Statement for the Record
American College of Physicians
Hearing before the House Energy and Commerce Subcommittee on Health
"Negotiating a Better Deal: Legislation to Lower the Cost of Prescription Drugs."
May 4, 2021

The American College of Physicians (ACP) is pleased to submit this statement and appreciates that Chairman Pallone and Chairwoman Eshoo are holding this hearing to examine legislation designed to lower the escalating cost of prescription drugs. We hope that this important discussion will provide a platform to act on bipartisan solutions that will provide greater access to necessary and often life-saving prescription drugs and treatments for patients at an affordable cost. We are pleased to offer our perspective on specific provisions of legislation under consideration today where we have established policy.

The American College of Physicians is the largest medical specialty organization and the second-largest physician membership society in the United States. ACP members include 163,000 internal medicine physicians (internists), related subspecialists, and medical students. Internal medicine physicians are specialists who apply scientific knowledge and clinical expertise to the diagnosis, treatment, and compassionate care of adults across the spectrum from health to complex illness. Internal medicine specialists treat many of the patients at greatest risk from COVID-19, including the elderly and patients with pre-existing conditions like diabetes, heart disease and asthma.

THE HIGH COST OF PRESCRIPTION DRUGS

For many years, ACP has continued to express concern over the rising cost of prescription drugs, particularly for patients as they struggle to afford basic and life-saving medications prescribed by their physicians to treat diseases and chronic conditions. Studies show that millions of Americans face the difficult choice of filling their prescriptions or paying for necessities such as food or housing. Patients may resort to cutting back or skipping doses of their medicines to save money, which can lead to more serious health complications.

Now, with the ongoing COVID-19 pandemic, patients are even more concerned about whether they can afford their medications and even whether they will have health coverage in general should they unexpectedly lose their job because of the pandemic. In a May 2020 study by Gallup, "nearly nine in 10 U.S. adults are very (55 percent) or somewhat (33 percent) concerned that the pharmaceutical industry will leverage the COVID-19 pandemic to raise drug prices. Americans are also concerned -- to a somewhat lesser extent -- about rising health insurance premiums and the cost of care generally. Overall, 79 percent are very or somewhat

concerned about their health insurance premiums rising and 84 percent are very or somewhat concerned about the cost of care generally rising, with 41 percent very concerned about each."

As outlined in ACP's 2019 position paper, *Policy Recommendations for Public Health Plans to Stem the Escalating Costs of Prescription Drugs*, the United States spends more on prescription drugs than other high-income countries, with average annual spending of $1443 per capita on pharmaceutical drugs and $1026 per capita on retail prescription drugs. In a 2021 study by the Rand Corporation, it was further affirmed that prices in the United States were 256 percent higher, on average, than in 32 other countries with comparable economies and when only comparing brand-name drugs, prices in the United States were 344 percent higher. In a 2020 study by the Medicare Payment Advisory Commission (MedPAC), it 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.

ACP released a position paper entitled, *Stemming the Escalating Costs of Prescription Drugs*, which provides an assessment of the causes of rising prescription drug prices and provides recommendations on policies that would lower prices. We remain concerned that drug prices have continued to rise, sometimes astronomically, and unless Congress takes action to address this issue, we fear for the health and financial future of our patients.

THE ELIJAH E. CUMMINGS LOWER DRUG COSTS NOW ACT (H.R. 3)

Title I – Lowering Prices through Fair Drug Price Negotiation: This title would mandate that the Secretary of Health and Human Services (HHS) identify 250 brand name drugs that lack competition in the marketplace and that account for the greatest cost to Medicare and the U.S. health system and then negotiate directly with drug manufacturers to establish a maximum fair price for a bare minimum of 25 of those drugs. The legislation establishes an upper limit for the price reached in any negotiation to no more than 1.2 times the volume-weighted average of the price of six countries (Australia, Canada, France, Germany, Japan, and the United Kingdom), known as the Average International Market (AIM) price. An eligible drug that lacks price competition is defined as a brand-name drug that does not have a generic or biosimilar competitor on the market. Insulin would also be included on the list for negotiation with Medicare.

ACP has longstanding policy supporting the ability of Medicare to leverage its purchasing power and directly negotiate with manufacturers for drug prices, although we have no policy on applying that same negotiating power to the commercial market and group/individual health insurance plans. ACP also supports the repeal of the current law, known as the non-interference clause, which strictly prohibits HHS from interfering with negotiations between drug manufacturers and pharmacies and prescription drug plan sponsors. Absent repeal of the noninterference clause, we believe it should be modified to allow for this type of negotiation by the government for high-cost drugs in which Medicare has substantial financial interest as is included in Title I of this legislation.

Title II - Prescription Drug Inflation Rebates: Among other things, this title includes additional restrictions on the ability of drug manufacturers to raise Part B/D drug prices above the rate of inflation since 2016. Under H.R. 3, manufacturers would be permitted to either lower the price or be required to pay the entire price above inflation in a rebate back to the Treasury.

While ACP does not have specific policy regarding prescription drug inflation rebates, we remain alarmed by the egregious practices of some manufacturers that dramatically raise the price of their products, not only for new medications but for ones that have been in circulation for decades, to levels that are simply unaffordable to patients.

A report by the Senate's Homeland Security and Governmental Affairs Committee found that "the prices of many of the most popular brand-name drugs increased at nearly ten times the cost of inflation from 2012 to 2017. On average, prices for these drugs increased 12 percent every year for the last five years—approximately ten times higher than the average annual rate of inflation."

Title III – Part D Improvement and Maximum Out-of-Pocket Cap for Medicare Beneficiaries: This title would establish an annual out-of-pocket limit of $2,000 for Medicare beneficiaries enrolled in the Part D program. It would also realign incentives to require health plans to pay more of the costs when seniors reach the catastrophic phase of coverage and reduces government reinsurance subsidies.

ACP supports this policy as we believe that policymakers should implement caps on out-of-pocket expenses for prescription drugs in the catastrophic phase of coverage. Medicare beneficiaries can and do face substantial out-of-pocket costs for prescription drugs, especially when they take costly specialty medications and reach the catastrophic coverage phase. ACP policy calls for the federal government to fund programs to assist low-income Medicare beneficiaries in paying their Part D costs, such as the low-income subsidy, which should be provided and adjusted as needed. The federal government should improve its efforts to alert qualified beneficiaries of their eligibility to receive financial assistance related to Part D cost-sharing.

In a December 2020 study by the KFF, "over one million Part D enrollees had out-of-pocket spending in the catastrophic phase in 2017, with average annual out-of-pocket costs exceeding $3,200 – over six times the average for all enrollees who did not receive Part D Low-Income Subsidies that year. Part D enrollees without low-income subsidies who had high out-of-pocket drug costs in 2017 would have saved approximately $1,400 per person, on average (or $1.4 billion in the aggregate) if Part D had a hard cap on out-of-pocket spending that year, rather than requiring enrollees to pay up to 5 percent coinsurance in the catastrophic phase, assuming no other changes to the benefit design."

Title IV – Drug Pricing Transparency: This title establishes mandatory reporting requirements applicable to manufacturers if they increase the price of a prescription 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. If this reporting requirement is triggered, the manufacturer must then 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. Failure to do so would result in penalties.

ACP policy supports transparency in the pricing, cost, and comparative value of all pharmaceutical products. Pharmaceutical companies should disclose actual material and production costs to regulators, research and development costs contributing to a drug's pricing, including those drugs which were previously licensed by another company. Rigorous price transparency standards should be instituted for drugs developed from taxpayer-funded basic research.

PROTECTING CONSUMER ACCESS TO GENERIC DRUGS ACT OF 2021 (H.R. 153)

This legislation would prohibit brand name drug manufacturers from compensating generic drug manufacturers to delay the entry of a generic drug into the market (pay-for-delay) and would prohibit biological product manufacturers from compensating biosimilar and interchangeable product manufacturers to delay entry of biosimilar and interchangeable products. Penalties for violations of the bill include civil penalties and loss of the 180-day exclusivity period for a generic drug. The Federal Trade Commission (FTC) shall have exclusive authority to litigate to enforce the bill.

ACP policy supports robust oversight and enforcement of restrictions on product-hopping, evergreening, and pay-for-delay practices as a way to increase marketability and availability of competitor products. We support reducing the period of data and market exclusivity for biologic drugs from 12 years to 7 years and support removing additional barriers to biosimilar market entry, such as modifications to the current patent system that would reduce excessive patenting on brand-name and biologic drugs. ACP opposes anticompetitive pay-for-delay arrangements that curtail access to lower-cost alternative drugs.

CONCLUSION

We appreciate this opportunity to offer our input on legislative proposals before this committee on ways to address the high cost of prescription drugs. We hope that the outcome of this legislative hearing will result in bipartisan solutions to this crisis and in the interest of what is best for patients. Should you have any additional questions, please contact Jonni McCrann at jmccrann@acponline.org.