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1170 Market Street, Suite 500
San Francisco, CA 94102

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Prescription drug cost crisis

The fight for lower-cost prescription drugs

By Ruth Susswein

There are few issues that Americans agree upon more than this: The cost of prescription drugs is out of control. Drug prices are ballooning inexplicably and consumers are fed up. Some consumers are taking matters into their own hands and are caravanning to Canada for cheaper drug prices.

Outrage over skyrocketing prescription drug prices has drawn such consensus that Congress has been pumping out potential solutions to mounting prices in a multitude of new bills.

The problem

The average annual cost of brand-name drugs has more than tripled in the last 10 years, according to the AARP Public Policy Institute. While drug manufacturers argue that prices rise to cover the cost of research and development for new treatments and drugs, it does not account for the large percentage of taxpayer-funded research and development dollars provided by the National Institutes of Health. Nor does it explain dramatic price hikes in older medicines that have not changed in many years.

The list price for the life-saving drug insulin has risen 600% since 2002. These price hikes on a nearly century-old drug are forcing some diabetics to dangerously ration their insulin. A 2019 survey confirms previous studies' findings that one in four U.S. diabetics has felt forced to ration their insulin.

Limiting insulin doses can be life threatening. In May, Colorado capped the price of insulin copayments (at $100 a month) for those with insurance. The law does not cover all diabetics, or even all insured diabetics, but it is the first state action to curb insulin price gouging.

Humira, a drug used to treat arthritis, colitis, psoriasis and Crohn's disease, cost $19,000 per year in 2012. The same drug in 2018 cost $38,000 annually—with no plausible explanation from parent company AbbVie Inc.

Price spikes have hit senior citizens particularly hard—even those with Medicare drug coverage—because older Americans take four to five prescription medicines per month, on average. AARP says that its not unusual to find seniors facing costs of $30,000 a year for brand-name drugs.

There are a few factors that have led to this broken market. Federal law currently prohibits the Secretary of Health and Human Services from negotiating prescription drug prices for the tens of millions of consumers who participate in Medicare's drug programs, despite the fact that Medicare Part B and Part D plans account for 30% of drug spending in the U.S.

Patent abuse keeps drug prices artificially high and generic drugs off the market.

Drugmakers are entitled to hold patents on the new drugs they create to compensate them for the cost of developing new treatments for chronic conditions and deadly diseases. This gives drug manufacturers exclusive rights to sell a medication, often for 20 years. However, drug companies have a history of tweaking their patents to extend their monopoly control over the market and keep the competition out.

Drug companies also participate in "pay-for-delay" deals, in which they pay generic drugmakers to delay bringing much lower-cost versions of the drug to market. For more on these issues, see "Attacking barriers to lower drug prices," at upper right.

Pharmacy benefit managers (PBMs)—the middlemen in this complex system—have also come under criticism. They are supposed to help reduce drug costs by controlling which prescription drugs are approved for insur-

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Attacking barriers to lower drug prices

By Monica Steinisch

Considering the outcry by consumers, advocacy groups and lawmakers for lower drug prices, it's difficult to understand why there hasn't been greater progress on controlling soaring prescription costs. Here are some of the major impediments to affordable prescriptions.

Monopoly pricing. Once the FDA approves a drug for market, the company that owns it can begin selling it at virtually any price it chooses. Public Citizen explains (*http://bit.ly/2n30cUd*) that patent law and regulatory protections allow pharmaceutical pricing practices to go virtually unchecked. As a result, Americans pay the highest drug prices

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A bitter pill

Cost of medicine leaves little for basic necessities

By Lauren Hall

The public is angry and desperate over ballooning drug prices. Pharmaceutical company executives are enjoying record profits after raising the prices of more than 3,400 drugs in 2019 alone. Meanwhile, individuals and families have been forced to choose between tending to their health and paying for basic necessities.

Consumer Action conducted a survey of more than 100 organizations this year to determine the impact of high drug costs on our network of community-based organizations and their clients. A whopping 85% of respondents stated that they or their clients were burdened by high drug prices. Perhaps most startling, more than three-quarters (77%) reported that their clients were forgoing needed goods and services to pay for their medications, with the vast majority (over 60%) cutting back on food.

Survey respondents said that, due to high drug costs, they or their clients had purchased drugs from a foreign country (over half from Mexico, approximately 35% from Canada, and another 37% from other countries). The survey revealed that 88% of respondents did not know how to tell whether they were buying drugs from an official pharmacy when they bought drugs online. Furthermore, about 37% said that, due to high prices, their

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Consumer Action has been a champion of underrepresented consumers nationwide since 1971. A non-profit 501(c)(3) organization, Consumer Action focuses on financial education that empowers low- and moderate-income and limited-English-speaking consumers to financially prosper.

By providing financial education materials in multiple languages, a free national hotline and ongoing financial services research, Consumer Action helps consumers assert their rights in the marketplace and make financially savvy choices.

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San Francisco

1170 Market Street, Suite 500
San Francisco, CA 94102
(415) 777-9648
Email: info@consumer-action.org

Ken McEldowney
Executive Director

Michael Heffer
Business Manager

Kathy Li
Director, San Francisco (SF) Office

Nani Susanti Hansen
Associate Director, SF Office

Audrey Perrott
Director, Strategic Partnerships

Monica Steinisch
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Web Manager

Ricardo Perez
Mail Room Operations

Rose Chan
Consumer Advice Coordinator

Schelly Gartner
Consumer Advice Counselor

Alden Chan, Robert La, Michelle Liu
Support

Los Angeles

(213) 624-4631

Nelson Santiago
Community Outreach Manager

Linda Williams
Community Outreach & Training Manager

Washington, DC

(202) 544-3088

Linda Sherry
Director, National Priorities

Ruth Susswein
Deputy Director, National Priorities
(Editor, *Consumer Action News*)

Lauren Hall
Policy Advocate, National Priorities

Alegra Howard
Policy Advocate, National Priorities

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An unseen hand in prescription drug pricing

By Alegra Howard

There are powerful middlemen you've never heard of that decide which drugs you get—if any—and at what price.

Prior to the late 1960s, health insurers would negotiate the price of prescription drugs directly with pharmaceutical companies. That changed when, in an effort to save money, insurance companies began outsourcing the management of prescription drugs to pharmacy benefit managers, or PBMs.

Today, just three companies control more than 85% of the PBM marketplace: Express Scripts, CVS Health Corporation (formerly CVS Caremark) and OptumRx (a part of UnitedHealth Group).

These middlemen negotiate pricing with pharmaceutical companies and have the power to decide which drugs will be approved for insurance coverage (and when to cover them). This affects which medications consumers use and how much they pay for them. PBMs also contract with pharmacies to distribute medicines to patients, handle drug payments and oversee an opaque rebate system for drug discounts.

PBMs negotiate the price of drugs for health insurers, Medicare Part D plans, the Federal Employees Health Benefits Program and state government employee health plans.

PBMs influence both the choice of medications used and the price. Drug choice is affected by whether a drug makes the list of medications covered by insurance plans (the plan's "formulary"). PBMs receive price discounts and rebates from drug manufacturers when they include certain medications on the list of approved drugs. These discounts and rebates are passed on, in part, to health plans. An unknown amount remains with the PBMs.

While the PBM's role was supposed to result in more bargaining power and a reduction in drug costs for insurers and consumers, there is a growing question as to how much money PBMs actually save patients versus how much these middlemen profit. As a drug's list price grows, so does the amount of revenue PBMs receive from drugmakers in the form of rebates. However, pricing and rebate information is usually secret. *(Read more about rebates in "Attacking barriers to lower drug prices," on page 1.)*

In the interest of saving insurance companies money, PBMs can also require that patients jump through multiple hoops (*http://bit.ly/2lGOluR*) before they are allowed to receive a medicine prescribed by their doctor. Sometimes patients are required to receive special authorization to ensure coverage for particular drugs, or they must try a less expensive medication before receiving the one their doctor actually prescribed, a practice known as "fail first." Often, patients just don't get the drug their doctor prescribed because the authorization process for "off-formulary" drugs is so daunting.

Critics cite controversial practices like "clawbacks" (*https://to.pbs.org/2nk4wP6*), overpayments that occur when insured patients' copayments exceed the total cost of the prescription, and "price spreading," when PBMs pocket the negotiated cost savings instead of sharing it with patients, as proof that these powerful middlemen are simply in it for the large profits, and aren't interested in cutting prescription drug costs for consumers.

Critics blame weak government oversight as the primary reason PBMs wield such power over drug pricing.

In the 1990s, pharmaceutical companies began buying PBMs, fostering a blatant conflict of interest. The Federal Trade Commission eventually cracked down on the drug companies by forcing drugmakers to sell their affiliated PBMs.

In the last decade, pharmacies have gotten into the PBM business, and, more recently, PBMs are entering the health insurance market. For example, CVS Health Corporation—a major PBM—purchased the health insurer Aetna in a recently approved deal opposed by Consumer Action and other public and patient interest groups.

Merging these types of companies presents a conflict of interest that can greatly disadvantage consumers, who may be forced to pay higher drug prices, or who could be steered into affiliated pharmacies, which are usually huge chains rather than smaller drugstores that may be more convenient for patients. This was the case after the 2007 CVS pharmacy merger with the PBM Caremark. Before the merger, only 12% of CVS's retail prescription revenue came from Caremark. By 2014, that figure had tripled to 35% (*http://bit.ly/2nf9cG4*).

As Big Pharma, PBMs and insurers are seeing their annual profits rise into the billions, Americans continue to pay more for prescription drugs than any other country, and drug costs continue to rise relatively unchecked. Until the pharmacy benefit manager business model is more transparent and closely aligned with the interests of patients, consumers will be at the mercy of this hidden hand. ■

Despite opposition, CVS-Aetna merger is approved

Late last year, the national drugstore chain CVS purchased health insurer Aetna for $70 billion. In early September, a judge signed off on the merger, allowing CVS to retain its tens of thousands of retail pharmacy outlets, its status as a powerful pharmacy benefit manager (PBM) making drug coverage decisions and negotiating drug prices for health insurers, and, now, one of the country's largest health insurers.

Consumer Action joined the American Medical Association, the AIDS Healthcare Foundation, and U.S. PIRG as friends of the court (amici) to oppose the merger on behalf of the millions of consumers who now stand to see higher drug prices and restricted pharmacy access.

In his initial review of the merger, Judge Richard Leon of the U.S. District Court in Washington, D.C., raised eyebrows by delaying his decision in order to hold a hearing with testimony from both sides of the deal.

As one massive healthcare company, CVS-Aetna could crush the competition and leave consumers with little choice on price and market options. Given the lack of drug pricing transparency in PBM contracts (see above), further concentration of power in industries that already lack competition could mean higher drug prices for consumers and a lack of pharmacy choice for those in Aetna health plans. It's also feared that CVS could give Aetna what has so far been proprietary information that could disadvantage patient health privacy and harm competitors' businesses.

Prior to Judge Leon's recent approval, the U.S. Department of Justice (DOJ) had signed off on the CVS-Aetna merger. The DOJ's consent is required for large acquisitions, in order to prevent monopolies and anti-competitive deals. The DOJ required that Aetna enter into a consent decree to sell off its Medicare prescription drug (Part D) business to WellCare Health Plans to avoid conflicts of interest. (Nevertheless, CVS remains WellCare's pharmacy benefit manager—a seeming conflict of interest.)

However, while Judge Leon allowed testimony on behalf of amici, and criticized the DOJ for its very narrow consent decree, he ultimately signed off on the deal.

Enrollees in Aetna's Medicare drug plans recently were notified that they will be covered by WellCare. ■

Programs help families with drug coverage

By Lauren Hall

Despite criticism from opponents, and congressional/administration efforts to ax it, the Patient Protection and Affordable Care Act (or ACA) has successfully expanded health insurance and, by extension, prescription drug coverage. The ACA, still called Obamacare by many, mandates that qualified health plans provide prescription drug coverage as one of 10 "essential health benefits."

The ACA (enacted in 2010, under the Obama Administration) has been particularly beneficial to low-income individuals and families, those with pre-existing conditions, and young adults. Consumers have benefited from expanded state Medicaid programs and the extended period during which dependents can be covered by their parents' insurance (up to age 26). The ACA has given states the option to extend Medicaid eligibility to nearly all individuals with incomes at or below 138% of the federal poverty level. (As of March, 14 GOP-led states have continued to refuse to expand Medicaid.)

Due in no small part to the ACA, the nation's uninsured rate hit a historic low of 8.8% in 2016, and again in 2017.

Another federally funded initiative, the Children's Health Insurance Program (CHIP), offers low-cost health coverage to children in households with incomes too high to qualify for Medicaid. State rules regarding who qualifies for CHIP and what is covered vary, but certain fundamental elements remain the same: Doctor visits, vaccines and prescriptions are covered.

Premium dollars returned

Another ACA requirement that helps consumers financially and encourages insurers to use premium dollars wisely is the 85/15 medical loss ratio.

This provision states that if a health insurer spends less than 85% of large-group plan premiums (80% for individual and small-group plans) on actual medical care and "quality improvements" for plan participants, they must give the money back to employees and plan members through rebate checks each fall.

The provision is designed to prevent insurer overspending on administrative overhead, marketing and the like. The refund requirement applies to all licensed health insurers, but does not apply to companies that self-fund their health insurance plans.

According to HealthInsurance.org, due to the 85/15 policy, insurers returned approximately $707 million to almost 6 million consumers in 2018, with an average rebate check of $119.

In addition to federal initiatives, state governments are taking steps to reduce the cost of medications for consumers. In May, Colorado became the first to limit the price of insulin copayments to $100 per month (*https://dpo.st/2mWYow8*). Maryland has also been considering legislation that would create an "affordability commission" to allow the state and its payers—pharmacies, insurers and hospitals—to set a limit on how much they would have to pay for certain drugs (*https://wapo.st/2m3dxfi*).

Some private companies also are contributing to medication affordability. Insurer Cigna and its PBM Express Scripts, for instance, announced in April that they would cap the price of insulin at $25 per month for patients in participating plans (*http://bit.ly/2m6zES7*). ■

Fight

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ance coverage and by negotiating prices with drugmakers on behalf of insurers.

Instead, PBMs often rely on rebates from drugmakers to control costs. However, the rebate amounts and the rebate process are opaque. It is not known how much money is returned to insurers to hold down insurance premiums versus how much rebate money remains with the middlemen. What is clear is that rebate dollars are not going directly to the patients who pay for the drugs. *For details on the hidden PBM market, see "An unseen hand in prescription drug pricing," on page 2.*

Mergers of major drug manufacturers (such as AbbVie and Allergan), or mergers of insurance companies and pharmacy benefit managers (such as the recently approved marriage of Aetna and CVS), are also blamed for rising drug prices, by decreasing market competition and offering fewer choices for consumers. Consumer advocates argue that companies are investing their money in mergers rather than using those funds for drug research and development.

Some solutions

While there's tremendous consensus that a drug pricing crisis exists, there's no one solution. Here are some proposals that would have a genuine impact on the people directly affected. *(For details, see "Attacking barriers to lower drug prices," on page 1.)*

Government negotiation. Give Medicare the ability to negotiate drug prices directly with drug manufacturers. Nearly all other foreign governments help contain drug costs through negotiation.

Patents. Grant patents for true innovations, not for the questionable repurposing of existing drugs.

Generics. Prohibit pay-for-delay deals, the elimination of which could encourage generic versions of drugs to come to market quicker.

International reference pricing. Base the price of prescriptions on what other developed countries are paying.

Imports. Allow drugs to be imported from Canada in cases where there would be significant savings for U.S. residents.

Rebates. Require PBMs to pass rebates on to group health plans to help reduce the cost of insurance premiums, and on to consumers, who use and pay for the drugs.

Cap consumer costs. Cap consumers' out-of-pocket spending, especially for Medicare Part D drug plan enrollees.

Many of these solutions have been proposed in legislation this year. In fact, U.S. House Speaker Nancy Pelosi and colleagues unveiled a package of drug price proposals in September. For a summary of some of the key drug pricing bills, see "Pending legislation could lower drug prices" on our website (*https://bit.ly/2o28BIo*). ■

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clients had bought, or had been tempted to buy, prescription drugs on the street or at flea markets.

Congress is working to address out-of-control drug pricing. In a congressional hearing this summer, David Mitchell, head of the non-profit Patients for Affordable Drugs (*https://www.patientsforaffordabledrugs.org/about/*), and a group of patients shared stories about catastrophic drug prices.

Mitchell has an incurable form of blood cancer. As he pointed out to Congress, "prescription drugs are keeping me alive." The medications Mitchell requires are priced at $650,000 annually.

The high costs have led to people being forced to take half doses of their medications, or forgo treatment altogether. Like many Americans, Mitchell suffers because the maker of one of the drugs he needs has thwarted generic competition, enabling the price to hit the stratosphere.

"Price gouging and patent abuse is a huge problem in the prescription drug industry," said Consumer Action executive director Ken McEldowney. "The drug companies extend their patents for years, and even decades, to drive down competition from less expensive, generic drugs, and consumers—who are forced to pay unnecessarily high prices for name-brand drugs—are harmed as a result."

At the hearing last month, Ashley Krege, a woman with a chronic autoimmune condition who uses the top-selling drug Humira to treat it, outlined how she was paying $753 per month, "which was a huge burden," before being informed that the drugmaker, AbbVie, had raised the price to $1,100 per month, making the medicine unaffordable for her and leading to terrible pain due to her unmanaged condition.

"AbbVie is making billions on the backs of patients and has done everything in its power to block competition and keep generics off the market. In Europe, where biosimilars have come to the market, AbbVie is selling Humira for 80% less," Craig pointed out. (Biosimilars are the generic versions of biologic drugs like Humira.)

Many patient-centered groups have sprung up in response to the drug-pricing crisis. Groups like Affordable Insulin NOW and Lower Drug Prices Now promote events and protests to help Americans reach lawmakers and the administration. Last summer, Affordable Insulin NOW held a protest outside of Eli Lilly's headquarters to call attention to the skyrocketing cost of the drug. (Lilly's Humalog brand of insulin has increased in price by 500% since the early 2000s.)

Insulin price hikes are a prime example of drug company price gouging that impacts millions of Americans. The mainstream news media is increasingly covering the consequences for diabetics like 26-year-old Josh Wilkerson (*https://wapo.st/2nlMhJ3*), who have been forced to purchase cheaper, less effective insulin or ration their supplies due to costs. Wilkerson represents the one in four Americans who rations insulin due to lack of affordability. Unfortunately, his story ended in tragedy. After aging out of his family's health insurance plan, Wilkerson turned to a cheaper, less effective form of insulin that takes much longer to work. His family believes this insulin switch contributed to his blood sugar skyrocketing and Wilkerson falling into a diabetic coma.

This summer Senator Bernie Sanders led a caravan of a dozen diabetic patients to Canada to purchase affordable insulin over the counter (which is often sold for less than one-tenth of the cost in the U.S.). The highly-publicized trip brought attention to the fact that lawmakers could, and should, create laws to make insulin comparatively affordable in the U.S. ■

Going after the gouging

Elected officials are placing a priority on addressing high drug prices. Visit our website for a rundown of key drug pricing bills pending in Congress (*https://bit.ly/2AVD5yE*).

Barriers

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in the world. In reality, U.S. consumers pay twice—once through their tax dollars, which support publicly funded drug research and development, and again when they purchase the drugs.

Patent abuse. Manufacturers employ a combination of tactics to maintain a monopoly on the drugs they've developed. One is to exploit loopholes or ambiguities in the law to extend their patent beyond the usual 20 years. In this article (*http://bit.ly/2njC14o*), AARP explains how manufacturers can "add as many as 20 years or more to their monopoly periods."

Another is to withhold samples of their brand-name drugs from other manufacturers, since a competitor can't develop a "bioequivalent" drug—an FDA requirement for generics—if it doesn't have access to the drug it is trying to reproduce.

Yet another tactic is to simply pay other drug companies to hold off on introducing a generic version. These "pay-for-delay" contracts postpone the introduction of generics and delay the lower prices that typically result.

Unethical price hikes. Another trick of the trade is to spike drug prices just before a generic version is released. While this doesn't prevent generics from hitting the market, it causes them to be priced higher than they would have been. Analysis by GoodRx (*http://bit.ly/2lDCJbY*) found several instances where, because of this tactic, the generic's price might still be 20-50% lower than the branded price, but actually higher than what the brand price had been before the spike. Price spikes aside, pharmaceutical companies routinely impose unjustified annual price increases on their products that almost always far outpace inflation.

PBMs. Pharmacy benefit managers (PBMs) are employed by health plans to, among other functions, develop the plan's formulary (the list of drugs covered by the plan and the copay level). PBMs also negotiate discounts and rebates with drug manufacturers. But the system is seriously flawed. According to a Forbes article (*http://bit.ly/2mnFq1P*), rebates generally are calculated as a percentage of the list price of a drug, so the higher the list price, the greater the kickback (rebate), which benefits the PBM's bottom line but not yours.

As consulting firm Milliman explains (*http://bit.ly/2meIGwy*), the secrecy around rebate contract terms means that nobody knows how much of a rebate the PBM is pocketing as profit before passing the remainder on to the health plan (to lower premiums and/or copays for consumers).

PBMs also make money when they collect a copay from the consumer that's higher than the cost of the drug and keep most of the difference. There is no transparency on discounts, pricing or profits. A PBS story (*https://to.pbs.org/2nk4wP6*) covered a customer who paid a $285 copay to her health plan PBM for a drug that Costco sells for $40, throwing light on the hidden, convoluted system that enables such inequity.

Lobbying and financial influence. Big Pharma invests huge amounts of money in political contributions and lobbying to influence lawmakers to maintain the unregulated drug pricing status quo. On the consumer side, companies make charitable contributions and fund patient assistance programs to squelch critics. Research by a UCLA associate professor (*http://bit.ly/2mnkXtS*) reveals that "pharmaceutical companies are spending something like double the amount that they spend on research and development [of new drugs] on marketing to doctors," with the goal of convincing doctors to write more prescriptions for their drugs.

Reduced competition. Megamergers such as last year's union between health insurer Aetna and CVS, the nationwide pharmacy chain that also is a top PBM deciding on drug pricing and drug coverage availability, is the latest example of cuts in consumer healthcare choices and pricing options. Consumer Action filed a friend of the court (amicus) brief opposing the merger on behalf of consumers *(see "Merger," on page 2, for additional details)*.

Taming the massive, multi-layered pharmaceutical industry has proved to be a Herculean task because proposed measures require buy-in from diverse stakeholders with different objectives. For example, Forbes reports that, in 2018, pharmaceutical company Amgen reduced the list price of its drug Repatha by 60%. Competitor Sanofi followed suit by reducing the price of its competing drug. These moves should have lowered copays for consumers. However, PBMs resisted restructuring patient copayments around the lower price. PBM Optum Rx stated in writing that it "required at least seven quarters notice before any list-price reduction. And if a drug company lowers its list prices, Optum wanted rebates equivalent to what they would have received before the price cut."

The Trump Administration proposed a rule this year (*http://bit.ly/2moYVqO*) encouraging manufacturers to provide discounts directly to patients at the pharmacy rather than give rebates to the middlemen PBMs.

Even such a seemingly straightforward solution is anything but simple. While manufacturers generally don't object to consumer discounts, others predict that without rebates (which PBMs share with insurers), health plans will hike insurance premiums to recoup the lost revenue, negating the benefit of lower drug prices to consumers.

There's also the questionable argument from the drug companies that lower prices will quell further drug innovation.

The Coalition for Fair Drug Prices recommends that (*https://bit.ly/2AUqg7G*) Congress leverage the federal government's power, as the funder of Medicare and other federal healthcare programs, to negotiate drug prices (currently prohibited) for the benefit of all Americans. It also advocates for an effective enforcement mechanism to ensure all drug manufacturers and PBMs play by the same rules. Other recommendations include:

- establishing a drug pricing policy that reflects actual research and development (R&D) costs, benefits to patients, and the cost of the drug in other countries;
- prohibiting price increases that outpace inflation; and
- requiring industry transparency.

But the coalition's members are not placing all their hopes on the federal government. Families USA is working with partners nationwide to enact reforms on the state level. The organization says that "many states are already leading the way on prescription drug price transparency, pharmacy benefit manager protections, protections from price gouging, and more."

Nevada recently passed a law (SB 262) that requires drug companies to disclose how they price asthma medications, including specifics about R&D investments and manufacturing costs. A few days later, the state passed a law (SB 276) to study the impact of rebates, price reductions and other compensation from drug manufacturers on the cost of prescription drugs.

As Congress, regulators, industry and patient advocates wrangle over strategy for resolving the prescription drug pricing crisis, consumers should be proactive about finding their prescriptions at the lowest cost. Since prices can vary widely by pharmacy, consumers are advised to compare costs (and get coupons) from services like GoodRx (*https://www.goodrx.com*), WellRx (*https://www.wellrx.com*), WeRx (*https://werx.org*) and Blink Health (*https://www.blinkhealth.com*).

Consumers can also ask a pharmacist directly what options they have to get the very lowest price for their prescription drugs. For example, you might be advised to pay the entire amount out of pocket instead of paying a higher copay, or to buy a three-month supply rather than a month's worth. ■

Why are drug prices lower in other countries?

The U.S. government does not regulate or negotiate the price of prescription drugs when they hit the marketplace. Once the Federal Drug Administration deems a drug "safe," drug companies can set their own prices.

Other countries, including Australia, Canada and Great Britain, have government agencies that negotiate prices with drugmakers. These regulatory bodies also review the risks and benefits of new drugs, making sure they really are a better alternative than drugs already on the market. As a result, not every new drug that is developed is available in these countries—something critics of this process say is harmful to patients.

However, patient advocates argue that just because a new drug is available in the U.S. does not mean it is an improvement on an older, less expensive option. Since no U.S. agency weighs the value of a new drug, Americans could be paying for an expensive new prescription that offers no greater benefit than a cheaper alternative, if one is available.

—A.H.