TESTIMONY OF HANI JARAWAN, M.D.

IN SUPPORT OF

L.D. 1272, AN ACT TO INCREASE ACCESS TO LOW-COST PRESCRIPTION DRUGS;

L.D. 1387, AN ACT TO INCREASE ACCESS TO AFFORDABLE AND SAFE PRESCRIPTION DRUGS; AND

L.D. 1499, AN ACT TO ESTABLISH THE MAINE PRESCRIPTION DRUG AFFORDABILTIY BOARD

Joint Standing Committee on Health Coverage, Insurance & Financial Services
Room 220, Cross State Office Building, Augusta, Maine
Wednesday, April 17, 2019, 10:00 a.m.

Good morning Senator Sanborn, Representative Tepler, and Members of the Joint Standing Committee on Health Coverage, Insurance, & Financial Services.

My name is Hani Jarawan, M.D. I am a general internist in Portland, specializing in adult inpatient hospital medicine. I am a member of the MMA Board of Directors and Chair of the Maine Chapter of the American College of Physicians Health and Public Policy Committee. I am here today on behalf of the MMA and Maine chapter of the ACP to speak in favor of the package of bills addressing prescription drug costs.

The 600 members of the Maine ACP are our state's front-line medical providers, who care for Mainers in communities from Kittery to Caribou. As primary care doctors, hospitalists, and related subspecialists, we diagnose, treat, and provide compassionate care for Mainers with everything from routine health needs to complex illnesses. We play a critical role in preventing disease and promoting health and well-being.

The ACP, along with our partners at the MMA, supports consideration of a process to ensure the safe re-importation of drugs that you are discussing today. I would refer you to background materials attached to my testimony on the details of the policies at hand. I am here today to share my experience about the toll that the rising cost of drugs have on my patients, my colleagues, and my community.

The skyrocketing costs of prescription drugs is far from the only emergency affecting Maine medicine today, but it is so deeply intertwined in all the other crises that it may be the most important.

- Every day, a 55 year-old woman from Waterboro comes to the emergency department with left-sided paralysis or crushing chest pain. When I admit her, I learn that she has been cutting her insulin dose in half and skipping doses of her blood pressure medication because of cost. She's lucky enough to have

insurance, otherwise her stroke or heart attack might have happened even earlier. The debility from these treatable diseases often means rehab stays, loss of independence, depression, lost wages, and significant strain on loved ones during recovery. And of course, with these new complications come the need for new, often-expensive, but nonetheless life-sustaining medications. Sadly, the crisis of metabolic syndrome, from which one third of Americans like her suffer, is worsened by patients being unable to afford their medications.

- Americans are living longer. Maine's aging population means that more of my patients are living with chronic kidney disease and congestive heart failure. They are on active chemotherapy, and are taking blood thinners. When a 68-year old chronically ill patient sees my colleague in the clinic for a simple skin infection, the antibiotic choice is medically challenging. The liver and kidneys do not care what drugs are on his insurer's formulary, yet prescription drug coverage policies can trump the risks of severe side effects. If any one of the medications this patient needs is too expensive, there may be no other cocktail of drugs available to keep him healthy and prevent the next problem.

As doctors, we don't throw up our hands when our patients cannot afford their medications. We roll up our sleeves and help them find cheaper alternatives. Often, that means diverting time to calling around to different pharmacies, searching the internet for discount drug programs, and completing mountains of prior authorization paperwork to get the treatment that over a decade of training and clinical experience tell me is right for the person sitting in front of me. The price tag often says otherwise.

And, with physician shortages throughout the country, these hours spent means even longer wait times for a routine checkup, potentially delaying treatable disease. The prior authorization calls I have to make from the hospital mean longer lengths of stay, delaying the important work of rehab. The preventable hospitalization for someone who could not afford insulin means the patient in Houlton has to wait longer to be transferred for highly-specialized care. My patients are rightly frustrated at the medical system and my colleagues increasingly demoralized. The rising drug costs rippling through our health system now feel like a tsunami, and my patients tell me they are drowning.

The legislation before you today would help to ensure high quality of care, lower the overall costs of health care in Maine, and retain medical providers in high-need and underserved communities across the state. I am happy to answer any questions you have and to be a resource to you in the future.

1) American College of Physicians Fact Sheet
2) "Stemming the Escalating Cost of Prescription Drugs: A Position Paper of the American College of Physicians." Hilary Daniel, BS; Annals of Internal Medicine, 5 July 2016.
3) Statement for the Record from the American College of Physicians to the United States House Chairman and Ranking Member of the Committee on Ways and Means dated February 12 2019. "The Rising Cost of Prescription Drug Prices."

4) Statement for the Record from the American College of Physicians to Chairman and Ranking Member of the United States Senate Committee on Finance dated January 29, 2019. "Hearing on Drug Prices in America: A Prescription for Change."

ACP Facts

Background

The American College of Physicians (ACP) is a national organization of internists – 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. Internists are major providers of primary care in the United States. They are especially well-trained in the diagnosis of puzzling medical problems, in the ongoing care of complicated illnesses, and in caring for patients with more than one disease. Internists not only treat disease but also coordinate health care and play a critical role in preventing disease and promoting health and well-being.

Internists and Subspecialists

An M.D. or D.O. who completes a three-year internal medicine residency program is an internist. The *general internist* is an expert in the general care of the adult but also may have special areas of expertise. A *subspecialty internist* is an internist with one to three years of additional training in a particular organ (nephrology/kidney), system (endocrinology/glands), or age group (geriatrics). Some internists practice a combination of both general and subspecialty medicine.

Mission and History

The ACP mission is to enhance the quality and effectiveness of health care by fostering excellence and professionalism in the practice of medicine. ACP was founded in 1915 to promote the science and practice of medicine. In 1998, ACP merged with the American Society of Internal Medicine (ASIM), which was established in 1956 to study economic aspects of medicine.

Membership

With 152,000 members, ACP is the largest medical specialty organization and second-largest physician group in the United States. ACP provides information and advocacy for its members as they practice internal medicine and related subspecialties such as cardiology and gastroenterology. ACP members are also involved in medical education, research, and administration.

Levels of ACP membership are **Medical Student**, **Associate**, **Member**, **Fellow** (FACP), **Honorary Fellow**, and **Master** (MACP). Fellowship and Mastership recognize achievements in internal medicine. Masters are selected for outstanding contributions to medicine.

ACP Publications

Annals of Internal Medicine is one of the top medical journals in the world. *ACP JournalWise* summarizes the most important medical articles from more than 120 journals. *ACP Internist* is an award-winning semi-monthly newspaper for internists, while *ACP Hospitalist* is written for those in hospital practice.

Activities

The ACP Washington, D.C., office monitors and responds to policy issues that affect public health and the practice of medicine. Activities include development of policy statements and communication with legislative and administrative sectors of government.

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The **Center for Ethics and Professionalism** seeks to advance physician and public understanding of ethics and professionalism issues in the practice of medicine in order to enhance patient care by promoting the highest ethical standards.

Education and Information Resources
ACP supports the optimal practice of medicine by providing opportunities for continuing medical education. ACP medical education programs include the development of evidence-based clinical practice guidelines. ACP's annual scientific meeting, **Internal Medicine Meeting 2019**, will be held April 11-13 in Philadelphia.

ACP's **Medical Knowledge Self-Assessment Program** (MKSAP) gives internists an opportunity to test their knowledge and compare their results with national averages. In addition, ACP offers postgraduate board review courses, recertification courses, and chapter/regional meetings. For future internists, ACP provides education and career information, produces, and administers an In-Training Examination for residents.

ACP's **Practice Support** area, offers practice-support tools to enhance the efficiency, quality, and delivery of care, including a Physician & Practice Timeline which helps physicians stay on top of important dates and track deadlines for a variety of regulatory, payment, educational, and delivery system changes and requirements.

ACP works with internists and health literacy and communication experts, through the **Center for Patient Partnership in Healthcare** to create innovative health information tools to help patients better understand and manage their health. Resources include patient education brochures and DVDs for physicians who wish to raise awareness and educate their patients and communities.

Structure
ACP is governed by an elected Board of Regents. The Board is advised by a network of ACP committees and by the ACP Board of Governors, which is composed of elected Governors in chapters and regions of the United States, Bangladesh, Canada, Caribbean, Central and South America, India, Japan, Saudi Arabia, Southeast Asia (which includes: Indonesia, Malaysia, the Philippines, Singapore, Thailand) and the Gulf chapter (which includes Bahrain, Kuwait, Oman, Qatar and the United Arab Emirates). ACP sponsors the Council of Subspecialty Societies, which represents 25 subspecialty societies and internal medicine organizations. ACP is represented in the American Medical Association, the Council of Medical Specialty Societies, and other organizations.

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American College of Physicians
Leading Internal Medicine, Improving Lives

Statement for the Record
Committee on Ways and Means
hearing entitled
"The Cost of Rising Prescription Drug Prices"

February 12, 2019

The American College of Physicians (ACP) would like to express our appreciation to the Committee on Ways and Means for calling this hearing on prescription drug pricing in America. ACP is the largest medical specialty organization and the second largest physician group in the United States. ACP members include 154,000 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.

We understand that this issue is a top priority for the committee. ACP members see first-hand the choices that patients are all too often forced to make about their health when trying to budget between the cost of their medications and every-day living expenses. Dr. Nitin Damle, a practicing physician in Wakefield, RI, and the founding and managing partner of South County Internal Medicine, related the obstacles encountered by his patients in taking their medications in one day of his practice in his testimony to the Senate Judiciary Committee on June 21, 2016. That hearing examined methods drug companies use to raise prices of medications.

- A 67-year-old patient with diabetes, hypertension and heart disease can no longer afford his medications, as he has fallen into the "doughnut hole" of drug coverage. He must take brand-name drugs due to lack of cheaper generic alternatives to control his diabetes and prevent another heart attack.

- A 40-year-old patient with asthma cannot afford his preventive and rescue inhalers because of the high cost and his high deductible plan. There are again no generic alternatives. His non-compliance with medication will lead to an asthma exacerbation that may lead to an emergency room visit and even admission to the hospital.

- A third patient with rheumatoid arthritis cannot afford the immune modulating medications that are the standard of care due to the cost of the brand name medication with no generic alternatives. The inability to treat early rheumatoid arthritis with these medications will lead to more serious joint problems including joint replacement surgery and other medical complications of the disease.

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These examples are just three of many that play out in physicians' offices day in and day out. Advances in medicine have been life-saving but they need to be affordable to society. Non-compliance with medication regimens can lead to more serious health complications, more patients suffering from disease and additional costs to society. The pharmaceutical industry needs a reasonable return on investment but there needs to be a balance between profits and the service they provide in treating and maintaining the health of our patients.

We look forward to working with members of the Committee in a bipartisan fashion to develop policies to lower the cost of drugs for our patients and share our perspective as internal medicine physicians on how the rising cost of prescription drugs are making medications unaffordable for our patients. As the Committee examines solutions to lower the cost and price of prescription drugs, we urge committee members to consider the enactment of policies that will achieve the following objectives: promote competition in the pharmaceutical industry, increase transparency in the pricing and costs associated with the development of drugs, implement reforms to Medicare to lower out of pocket costs for seniors, and increase the value of drugs in the marketplace.

Drug Prices Continue to Rise

According to a multitude of studies published over the last several years, drug companies dramatically and repeatedly continue to raise the price of their products to levels that are simply unaffordable to patients.

- A recent study found that between 2002 and 2013, the price of insulin increased dramatically, with the typical cost for patients increasing from approximately $40 a vial to $130. As a result, according to a published report on the new study "a surprisingly large number of people with diabetes are using less insulin than prescribed because of the rising cost of the drug, putting themselves in danger of serious complications. Those are the findings of a small new study by researchers at Yale University, who found that at one clinic in New Haven, Conn., one in four patients admitted to cutting back on insulin use because of cost."

- 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. Prices increased for every brand-name drug of the top 20 most-prescribed brand-name drugs for seniors in the last five years. 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. Twelve out of the 20 most commonly prescribed brand-name drugs for seniors had their prices increased by over 50 percent in the five-year period. Six of the 20 had prices increases of over 100 percent. In one case, the weighted average wholesale acquisition cost for a single drug increased by 477 percent over a five-year period."

- Generic drugs, which usually are expected to offer a lower-priced competitive alternative to bioequivalent brand name drugs, are also experiencing price increases. A study in the October issue of Health Affairs shows that the portion of generic drugs that

at least doubled in price, year-over-year, represents a small but growing share of the market: from 1 percent of all generic drugs in 2007 to 4.39 percent in 2013. "For consumers, this can mean soaring costs to purchase some drugs that are life-savers, sparking public outrage and leading many to question whether the market — which has historically functioned well — is still working."[i]

- According to an article published in the Journal of General Internal Medicine, between 2010 and 2015 300 off-patent drugs experienced price increases of 100 percent or more, and some drugs were sold at 5500 percent higher than in previous years.[ii]

Promoting Competition to Lower Drug Prices

As the Ways and Means Committee continues to examine ways to lower drug costs, we encourage the Committee to use its oversight and legislative authority to develop policies to promote competition for brand-name and generic drugs and biologics. ACP provides the following recommendations to the committee to prevent a number of techniques that brand name drug companies use to block the approval of other drugs to compete with their products in the marketplace including: improving competition for single-source drugs, product hopping, ever greening, and pay for delay tactics.

- **Improving competition for single-source drugs** - Increasingly, the pharmaceutical marketplace is narrowing its focus to highly innovative, biologic, or specialty drugs for which there are few, if any, competitors, creating monopolies and limiting the cost-controlling power of competition. The focus on brand-name drugs and new biologics results in a greater desire for companies to protect the investments in these drugs and keeping them as profitable for as long as possible.

- **Increase oversight of companies that engage in product-hopping or ever greening** – In these practices, companies 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.

- **Enforce restrictions against pay for delay practices-** 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 Congressional Budget Office estimated that enacting legislation restricting pay-for-delay settlements would cut the federal deficit by $4.8 billion over 10 years.

Senators Grassley and Klobuchar have recently introduced legislation S. 64, The Preserve Access to Affordable Generics and Biosimilars Act. This legislation 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.

Improve Access to Generic Drugs

Limited competition—even in the generic market—can also drive up the cost of a medication. The generic manufacturing market is becoming more consolidated, and progressively some generics are being manufactured by a single company or are disappearing from the market. Limited competition – in almost any sector – limits the cost-containing power of competition. When there is no competition, patients have little choice. For example, if there is only one costly name brand drug for the patient, they really only have two options – either pay for the drug or forgo treatment and risk escalating their condition. Even the generic market is not immune to this happening, single-source generics are more expensive than other generics; some health plans place these drugs in the preferred drug tier in absence of a competitor, resulting in higher costs to the patient.

There have also been anti-competitive practices by a few manufacturers of brand name drugs to prevent or delay other companies from developing alternative lower-cost products. These few brand name manufacturers utilize the FDA's Risk Evaluation and Mitigation Strategies (REMS) process and its accompanying Elements to Assure Safe Use (ETASU) requirements in a manner that prevents development of lower-cost alternatives. In some instances, the REMS process and ETASU requirements have been used to deny availability of drug samples and participation in FDA safety protocols. Using the REMS process and ETASU requirements in this way by a few brand-name drug companies keeps lower-cost generics and biologicals off of the market, thereby decreasing patient access to lower-cost medications.

- **ACP supports House passage of legislation that would be the equivalent to S. 340 - the Creating and Restoring Equal Access to Equivalent Samples (CREATES) Act-** This legislation was recently introduced in this Congress by Senators Leahy, Grassley, Lee, and Klobuchar. It attempts to stop brand name companies from mis-using the REMS process and ETASU requirements by determining when the denial of adequate samples and impending participation in joint-safety protocol have occurred and creates a process a pathway for the lower-cost manufacturer to bring a cause of action in federal court for injunctive relief.

A former President of the American College of Physicians, Dr. Nitin Damle testified in support of this legislation at a Senate Judiciary Committee hearing regarding this bill in 2016. This legislation was introduced in the 115th Congress and approved by the Senate Judiciary Committee. In May of 2017, ACP also submitted a letter in support of this legislation.

Develop a Process to Ensure Safe Reimportation of Drugs

As the Ways and Means Committee continues to examine the causes of rising drug costs, we urge you to consider policies to develop a process to ensure the safe reimportation of drugs. The ACP continues to support consideration of the reimportation of drugs, especially sole-source generic drugs, provided that their safety can be reasonably assured by regulators, as part of larger efforts to control the cost of prescription drugs. The ACP believes it should be a

closed system, with participating pharmacies and suppliers required to meet FDA standards; have a tightly controlled and documented supply chain; not include controlled substances, biologics, or products that are infused or injected; and include adequate resources for inspections of facilities and enforcement of U.S. requirements, among others. The ACP acknowledges that drug importation is not a long-term solution to the high price of prescription medication, and there are various safety concerns about the reimportation of prescription drugs. Yet, we continue to support a careful evaluation of how existing federal importation standards may be used to encourage the reimportation of drugs to the United States, and how existing technology and recent legislative initiatives may assist in safeguarding the supply chain against counterfeiting or contamination.

Increase Transparency in the Marketplace

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. In 2018, a number of drug manufacturers announced they would not raise prices on drugs, noting the public concern about increasing drug prices. However, these decisions created a false sense of confidence that the issue was being addressed and in late 2018, most of companies reneged on these announcements and raised the prices of their products.

ACP urges the Committee to exercise its oversight authority to urge pharmaceutical companies to disclose:

- **Actual material and production costs to regulators-** Pricing methodologies for biomedical products are notoriously covert, and it is difficult to pinpoint to what extent a price reflects research, development, marketing, or administration costs.

- **Research and development costs contributing to a drug's cost, including those drugs which were previously licensed by another company-** Pharmaceutical companies are often publicly held and disclose information on their research and development marketing portfolios which has allowed outside analysts to review how, and how effectively, companies use their research and development budgets. The average amount that a company spends on research and development per drug may vary, depending on the number of drugs each company is developing and how many gain regulatory approval.

- **Rigorous price transparency standards for drugs developed with taxpayer-funded research-** Companies that use basic research funded through the government as part of the development of a drug should be held to a high standard of pricing scrutiny. The National Institutes of Health (NIH) have historically made the largest government investments in basic research and play a key role in spurring innovations and breakthroughs. Between 1988 and 2005, federal research funding contributed to 45 percent of all drugs approved by the FDA and 65 percent of drugs that received priority

review. Without this assistance, the cost of discovery, research, and development on the part of pharmaceutical companies may be prohibitive. At a minimum, pharmaceutical companies should disclose any grants, licensing agreements, or other investments by the federal government in the discovery, research, and development of the drug, in addition to material, production, and other research and development costs.

ACP supported several bills in the last Congress to improve the disclosure of information from pharmaceutical companies concerning their research and development costs and information regarding price increases of their products. These bills include:

- **The Drug Price Transparency in Communications Act-** This legislation, offered by Senator Durbin, would require drug companies to disclose the Wholesale Acquisition Cost of an Rx in Direct-to-Consumer Advertising. We are pleased that a similar measure offered by Senator Durbin to support mandatory price disclosures in DTC ads, passed the Senate in the last Congress. ACP also applauds an announcement by the Department of Health and Human Services (HHS) to issue a new regulation requiring pharmaceutical companies to list prices of their prescription drugs in DTC advertisements.

- **The Fair Accountability and Innovative Research (FAIR) Pricing Act-** This legislation, offered by Senator Baldwin, would require manufacturers to disclose and provide more information about planned drug price increases, including research and development costs.

Reforming Medicare to Lower the Cost of Prescription Drugs

The Ways and Means Committee may have the greatest impact on lowering the cost of prescription drugs through its ability to conduct oversight over CMS and pass legislation to reform the Medicare Part B and D programs. ACP policies support a number of reforms to Medicare which will bring down the cost of prescription drugs for seniors.

Allow Medicare Part D to negotiate drug prices

The ACP has a long-standing policy of advocating for the ability of Medicare Part D to negotiate drug prices and rebates directly with pharmaceutical manufacturers as a way to lower costs within the program. This idea has the bipartisan support of the American people and a 2018 poll conducted by the Kaiser Family Foundation showed that 92 percent of the American people favor allowing the federal government to negotiate with drug companies to get a lower price on medications for people on Medicare.

Although employer and self-insured plans are able to negotiate and use their bargaining power to lower the price of drugs, Medicare and Medicaid programs are directed by statutes that can impede their ability to obtain the best prices. Medicare Part D pays on average more than other federal health programs: 73 percent more than Medicaid and 80 percent more than the Veterans Health Administration. We believe that seniors can get a better deal on their drug costs if Medicare were allowed to negotiate prices and we urge the Ways and Means

Committee to support the following legislation that would allow Medicare to negotiate drug prices.

- **S. 62, The Empowering Medicare Seniors to Negotiate Drug Prices Act-** This legislation, offered by Senator Amy Klobuchar (D-MN) will empower the Secretary of Health and Human Services to negotiate with pharmaceutical manufacturers the prices (including discounts, rebates, and other price concessions) that may be charged for prescription drugs. ACP submitted a letter of support for this legislation in the last Congress and we also intend to support this bill in the 116th Congress.

Trump Administration Proposed Regulations to Reform Medicare to Lower Drug Costs

President Trump has also been an outspoken advocate for lowering the prices of prescription drugs and has issued a series of proposals designed to accomplish this goal. In May of 2018, the Department of Health and Human Services (HHS) issued a blueprint to lower drug prices that identified four key strategies for reform including: improved competition, better negotiation, incentives for lower list prices, lower out-of-pocket costs. ACP issued a comment letter that shared our views concerning key elements of the blueprint, expressed our key recommendations to lower drug costs, and urged the HHS to use the rulemaking process to continue to seek input from stakeholders prior to the implementation of any policy.

The President also seeks to issue a new regulation that would implement a new International Pricing Index payment model to lower drug costs for patients in the Medicare Part B program. The goal of this proposed rule would be to shift drug prices in the United States to more closely align them with prices in European countries that pay much less for the same drugs. Although ACP does not have direct policy on this pricing model, we did provide a comment letter to HHS that provides our views regarding a number of issues that should be considered before implementation of this rule.

CMS has also announced proposed changes to Medicare Part D designed to lower prescription drug prices for beneficiaries. The proposed rule would seek to allow plans to exclude certain protected class drugs if the manufacturer raises the price of the drug at a rate greater than inflation or if the drug maker brings to market a new formulation of the drug without any meaningful change to original formulation of the drug, regardless of whether or not the original formulation remains on the market or not. Additionally, the proposal introduces prior authorization and step therapy to the protected classes in an attempt to introduce more competition.

The administration also recently announced a new proposed rule that would attempt to lower out of pocket costs for patients using drugs with high prices and high rebates, particularly during the deductible or coinsurance phases of their benefits. This proposal aims to change perverse incentives in the system that allow drug companies to continue to increase the list prices of their drugs. The proposal would create a new safe harbor protecting discounts offered to patients when they purchase their drugs at the pharmacy. It would also create new safe harbor for fixed fee services arrangements between manufacturers and pharmacy benefit managers. We are currently reviewing this proposal to evaluate how it relates to ACP policy

and will most likely submit a comment letter to CMS to share our ideas regarding this new proposal.

Reforming Drug Formularies to ensure lower costs for patients

When health plans are faced with rising cost associated with high drug prices, they often look to increased cost-sharing, utilization management, or tiered formularies that place all drugs of a certain class into the highest tier, putting patients at risk for not being able to access or afford the medications they need or adhere to drug regimens properly.

Drug formularies divide prescription drugs into 4 or 5 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 2 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. Usually only the specialty tier has been subject to cost-sharing; all other tiers have copayments.

ACP believes that payers that use tiered or restrictive formularies must ensure that patient cost sharing for specialty drugs are not set at a level that imposes a substantial economic barrier to enrollees obtaining needed medications, especially for enrollees with lower incomes. Health plans should operate in a way consistent with ACP policy on formularies and pharmacy benefit management.

The ACP has a comprehensive policy on formulary benefit design including:

- ACP opposes any formulary that may operate to the detriment of patient care, such as those developed primarily to control costs
- Decisions about which drugs are chosen for formulary inclusion should be based on the drug's effectiveness, safety, and ease of administration rather than solely based on cost.
- ACP recommends that pharmacy and therapeutic committees be representative of, and have the support of, the medical staffs that will utilize the formulary.

Improve value within the prescription drug market

ACP supports research into novel approaches that would further value based decision making and encourages research into policies that would tie price innovations to clinical value. We urge the Ways and Means Committee to consider the following options:

- **Value Frameworks-** With the great attention being paid to the price of drugs, determining how to assess the value of a drug, which patients may benefit the most from a certain drug, and the economic value of a drug has charged the conversation.

- **Bundled Payments-** The approach may encourage the use of older, lower-priced drugs before newer, more expensive treatments with similar benefit and in turn affect drug utilization. This shift to paying for value as opposed to the number of services provided mirrors other similar shifts toward an evidence- and value-based system of health care.

- **Indication Specific Pricing-** The variability of disease and how patients react to medications makes indication-specific pricing potentially beneficial for such diseases as cancer.

- **Evidence Based Benefit Designs-** Innovative benefit designs can include incentives that vary by service, type of patient condition, or income. Evidence-based benefit design has also been advocated as a way to reduce health care costs and would be in line with the movement toward evidence-based medicine. Policies that encourage value-based benefit design can help consumers make educated choices about prescription drugs and keep costs low.

Improve the Use of Comparative Effectiveness Research

More and more, physicians, patients, and other stakeholders are questioning the value of drugs relative to their price. Many of the new specialty drugs coming to the market represent real breakthroughs and benefits for patients, and the market should encourage future innovation. Those innovations do not mean that all other drugs should also be priced at the same level. Independent organizations, such as the Institute for Clinical and Economic Review and the Patient-Centered Outcomes Research Institute (PCORI), develop and evaluate clinical effectiveness data compared with other treatments. For example, PCORI has funded millions of dollars in head-to-head CER that can inform physicians and help patients understand all therapeutic options available as they relate to existing therapies and encourage informed decision-making and patient involvement. Establishing an evidence base of clinical effectiveness data is the crux of transitioning to a health care system that pays for and rewards value. Not only do comparative effectiveness data inform value judgments they can also help physicians and patients understand all available options as they relate to existing therapies, encouraging informed decision making and involvement by patients in their health care choices. ACP policy supports CER to measure the effectiveness of health care services and clinical management strategies and that all health care payers, including Medicare and other government programs, should use both comparative effectiveness and cost effectiveness in the evaluation of a clinical intervention. However, cost should not be used as the sole criterion for evaluating a clinical intervention,

However, by statute, PCORI is prohibited from using Quality Adjusted Life Years (QALYs), is a metric of cost-effectiveness research that takes into account the quantity and quality of life associated with a treatment and assigns an index number to that treatment, as "a threshold to establish what type of health care is cost effective or recommended". QALYs are commonly used in cost-utility studies to determine the cost of a treatment per QALY and compare medical interventions; however, they have been criticized for lacking sensitivity to patient preferences or goals. Incorporating QALYs into cost effectiveness studies will help patients, physicians, and policymakers compare the cost and health benefits of treatments and facilitate a better

understanding of the value of different treatments. Part of a patient's overall determination of value may include the cost effectiveness of the treatment along with the benefits or risks of a drug.

Conclusion

ACP commends the Ways and Means Committee for conducting this hearing on drug pricing in America and we look forward to working with you, the Administration, and other stakeholders to develop and implement solutions to ensure that every patient has access to the medications that they need at a cost that they can afford. Should you have any further questions, please contact Rich Trachtman at rtrachtman@acponline.org.

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[i] https://news.usc.edu/149667/do-price-spikes-on-some-generic-drugs-indicate-problems-in-the-market/

[ii] https://link.springer.com/article/10.1007/s11606-018-4372-3