July 2, 2021

The Honorable Ron Wyden
Chairman Senate Finance Committee
United State Senate
Washington, DC 20510

Dear Chairman Wyden:

On behalf of the American College of Physicians (ACP), I am writing to commend you for releasing your paper, Principles for Drug Pricing Reform, which provides recommendations for lawmakers to consider when drafting legislation to lower the cost of prescription drugs. We support many of these principles and urge you to continue to work with your colleagues on the Finance Committee to move forward with legislation that can be approved in the 117th Congress to improve access to life-saving treatments for patients who are unable to afford high out-of-pocket costs for their medicine. Our letter will provide you with our comments regarding each of the five principles that you have outlined to lower drug costs along with some additional policies that should be included in a final prescription drug pricing reform bill that should be considered by the Senate later this year.

ACP 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.

Although it has been difficult to reach a consensus on the best way to lower drug costs, our nation and patients can no longer afford to wait for Congress to act as the high cost of prescription drugs continues to strain the budget of federal and state governments and compels our patients to resort to cutting back or skipping doses of their medicines to save money, which can lead to more serious health complications. 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 any other high-income country, with average annual spending of $1,443 per capita on pharmaceutical drugs

and $1,026 per capita on retail prescription drugs. In a 2021 study by the Rand Corporation, prescription drug prices in the U.S. average 2.56 times those seen in 32 other Organization for Economic Cooperation and Development (OCED) nations. Global spending on prescription drugs in 2020 was expected to be $1.3 trillion, with the U.S. spending approximately $350 billion.

ACP also released a position paper that provides Policy Recommendations for Public Health Plans to Stem the Escalating Cost of Prescription Drugs. The paper examines the increasing price of prescription drugs in Medicare and Medicaid particularly for patients with chronic health conditions who are using multiple medications and patients in these programs taking high-priced brand-name specialty drugs. Shifts in benefit design, including higher deductibles and a movement away from copayments to coinsurance, have increased patient out-of-pocket costs and put pressure on program budgets. ACP provides the following recommendations to reverse this trend including:

- ACP supports modification to the Medicare Part D low-income subsidy (LIS) program cost-sharing and copayment structures to encourage the use of lower cost generic or biosimilar drugs, such as eliminating cost sharing for generic drugs for LIS enrollees.
- ACP supports annual out-of-pocket spending caps for Medicare Part D beneficiaries who reach the catastrophic phase of coverage.
- ACP supports the adoption of Medicare Part D negotiation models that would drive down the price of prescription drugs for beneficiaries. While ACP reaffirms its support for a full repeal of the noninterference clause, ACP also supports an interim approach, such as allowing the Secretary of Health and Human Services (HHS) to negotiate for a limited set of high-cost or sole-source drugs. ACP also supports a public Medicare Part D plan option that allows the Secretary of HHS to negotiate prices with drug makers. Any Medicare-operated public plan must meet the same requirements as private plans and be consistent with ACP's policy on formularies.
- ACP supports efforts to minimize the financial impact on the federal government of prescription drug misclassification in the Medicaid Drug Rebate Program (MDRP). The Centers for Medicare & Medicaid Services should identify which legal authorities are necessary to ensure compliance with the MDRP and Congress should pass legislation to grant such authorities.
- ACP supports further study of payment models in federal health care programs, including methods to align payment for prescription drugs administered in office in a way that would reduce incentives to prescribe higher-priced drugs when lower-cost and similarly effective drugs are available.

ACP Policies Regarding Sen. Wyden's Principles for Drug Pricing Reform

As you and your colleagues consider solutions to lower the cost of prescription drugs, we offer our comments concerning the principles that you outlined in your paper Principles for Drug Pricing Reform.

1. **Medicare must have the authority to negotiate with pharmaceutical companies, especially when competition and market practices are not keeping prices in check.**

   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 noninterference clause, which strictly prohibits HHS from interfering with negotiations between drug manufacturers and pharmacies and prescription drug plan sponsors.

   While ACP reaffirms its support for a full repeal of the noninterference clause, ACP also supports an interim approach, such as allowing the Secretary of Health and Human Services (HHS) to negotiate for a limited set of high-cost or sole-source drugs.

2. **American consumers must pay less at the pharmacy counter. The Medicare Part D benefit structure leaves millions of patients exposed to extreme out-of-pocket spending, while failing to create the proper incentives to direct patients towards drugs that cost less. The legislation will include and build upon existing bipartisan proposals to restructure the Part D benefit in order to realign these incentives and reduce high patient out-of-pocket spending to affordable monthly limits.**

   ACP was pleased to support a provision in legislation that you and Senator Grassley introduced in the last Congress, the Prescription Drug Pricing Reduction Act of 2019, which would cap annual out-of-pocket spending for Medicare Part D beneficiaries who reach the catastrophic phase of coverage. In addition, ACP supports adoption of a cap on out-of-pocket drug costs to protect Medicare beneficiaries from excessive exposure to these costs, too often the case today. Although we are supportive of these policies, we urge the Committee to consider the full gamut of likely ramifications from such changes, particularly when programmatic changes of this magnitude are being put forward.

   One potential result, for example, is that such a cap on beneficiary out-of-pocket costs is substantially likely to be offset at least in part by higher premiums, unless accompanied by other measures that address the underlying reason for high out-of-pocket costs, like excessive pricing. Notable among these is the application of any cap brought about by Part D reforms should be on a quarterly as opposed to an annual basis. This will help beneficiaries better afford their medications at the time they have to pay out-of-pocket for them—rather than at the end of a full calendar year--which could be many months after they have incurred the expense. Limiting beneficiary out-of-pocket expenses on a quarterly basis will make it much less likely they will forgo needed medications because they can't afford them.

3. **Prices of drugs that increase faster than inflation will not be subsidized by patients and taxpayers. Americans are paying more than ever for the same drugs they've been using for years, because pharmaceutical companies have been allowed to raise prices at will while patients and taxpayers foot the bill. Requiring rebates on price hikes above inflation will rein in companies that gouge the millions of patients who take older drugs.**

   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 also 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."

   We also support additional measures to improve transparency in the price of prescription drugs so that drug manufacturers disclose additional information concerning the reasons why drug prices may rise beyond the rate of inflation. 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.

4. **Drug pricing reforms that keep prices and patient costs in check should extend beyond Medicare to all Americans, including those covered by employer and commercial health plans.**

   ACP supports this principle and urges the Senate Finance Committee to adopt policies to ensure that payers that use tiered or restrictive formularies do not impose patient cost-sharing for specialty drugs at a level that imposes a substantial economic barrier to enrollees obtaining needed medications, especially for enrollees with lower incomes. We are concerned that drug formularies divide prescription drugs into four or five tiers with varying levels of fixed prices (copayments) for all drugs in each tier, with the exception of the highest tier. The highest tier, typically the specialty tier, is subject to either the highest copayment or coinsurance in which the patient pays a percentage of the cost of the treatment. There has been a shift toward prescription drug plans with coinsurance in the top two tiers, typically the specialty tier and a non-preferred brand tier that has no restrictions on which drugs can be placed on the tier. This can lead to higher coinsurance rates than that of the specialty tier.[i]

5. **Drug pricing should reward scientific innovation, not gaming of the patent system.**

ACP 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 and we urge the Finance Committee to adopt policies that will prohibit drug companies from gaming the patent system through these practices.

Companies use product hopping or evergreening to prevent generic competition from entering the market by making small adjustments to a drug with no real therapeutic value that grant the company longer patent protection, or they remove the drug from market, forcing patients to switch to a reformulated version of the same drug.[ii] The two proposals would save the federal government an estimated $16 billion over 10 years, including in Medicare and Medicaid.[iii]

ACP opposes anticompetitive pay-for-delay arrangements that curtail access to lower-cost alternative drugs. ACP believes applicable federal agencies should be empowered through guidance, congressional action, or additional resource support to address anticompetitive behaviors and gaming. Pay-for-delay, also known as "reverse payment settlement," is a patent settlement strategy in which a patent holder pays a generic manufacturer to keep a potential generic drug off the market for a certain period. The number of pay-for-delay agreements increased from 3 in 2005 to 19 in 2009, after court decisions upheld the legality of such agreements, which prohibit generic drugs from entering the market on average nearly 17 months longer than agreements without compensation.[iv] In 2013, the Supreme Court ruled that although pay-for-delay agreements are not presumptively illegal, the FTC cannot be prevented from initiating legal action in regard to such agreements.[v]

Pharmaceutical companies also claim that long exclusivity periods are needed to support innovation and allow a return on their investment and promote future innovation. Marketing exclusivity is granted by the FDA upon approval, during which a competitor, typically a generic drug, is prohibited from being marketed. Data exclusivity prohibits a competitor company from using the data collected by an originator company to gain approval of their drug. In the case of biosimilars, the high cost of developing and conducting trials undermines the potential cost-savings to the manufacturer if they are required to collect new data. ACP opposes extending market or data exclusivity periods beyond the current exclusivities granted to small-molecule, generic, orphan, and biologic drugs and we support reducing the period of data and market exclusivity for biologic drugs from 12 years to 7 years. Reducing the exclusivity period from 12 to 7 years, combined with provisions to prevent product hopping or evergreening of biologic drugs, could get biosimilar or interchangeable drugs to market faster and save the federal government nearly $7 billion over 10 years.[vi] The Federal Trade Commission (FTC) also supports a reduction in biologic exclusivity, noting that 12 years is

unnecessary to promote innovation because biologic drug manufacturers are likely to earn substantial revenue even after the introduction of biosimilars.[vii]

Legislation that ACP Supports to Lower the Cost of Prescription Drugs

As you and your colleagues on the Senate Finance Committee work to draft drug pricing reform legislation in the weeks ahead, we urge you to include the following bills that have already been introduced in the 117th Congress that increase access to life saving medications at a cost that our patients can afford. ACP supports the following bills that would focus on implementing reforms to enable the federal government to negotiate drug prices and lower out-of-pocket costs for seniors, increase transparency in the pricing and costs associated with the development of drugs, and eliminate tax deductions pharmaceutical companies use to pay for drug advertising:

- **The Empowering Medicare Seniors to Negotiate Drug Prices Act of 2021 (S. 833), which would allow the Secretary of HHS to negotiate directly with drug companies for price discounts for the Medicare Prescription Drug Program, thus eliminating a restriction that bans Medicare from negotiating better prices.**

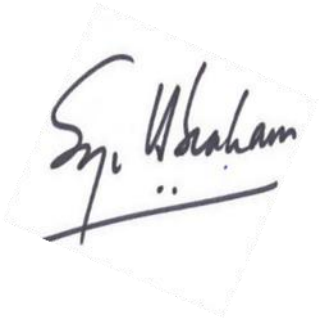
- **The FAIR Drug Pricing Act (S. 898), which would promote pricing transparency by requiring manufacturers to notify the Department of Health and Human Services (HHS) and provide a justification report 30 days before they increase the price of certain drugs.**

- **End Taxpayer Subsidies for Drug Ads Act (S. 141), which would prohibit a tax deduction for expenses for direct to-consumer advertising of prescription drugs, thus eliminating the deduction that pharmaceutical companies use to pay for drug advertising.**

Although it has been difficult to reach an agreement on the best way to lower the cost of prescription drugs, we believe that these principles that you have outlined provide a good start for the development of legislation on this issue that may be approved in both chambers of Congress.

We look forward to working with you in this effort and if you have any questions please do not hesitate to contact Brian Buckley, Senior Associate for Legislative Affairs on our staff at bbuckley@acponline.org.

Sincerely,



George M. Abraham, MD, MPH, FACP, FIDSA
President

---

[i] Pearson CF. Avalere analysis: Medicare beneficiaries will pay higher out of pocket costs as PDPs increase use of coinsurance in 2015. 13 November 2014. Accessed at avalere.com/expertise/life -sciences/insights/avalere-analysis-medicare-beneficiaries-will-pay -higher-out-of-pocket-costs/print on 8 May 2015.

[ii] Product hopping. The Pharma Marketing Glossary. Pharma Marketing Network. Accessed at www.glossary.pharma-mkting.com /producthopping.htm on 12 February 2016.

[iii] Office of Management and Budget. Fiscal Year 2016 Budget of the U.S. Government. Accessed at www.whitehouse.gov/sites /default/files/omb/budget/fy2016/assets/budget.pdf on 12 February 2016

[iv] Federal Trade Commission. Pay-for-delay: how drug company pay-offs cost consumers billions. January 2010. Accessed at www.ftc .gov/reports/pay-delay-how-drug-company-pay-offs-cost-consumers -billions-federal-trade-commission-staff on 14 March 2016.

[v] Federal Trade Commission v. Actavis, Inc. Accessed at www.scotusblog.com/case-files/cases/federal-trade-commission-v -watson-pharmaceuticals-inc/ on 14 March 2016.

[vi] Office of the White House. The Budget for Fiscal Year 2017: Summary Tables. Accessed at https://obamawhitehouse.archives .gov/sites/default/files/omb/budget/fy2017/assets/tables.pdf on 9 August 2017.

[vii] Federal Trade Commission. Emerging Health Care Issues: Follow-on Biologic Drug Competition. June 2009. Accessed at www .ftc.gov/sites/default/files/documents/reports/emerging-health-care -issues-follow-biologic-drug-competition-federal-trade-commission