Statement from American College of Physicians
Senate Finance Committee Hearing
Prescription Drug Price Inflation- An Urgent Need to Lower Drug Prices in Medicare
March 16, 2022

On behalf of the American College of Physicians (ACP), we are grateful for this opportunity to share our views with the Senate Finance Committee regarding its recent hearing on the rising cost of prescription drugs and the need to lower drug prices in Medicare. We appreciate that over the past several years the Finance Committee has conducted multiple hearings and developed polices on prescription drug reforms, but we urge the Congress to act now to approve legislation to lower drug costs that may be signed into law. 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. Our statement will provide this Committee with ACP's recommendations to increase access to prescription drugs in Medicare through policies that would: allow Medicare to negotiate drug prices; impose caps on out-of-pocket spending in Medicare Part D; increase competition in the prescription drug marketplace; eliminate tax deductions for direct-to-consumer drug advertising; and improve transparency regarding drug costs.

ACP is the largest medical specialty organization and the second largest physician membership society in the United States. ACP members include 161,000 internal medicine physicians (internists), related subspecialists, and medical students. Internal medicine physicians are specialists who apply scientific knowledge, clinical expertise, and compassion to the preventive, diagnostic, and therapeutic 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.

ACP remains committed to developing polices to lower the cost of prescription drugs and has published a series of papers that provide Congress with multiple options to address this issue. These papers include policy recommendations on the following topics:

- Stemming the Cost of Prescription Drugs through policies to Improve Transparency, Value, and Competition in the Marketplace
- Reducing the Cost of Prescription Drugs in Public Health Plans

- Recommendations for Pharmacy Benefit Managers to Stem the Escalating Cost of Prescription Drugs
- Improving Competition in the Prescription Drug Marketplace.

Because the topic of prescription drug pricing continues to be of interest to patients, physicians, and government officials, ACP believes policymakers should act immediately to address current issues in the Medicare and Medicaid programs that add costs to the health care system, may inadvertently incentivize higher prices for prescription drugs, and increase out-of-pocket costs for consumers.

Prescription Drug Costs Continue to Rise

The cost of prescription drugs continues to rise, which greatly affects access to life-saving treatments for patients who are unable to afford high out-of-pocket costs. Patients increasingly face higher co-pays, more drug tiers and prescription drug deductibles, adding to the burden they face in affording high-cost medications. Many Americans face the difficult choice of filling their prescriptions or paying for necessities such as food or housing.

According to a report published by the Congressional Budget Office (CBO) "nationwide spending on prescription drugs increased from $30 billion in 1980 to $335 billion in 2018. (All estimates of drug spending and prices in this report are expressed in 2018 dollars.") 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 $1,443 per capita on pharmaceutical drugs and $1,026 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.

Reports show that although use of prescription drugs in the United States is high, it is not an outlier compared with nine other high-income nations. The primary differences between health care expenditures in the United States versus other high-income nations are pricing of medical goods and services and the lack of direct price controls or negotiating power by centralized government health care systems.

Allow Medicare to Negotiate Drug Prices

We appreciate that during this hearing a significant portion of the debate was devoted to examining the impact of allowing Medicare to directly negotiate the price it pays for drugs in the Medicare Part D program. According to a Kaiser Family Foundation tracking poll, granting Medicare Part D the authority to negotiate drug prices is favored by a bipartisan majority of the public, with more than 90 percent of Democrats, Republicans, and Independents agreeing with this approach. Negotiating authority was also endorsed in a report by the National Academies of Sciences, Engineering, and Medicine on improving the affordability of prescription drugs as

part of a package of broader reforms for consolidating and leveraging purchasing power and strengthening formulary design.

ACP has longstanding policy supporting the ability of Medicare to leverage its purchasing power and directly negotiate with manufacturers for drug prices. We supported a provision in H.R. 3, the Elijah E. Cummings Lower Drug Costs Now Act, that 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. **In a 2019 estimate by the Congressional Budget Office, projections indicated that $456 billion in savings over 10 years would be realized by enacting the provision in H.R. 3 to allow Medicare to directly negotiate prescription drug prices with manufacturers.**

Last November, the House passed H.R. 5376, the Build Back Better Act (BBBA), that includes a provision to allow Medicare to directly negotiate the price of some drugs provided in Medicare Part D. We remain concerned that the House-passed BBBA does not include this more robust provision of price negotiation in H.R. 3. We believe that giving HHS the authority to negotiate drug prices with manufacturers is one of the most effective ways to lower the cost of prescription drugs and we urge lawmakers to include that provision of H.R. 3 or similar legislation in the final bill.

The House-passed BBBA allows HHS to negotiate the price of 10 of the most expensive drugs by 2025 and goes up to 20 drugs by 2028 on drugs that are beyond their period of exclusivity. The bill applies an excise tax on drug manufacturers for raising prices faster than the rate of inflation, reduces out-of-pocket expenses for customers and ensures patients pay no more than $35 a month for insulin products. **While ACP reaffirms its support for a full repeal of the noninterference clause, ACP is also supportive of an interim approach, such as allowing the Secretary of HHS to negotiate for a limited set of high-cost or sole-source drugs.**

Impose Caps on Out-of-Pocket Spending in Medicare Part D

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.

ACP was pleased to support a provision in legislation that Senators Wyden and 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, which is 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 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 cannot afford them.

Increase Competition in the Marketplace to Lower the Cost of Prescription Drugs

The prescription drug market in the United States relies on competition to keep prices reasonable. Although many policies have been implemented to spur competition and decrease costs for patients, these policies may be outdated and should be redesigned and updated to achieve success in the current prescription drug market.

Improve Competition in Medicare Part D Low Income Subsidy Program

ACP supports the Medicare Part D low-income subsidy program (LIS) that assists seniors with fewer resources in paying for their prescription drugs. We also support modifications to this program to encourage the use of lower-cost generic or biosimilar drugs by eliminating cost sharing for generic drugs for LIS enrollees. Twelve million Medicare Part D beneficiaries are enrolled in the LIS program. Although use of low-cost generic drugs by Part D beneficiaries is relatively high and continues to increase as more generics become available, the generic drug use rate is lower among LIS enrollees than among other Medicare beneficiaries.

Despite the current rate of generic drug dispensing among low-income subsidy (LIS) enrollees and non– LIS enrollees, additional savings are possible for Medicare and its beneficiaries. **The Centers for Medicare and Medicaid Services (CMS) estimates that Medicare could have saved nearly $9 billion if available equivalent generics were used instead of brand-name drugs and could have passed on $3 billion in savings to the Part D program and its beneficiaries.** Reducing or eliminating cost sharing for LIS enrollees would not require legislative action because it would not increase cost sharing, would reduce overall out-of-pocket costs for LIS enrollees, and would encourage use of generics among them. Reducing or eliminating cost sharing or copayments for generic drugs could also reduce Medicare spending on reinsurance payments because a majority of enrollees who reach the catastrophic phase of coverage are in the LIS program. In addition to traditional generic drugs, biosimilar cost sharing should also ensure that LIS enrollees have an incentive to choose lower-cost alternatives to brand name biologic drugs. Biosimilars have the potential to save $54 billion in direct spending on biologic drugs between 2017 and 2026.

Prohibit Gaming of the Patent System

ACP supports robust oversight and enforcement of restrictions on product-hopping, evergreening, and pay-for-delay practices to increase marketability and availability of

competitor products and we urge the Congress to adopt policies that will prohibit drug companies from gaming the patent system through these practices.

There are several ways in which pharmaceutical manufacturers use the existing patent system for their benefit. Companies may apply for multiple patents on a single drug, creating what has been referred to as a patent thicket, a "dense web of overlapping intellectual property rights that a company must hack its way through in order to actually commercialize new technology." In an egregious example, the parent company of the biologic drug Humira has filed 247 patent applications and has been granted more than 100, extending patent protection for the drug into the 2030s.

End the Practice of Product Hopping or Evergreening by Pharmaceutical Companies

Companies use product hopping or evergreening to prevent generic competition from entering the market by making small adjustments with minimal if any real therapeutic value to a drug 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. Applications for these types of modifications often occur toward the end of a product's patent life, when the drug is facing potential generic competition, in order to maximize the potential monopoly extension.

ACP Opposes Anti-competitive Pay-For-Delay Arrangements

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. 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.

Senators Klobuchar and Grassley have introduced legislation S. 1428, The Preserve Access to Affordable Generics and Biosimilars Act, which would prohibit brand name drug companies from compensating generic drug companies to delay the entry of a generic drug into the market. ACP calls for robust oversight and enforcement of pay-for delay agreement in order to limit anti-competitive behaviors that keep lower cost alternative off the market, and we appreciate that Senators have introduced legislation with the intent to address these harmful tactics.

Reduce Pharmaceutical Companies Market or Data Exclusivity Periods from 12 to 7 years

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. 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.

Eliminate Tax Deductions for Direct-to-Consumer Pharmaceutical Advertising

A study of the period from 1997 to 2016 showed that direct-to-consumer (DTC) advertising for prescription drugs experienced rapid spending growth, from $2.1 billion (11.9 percent) of total spending in 1997 to $9.6 billion (32.0 percent) of total spending in 2016. Another study showed that one third of the growth in drug spending is attributable to an increase in advertising. A review of available data showed that DTC advertising was associated with increases in prescribing of the advertised drug and drug spending. Although a complete ban on DTC advertising is unlikely given that many courts have ruled that it is allowed under the First Amendment, steps can be taken to limit the influence it may have on prescription drug expenditures.

Under current law, drug manufacturers may deduct the cost of advertising expenses from federal taxes. Eliminating the tax deduction only for prescription drug product claim ads does not run afoul of free speech concerns about banning DTC advertising. Further, a study of physicians by the FDA showed that although the physicians believed that DTC advertising prompted patients to ask questions and be more aware of possible treatments, they believed that such ads did not convey risks and benefits equally well.

We urge Congress to approve legislation, S. 141, the End Taxpayer Subsidies for Drug Ads Act, which would prohibit a tax deduction for expenses for DTC advertising of prescription drugs, thus eliminating the deduction that pharmaceutical companies use to pay for drug advertising.

Increase Transparency in the Marketplace

ACP policy supports transparency in the pricing, cost, and comparative value of all pharmaceutical products. For decades, pharmaceutical manufacturers have claimed that drug pricing is based on research and development cost and innovation and is well regulated by market forces. The spike in prices and increase in price for drugs already on the market have made many stakeholders wary, especially because many of these new therapies treat small populations and there are few data to support that overall health care costs are reduced.

We 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. Pharmaceutical companies should disclose actual material and production costs to regulators, and 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.

We urge Congress to approve 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.

Increase Transparency for Pharmacy Benefit Managers and Insurers

Pharmacy benefit managers (PBMs) are for-profit companies that act as intermediaries for health insurers, self-insured employers, union health plans, Medicare Part D prescription drug benefit plans, and government purchasers in the selection, purchase, and distribution of pharmaceutical products for more than half the U.S. population. The ACP believes increased transparency is needed on the part of PBMs and health plans to provide greater understanding of drug prices, help patients make informed decisions, and support a more sustainable health care system.

The continued lack of transparency from PBMs and insurers can hinder how patients, physicians, and others view the drug supply chain and can make it difficult to identify whether a particular entity is inappropriately driving up drug prices. This lack of transparency can also prevent viable policy solutions from being identified and further delay reforms that would help to rein in spending on prescription drugs. Although there have been many calls for transparency on the part of pharmaceutical companies and greater support for transparency in health care generally, all stakeholders must commit to improving transparency as the health care community works toward creating an innovative but sustainable prescription drug market.

We provide the following recommendations to improve transparency in the prescription drug marketplace:

- Banning gag clauses that prevent pharmacists from informing patients when lower-cost alternatives are available, such as paying cash for a prescription instead of going through one's insurance coverage, is a reasonable step that has garnered bipartisan support.

- ACP supports the availability of accurate, understandable, and actionable information on the price of prescription medication. ACP urges health plans to make this information available to physicians and patients at the point of prescribing to facilitate informed decision making about clinically appropriate and cost-conscious care.

- ACP believes health plans, PBMs, and pharmaceutical manufacturers should report the amount paid for prescription drugs, aggregate number of rebates, and nonproprietary pricing information to the Department of Health and Human Services and make it publicly available. Any disclosure mandate should be structured in a way that deidentifies negotiated rebates with specific companies and protects confidential information that could be considered trade secrets or could have the effect of increasing prices.

Implement Reforms Concerning Step Therapy Practices

PBMs have developed a series of price management tactics to curb the rising cost of prescription drugs. Among these, step therapy policies, commonly called "fail-first" policies, require patients to be initiated on lower-priced medications before being approved for originally prescribed medications. Carriers can also change coverage in an attempt to force patients off their current therapies for cost reasons, a practice known as nonmedical drug switching.

Evidence concerning the effectiveness of these tactics is mixed. Some studies have found they can successfully drive cost savings without negatively impacting patient care. Others have found overall health spending actually increased due to an uptick in hospitalizations and other services resulting from new symptoms or complications. Meanwhile, these policies have drawn scrutiny for restricting patient access to effective treatments, putting patient health and safety in jeopardy by subjecting patients to potential adverse effects, interfering with the patient—physician relationship, and absorbing practice resources with burdensome approvals and documentation requirements.

In 2020, ACP released a position paper, that details our policies concerning Mitigating the Negative Impact of Step Therapy Practices and Non-Medical Switching of Prescription Drugs. We provide the following recommendations to the Senate Finance Committee as it considers policies to reform the practice of step therapy and medication and medication switching:

- **All step therapy and medication switching policies should aim to minimize care disruption, harm, side effects, and risks to the patient.**

- **All step therapy and nonmedical drug switching policies be designed with patients at the center, taking into account unique needs and preferences.**

- **All step therapy and nonmedical drug switching protocols be designed with input from frontline physicians and community pharmacists; feature transparent, minimally burdensome processes that consider the expertise of a patient's physician; and include a timely appeals process.**

- **Data concerning the effectiveness and potential adverse consequences of step therapy and nonmedical drug switching programs should be made transparent to the public and studied by policymakers. Alternative strategies to address the rising cost of prescription drugs that do not inhibit patient access to medications should be explored.**

We also urge the Congress to approve The Safe Step Act (S. 464 and H.R. 2163), which would ensure patient access to appropriate treatments based on clinical decision-making and medical necessity, not arbitrary step therapy protocols. This legislation would require insurers to implement a clear and transparent process to request an exception to a step therapy policy.

Conclusion

We appreciate the sustained effort of the Senate Finance Committee to lower the price of prescription drugs for our patients, but we urge you to act on our recommendations as soon as possible to ensure our patients can afford drugs prescribed by their physician. Should you have any questions regarding this statement, please do not hesitate to contact Brian Buckley our Senior Associate for Legislative Affairs at bbuckley@acponline.org.