Jason Mast, *Pfizer Gets Biosimilar Approved for Humira, Setting Up Competition – in 2023*, ENDPOINTS (Nov. 18, 2019), <https://endpts.com/pfizer-gets-biosimilar-approved-for-humira-setting-up-competition-in-2023/>

⁶⁵ I-MAK, HUMIRA: OVERPATENTED, OVERPRICED 3 (Oct. 2020), <https://www.i-mak.org/wp-content/uploads/2020/10/i-mak.humira.report.3.final-REVISED-2020-10-06.pdf>.

net price from \$19,000 in 2012 to over \$38,000 in 2018.⁶⁶ Comparatively, several biosimilar versions of Humira have been on the European market for many years now.⁶⁷

More generally, of the ten top-selling drugs in Medicare Part D, the most recent FDA approval is from 2015, outside the Hatch-Waxman Act's five-year exclusivity period, and six of the ten drugs were approved in 2011 or earlier (including Humira). Of the ten top-selling drugs in Medicare Part B, the most recent FDA approvals are from 2014, but eight of the ten drugs were approved in 2011 or earlier — including two drugs approved more than twenty years ago.⁶⁸ Opponents of H.R. 3 ought to explain how empowering HHS to negotiate the price of decades-old drugs today — which have had lengthy periods to recoup their manufacturers' investments — would harm innovation in the future.

Third, arguments from industry usually imply that cuts to drug prices will translate directly into cuts to research and development spending, without considering whether there are other opportunities to obtain savings. This is not the case, as HHS Secretary Alex Azar — himself a former pharmaceutical company executive — asserted when the pharmaceutical industry claimed that the Trump Administration's own plan to engage in international reference pricing in Medicare Part B would result in lower innovation.⁶⁹ In addition to the large sums companies often spend on advertising, a recent analysis found that the top 18 pharmaceutical companies in the S&P 500 Index spent \$335 billion repurchasing their own shares from 2009 to 2018, more than their R&D expenditures over that period.⁷⁰

More generally, these arguments from opponents of drug pricing negotiation tend to ignore the baseline discussion. The passage of Medicare Part D in 2003 was framed around providing seniors with insurance to pay for treatments that they previously were unable to access.⁷¹ The goal of the law was not to provide a large, new innovation subsidy to the pharmaceutical industry, though it did have that effect. In other words, there is no reason to think that our current level of innovation — driven partially by current price levels — was chosen purposefully, or represents an optimal innovation strategy. Especially if some of the savings from H.R. 3 would be used to expand insurance coverage or offerings elsewhere, the pharmaceutical industry might gain many new customers, and recoup partially in volume what they make up for on price — but those individual prices would represent better deals for the American people.

⁶⁶ Danny Hakim, *Humira's Best-Selling Drug Formula: Start at a High Price. Go Higher.*, N.Y. TIMES (Jan. 6, 2018), <https://www.nytimes.com/2018/01/06/business/humira-drug-prices.html>.

⁶⁷ Arlene Weintraub, *Humira Biosimilars Catch Fire in Europe and Could Take Half the Market in a Year: Report*, FIERCEPHARMA (Jan. 25, 2019), <https://www.fiercepharma.com/pharma/humira-biosimilars-catch-fire-europe-and-could-take-half-market-a-year-report>.

⁶⁸ Cubanski & Neuman, *supra* note 55.

⁶⁹ Secretary Alex Azar, *Remarks on Medicare Drug Pricing Proposals* (Oct. 26, 2018), https://www.brookings.edu/wp-content/uploads/2018/10/es_20181026_hhs_medicare_transcript.pdf.

⁷⁰ Travis Whitfill, *To Create Value, Pharma Companies Should Prioritize Innovation, Not Shareholders*, STAT (April 23, 2021), <https://www.statnews.com/2021/04/23/create-value-shareholders-pharma-companies-prioritize-innovation/>.

⁷¹ Jonathan Oberlander, *Through the Looking Glass: The Politics of the Medicare Prescription Drug, Improvement, and Modernization Act*, 32 J. HEALTH POL'Y, POLITICS & L. 187 (2007).

V. CONCLUSION

This Committee has the ability to help solve the problem of high drug prices, not only for patients, but also for our public payers. In considering comprehensive prescription drug pricing reform, this Committee should consider reforms that help lower patients' high out-of-pocket costs, fix misaligned incentives in the system as it exists today, and reduce pharmaceutical prices through negotiation tools. Chairwoman Eshoo, Ranking Member Guthrie, and Members of the Committee, I am appreciative of your focus on this important issue and I thank you for the opportunity to testify before you today. I look forward to answering your questions.