COALITION FOR
FAIR DRUG PRICES

Reining in High Prescription Drug Prices: What Families Need from Congress

The United States is facing a prescription drug pricing crisis. High and rising prescription drug prices force consumers to take unacceptable risks with their health: Nearly three in 10 people report not taking their medicines as directed, including cutting pills in half, skipping doses, or not filling their prescriptions at all, due to the high costs of their drugs.[1]

Uncontrolled drug prices also force consumers to make impossible choices between their health and financial well-being. High drug prices drive nearly one in three consumers to more frequent credit card usage, and one in five to postpone paying non-medical bills.[2]

Prescription drug prices also contribute significantly to the cost of federal health care programs and rising insurance premiums. Medicare spent over $128 billion on prescription drugs in 2016, accounting for nearly 20 percent of all Medicare spending,[3] and prescription drug costs account for up to 25 percent of spending by commercial health plans.[4] Prescription drug spending has been rising at a faster rate than overall health spending, and this trend is only expected to continue in the coming years.[5, 6] This is due not only to high "launch" prices of new drugs,[7] but also to frequent, substantial price increases on existing drugs.[8]

Increases in prescription drug prices are pervasive for both name-brand and generic products. Prices for single-source brand name drugs (those that have no generic substitutes), however, account for some of the most startling increases. Between 2007 and 2017, prices of these single-source drugs rose by a cumulative 195 percent.[9] In fact, branded prescription drugs accounted for only 17 percent of all prescriptions in 2017, but still accounted for 79 percent of total spending on prescription drugs. This imbalance is even more pronounced among specialty drugs.[10] In 2015, branded specialty drugs accounted for 1 percent of prescriptions dispensed in Medicare Part D and Medicaid, but accounted for 30 percent of drug spending in those programs.[11] The lack of competition for these drugs and the United States' permissive drug pricing regime allows manufacturers to set extraordinarily high prices and raise these prices each year.[12] It should be noted that many generic drug manufacturers have implemented large price increases in recent years, driven by the decrease in competition

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in this market.[13] However, the overall substitution of generics for name-brand drugs continues to put downward pressure on drug prices.[14]

Abusive pricing of pharmaceuticals should not be allowed to continue. Congress created the patent system and market exclusivity laws that drug manufacturers are now so blatantly abusing in order to keep prices high.[15] And despite recent legislative reforms at the state level,[16] it is only Congress that has the power to change these rules to protect consumers and to reorient the incentives to drive real innovation.

Most other high-income countries regulate drug prices so that pharmaceutical corporations cannot charge consumers unrestricted, excessive prices and raise those prices on consumers whenever they want.[17] As a result, people in the United States pay far more than people in other countries for the same drugs — often three times, and up to seven times, more than other countries.[18, 19] As the largest purchaser of prescription drugs in the world, the United States government has significant leverage that it should use to ensure that prices for medicines are fair and affordable — truly reflecting a drug's value, which takes into account the drug's clinical benefit, budget impact, and other public interest considerations — for both consumers and for the health care system. Instead, the pharmaceutical industry has successfully lobbied to prohibit the federal government from leveraging this power. Despite broad public support, the government is currently prohibited from negotiating the price of drugs purchased through the Medicare program, which pays for almost one-third of retail prescription drugs and sets a benchmark for pricing in most health care sectors.[20]

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Indeed, across party lines and by wide margins, Americans want Congress to take serious action to rein in high and rising prescription drug prices. Eight in 10 think that the prices of prescription drugs are unreasonable,[21] and a similar percentage has said that taking action to lower drug prices should be a top priority for Congress.[22] *And the vast majority of Americans (86 percent) favor allowing the federal government to negotiate for lower drug prices in Medicare.*[23]

To this point, Congressional committees have advanced only modest legislation that does not make the structural reforms necessary to significantly lower prices. The bills have made modest changes to abusive practices of manufacturers that block access to generics and to some of the harmful practices of pharmacy benefit managers. Although many of these changes are welcome, they fall far short of the kind of action that will result in meaningful relief that consumers need and that the American people have demanded from their elected officials. In no way do these efforts serve as a substitute for more comprehensive action.

To leverage federal purchasing power effectively to obtain affordable and fair prices for prescription drugs, The Coalition for Fair Drug Prices and its members strongly urge that drug pricing legislation include the following key reforms:

Negotiating Power Coupled with an Effective Enforcement Mechanism That Can Meaningfully Lower Prices for All Consumers and All Payers

To be able to take advantage of the federal government's purchasing power to lower prescription drug prices, current statutory barriers to negotiation must be removed so that the federal government has the authority to negotiate with drug manufacturers, and this authority needs to be coupled with an effective enforcement mechanism. This mechanism must create a strong incentive for manufacturers to agree to fair and reasonable prices. This mechanism must, therefore, allow for the establishment of reasonable prices if a manufacturer refuses to agree to them.[24] This enforcement mechanism also should ensure patients have access to the drugs they need. Such safeguards should protect against administrative barriers that are not clinically appropriate and should hold manufacturers accountable for any efforts to strong-arm excessive profits at the expense of patients' lives and health.

Furthermore, the purpose of federal price negotiation should be to lower prices for all people, not just Medicare beneficiaries. Therefore, as a condition of negotiating with the federal government for inclusion in federal health care programs, drug manufacturers must agree to make the fair, negotiated prices available to all consumers and payers, and the enforcement mechanism must also provide a way for all consumers and payers to benefit.

Possible enforcement mechanisms that meet these standards include the following (in no particular order), some of which could be applied in concert or as stand-alone policies:

- **Issuing competitive licenses:** If the manufacturer refuses to agree to a fair price, the federal government would issue licenses to other manufacturers that would allow them to introduce generic competition for the drug. As a condition of being granted a license, these generic manufacturers would be required to price the drug affordably. The original manufacturer could receive reasonable compensation from the generic manufacturers to recoup a reasonable return on its investment in developing the drug.
- **Taxing excessive revenues:** If the manufacturer refuses to agree to a fair price, it would be subject to a 100 percent tax on the difference between the excessive price at which it sells the drug and the determined fair price. This tax would apply to all of a manufacturer's sales of the drug, not just its sales to Medicare or other federal health care programs. Revenue raised from this tax would provide for direct assistance in affording medicines for consumers and could also support federal investments in drug research.
- **Negotiating using the purchasing power of all federal health care programs:** If a manufacturer refuses to agree to a fair price for a particular drug, it would lose coverage by all federal health care programs for all of its drugs for which there are sufficient alternatives from other brands or generics.

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The Authority to Obtain and Enforce Fair Prices for All Drugs

Though single-source brand name drugs are the major drivers of increased prescription drug spending, manufacturers of drugs with multiple competitors and of generic drugs can and do still unjustifiably raise prices, putting these drugs out of reach for many consumers. Additionally, the pharmaceutical industry has already demonstrated its commitment to adapting to any attempts to rein in its high prices by finding and abusing new legal loopholes. For these reasons, the federal government must have the authority to leverage its purchasing power and utilize enforcement mechanisms like those described on page 3 for all drugs.

Enforceable Limits on Price Increases

High launch prices of new drugs are a major cause of high prescription drug costs. But price increases on existing drugs are also a significant driver of these rising costs. In order to ensure that drug prices continue to be fair, reflecting a drug's value — which includes the drug's clinical benefit, budget impact, and other public interest considerations — Congress must act to restrain these increases. Manufacturers should be prohibited from increasing prices at a rate higher than inflation. If they do raise prices at a rate above this threshold, they should be subject to enforcement mechanisms like those described on page 3. There should be a process for manufacturers to request an exemption from this limit ***only when reasonable*** (e.g., where shortages for key ingredients drive up manufacturing costs).

A Fair Price Determination that Reflects True Innovation and Ensures Affordable, Equitable Access for All Who Need the Drug

The way that pharmaceutical corporations set prices for drugs now has little connection to the cost of drug development, manufacturing costs, public health significance, or the added therapeutic benefit that drugs may bring to patients compared to existing therapies.[25, 26] Clinical impact or other benefits to patients and public health must be a key factor in determining a fair price for a drug.

Fundamentally, the central goal of drug pricing policy is to provide adequate incentives for innovations that serve the needs of the public and to ensure that these treatments are affordable to consumers. As is the case in other advanced countries, an independent assessment should guide fair price determinations and should consider at least the following factors:

- Cost-effectiveness and comparative clinical effectiveness
- Evidence of effectiveness for subgroups of patients who may not benefit sufficiently from existing therapies
- Budgetary impacts of covering the drug
- Unmet patient need for a drug attributable to price, including current inequities in access to existing therapies

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- Amount of federal investment in the drug's development, including direct financial investments, tax credits, and other forms of support
- Public health interests advanced by access to the drug
- The extent to which the manufacturer has obtained or is likely to obtain a reasonable return on its investment, factoring in existing and likely sales revenues both in the United States and globally
- Prices paid for the same drug in other countries

Robust Transparency and Conflict of Interest Standards

In order to secure truly fair prices, and for the American people to have confidence that a new prescription drug pricing framework is serving the public interest, there should be a strong principle of transparency and protection from industry influence throughout the system. The information used to make a fair price determination should be made publicly available to the fullest extent possible and should be gathered from independent assessments instead of relying solely on evaluations submitted by drug manufacturers. Independent pricing evaluations will likely require Congress to establish and invest in additional federal government comparative and cost-effectiveness capacity, as needed.

What About Pharmacy Benefit Managers?

Given their position as the "middlemen" between pharmaceutical manufacturers and purchasers, pharmacy benefit managers (PBMs) can have a significant impact not only on out-of-pocket costs that consumers face but also on the underlying list prices of prescription drugs. PBMs negotiate with drug manufacturers for drug rebates, but instead of passing along the resulting savings to consumers, they often keep a substantial portion for themselves.[27] PBMs' reliance on rebates for their business model can also result in incentives for manufacturers to raise list prices, or even in manufacturers being penalized if they reduce list prices. This is because PBMs make decisions about formulary placement for drugs based on the size of the rebates drug manufacturers offer, instead of choosing the drugs with the lowest prices.[28] Therefore, if a manufacturer were to lower its list price and offer a smaller rebate, it could lose formulary placement for that drug.[29] PBMs also utilize business practices that drive up costs at the point of sale for consumers and payers. Through "spread pricing," a PBM will reimburse a pharmacist at a lower rate than it charges its payer clients for a given drug and keep the difference. This spread pricing is a growing source of revenue for PBMs in recent years.[30]

While policymakers should address questionable PBM practices,[31] Congress should not lose sight of the main culprit behind high and rising drug prices — drug manufacturers. Regardless of the practices of other entities within the supply chain, prescription drug manufacturers still capture two-thirds of all U.S. revenues for prescription drugs.[32] To reform the current system in a way that most meaningfully benefits consumers who are struggling with high drug costs, policy change must therefore directly target manufacturers, who are the starting point for these high prices. Furthermore, determining fair initial prices for drugs and limiting price increases, as described in this paper, will bring improved transparency to the system and will limit the ability of other stakeholders throughout the supply chain, including PBMs, to unfairly profit from unreasonable prices.

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Endnotes

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