



February 12, 2019

The Honorable Elijah Cummings
Chairman
House Committee on Oversight and Reform
Washington, DC 20515

The Honorable Jim Jordan
Ranking Member
House Committee on Oversight and Reform
Washington, DC 20515

RE: January 29, 2019 Hearing - **Examining the Actions of Drug Companies in Raising Prescription Drug Prices**

Dear Chairman Cummings and Ranking Member Jordan:

On behalf of the American College of Physicians (ACP), I would like to express our appreciation to the House Committee on Oversight and Reform for conducting a hearing as well as launching an investigation into the practices of drug companies that contribute to the rising cost of prescription drugs. 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 look forward to sharing our clinician perspective on how the rising cost of prescriptions drugs are making medications unaffordable for many patients and creating barriers to patients getting the medications they need to maintain and improve their health. Physicians see first-hand the choices that patients must make about their health when trying to budget between the cost of their medications and every-day living expenses. Dr. Nitin Damle, a practicing internist in Wakefield, RI, and the founding and managing partner of South County Internal Medicine, relayed through [testimony](#) to the Senate Judiciary Committee in 2016 the daily challenges faced by his patients when it comes to their medications. The following excerpts are telling:

- 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.

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 more 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 the practices of pharmaceutical companies that contribute to increased drug prices, we urge Representatives to conduct oversight of this industry to achieve the following objectives: promote competition in the pharmaceutical industry, increase transparency in the pricing and costs associated with the development of drugs, 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 Internal General 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 House Oversight and Reform 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 urges your investigation to focus on ways to prevent a number of techniques that brand name drug companies use to block access to the FDA approval of generic drugs to compete with their products in the marketplace including extending market exclusivity, 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. Therefore, ACP believes it is important that policies addressing the increase in prescription drug prices cover not only new entrants to the market, but also drugs that have been on the market and may be generic or single-source drugs.

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 the passage of H.R. 965- The Creating and Restoring Equal Access to Equivalent Samples (CREATES) Act-** This legislation 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.

As we mentioned earlier, Dr. Nitin Damle [testified](#) in support of the Senate version of this legislation introduced by Senators Grassley, Leahy, Lee, and Klobuchar at a Senate Judiciary Committee hearing regarding this bill in 2016. In May of 2017, ACP also submitted a [letter](#) in support of the CREATES Act in the 115th Congress.

Develop a Process to Ensure Safe Reimportation of Drugs

As the House Committee on Oversight continues to examine the causes of rising drug costs, we urge you to consider oversight into 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.

We appreciate the efforts of the Chairman Cummings to increase transparency in the marketplace by investigating why drug companies are increasing prices, and what steps can be taken to reduce them. This effort to increase transparency in the prescription drug marketplace is necessary for Congress and the Administration to have the data that they need to enact legislative and regulatory policies to lower the cost of prescription drugs. 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 Representative Schakowsky, would require manufacturers to disclose and provide more information about planned drug price increases, including research and development costs.

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 Trump Administration 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.

Conclusion

ACP commends the House Committee on Oversight and Reform for conducting this hearing, and additional hearings in the coming weeks, 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 Brian Buckley at bbuckley@acponline.org.

Sincerely,



Ana Maria Lopez, MD, MPH, MACP
President

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>