



Drug Pricing Overview *116th Congress*



the campaign for
SUSTAINABLE Rx PRICING



@CSRxP



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www.csrp.org

www.csrp.org/commitment



Dear Member of Congress,

On behalf of the Campaign for Sustainable Rx Pricing (CSRxP), a nonpartisan coalition of doctors, physicians, nurses, hospitals, consumers, health plans, PBMs, pharmacists, patient advocates and businesses committed to lowering drug prices, congratulations on being elected to represent your constituents in the 116th Congress. Our organization believes no one should ever have to choose between paying for basic necessities and taking the medications that will improve their health – or even save their life. That's why we are eager to work with you to advance market-based solutions that will improve the lives of people in your community and across the country.

As you know, out-of-control drug prices is one of the biggest challenges facing our nation today. Drug spending is growing faster than any part of the health care system, increasing the cost of Medicare and Medicaid, while adding to our \$21 trillion national debt. Over the past five years, **brand name drug prices have increased at 10 times the rate of inflation, a trend that has left one-in-four Americans unable to afford the medications they need.**

As the number of families who are forced to choose between paying for a prescription drug and paying for other basic necessities continues to grow, the pharmaceutical industry is thriving. In fact, drug makers enjoy some of the largest profit margins of any industry – nearly 30 percent – and **nine out of 10 of the biggest drug makers spend 50 percent more on advertising their products** than they do researching and developing new ones.

In large part, Big Pharma's stronghold over our nation's health care system stems from the lack of competition and transparency needed to drive down the price of prescription drugs. For example, brand name drug makers are creating patent estates to protect their monopolies and keep cheaper biosimilars and generics off the market – a strategy that prioritizes profits over the patients they claim to be helping.

It's no wonder out-of-control drug prices was such a prominent issue on the campaign trail. In a September poll by NORC at the University of Chicago, 88 percent of Americans said lowering drug prices should be Congressional candidates' top priority. With House Speaker Pelosi, President Trump and Senate Majority Leader McConnell all committed to addressing this issue in 2019, Members of Congress have a rare bipartisan opportunity to convert their campaign promises into substantive action, upending the status quo with reforms that hold drug makers accountable and put patients' needs first.

CSRxP has supported many of the efforts already underway to boost competition and increase transparency in the drug marketplace, including:

- The Bipartisan Budget Act of 2018, which included a reduction in the out-of-pocket costs seniors pay for drugs in the Medicare Part D "donut hole" and also applied a 50 percent discount on biosimilars in the donut hole. Later in the year, Congress maintained those vital provisions despite the pharmaceutical industry's attempts to roll them back.
- Congress passed The Patient Right to Know Drug Prices Act to eliminate "gag clauses" that prevented pharmacists from advising patients about more affordable options when purchasing their medications.
- The Administration's efforts, along with Senators Durbin and Grassley, to advance a proposal that would require pharmaceutical companies to disclose drug prices in direct-to-consumer (DTC) advertising – a critical step that will not only give patients the information they need to make important health care decisions, but also hold drug makers accountable for the prices they set.
- The U.S. Food & Drug Administration (FDA) approving generic drugs at a record pace. According to a new report from PricewaterhouseCoopers, the FDA approved 781 generic drugs in fiscal year 2018, 90 percent more than it did in 2014.

This is important progress, but there is much more work to be done. That's why we wanted to provide you with a resource that further explains why drug prices have become so out-of-control and what lawmakers can do to reverse this trend and dramatically improve the lives of patients in their districts through:

- 1 **aggressive oversight of drug makers and**
- 2 **bipartisan, market-based reforms that boost competition, strengthen transparency and encourage innovation.**

If you or your staff need additional resources, please don't hesitate to reach out to our team at laronson@mc-dc.com.

CSRxP looks forward to working with you to tackle this important issue and make prescription drugs more affordable for all Americans.

Sincerely,

Lauren Aronson

Lauren Aronson
Executive Director
Campaign for Sustainable Rx Pricing



the campaign for
SUSTAINABLE Rx PRICING



About CSRxP

WHO WE ARE

The Campaign for Sustainable Rx Pricing (CSRxP) is a broad-based coalition of leaders – physicians, nurses, hospitals, consumers, health plans, PBMs, pharmacists, and businesses – promoting bipartisan, market-based solutions to lower drug prices in America.

OUR MISSION

To make prescription drugs more affordable for all Americans. CSRxP advocates for bipartisan solutions that hold pharmaceutical companies accountable for out-of-control drug prices and provide more affordable choices for patients. We believe in market-based reforms that address the underlying causes of high drug prices in the U.S. through increased transparency, competition and value.



EXPERTS AVAILABLE TO YOU

Our CSRxP leadership team is always available to provide additional background or speak on the issue.

- **Lauren Aronson**, CSRxP Executive Director, laronson@mc-dc.com
- **CSRxP Communications Team**, CSRxP@CSRxP.org

WHERE YOU CAN LEARN MORE

To learn more about the Campaign for Sustainable Rx Pricing (CSRxP) and our proposals to change the drug pricing market, visit www.csrxp.org and www.csrxp.org/commitment.

Sign up to receive our weekly newsletter to learn about the biggest developments each week on the rising prescription drug crisis at www.csrxp.org/contact.

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the campaign for
SUSTAINABLE Rx PRICING



Out-Of-Control Rx Prices: Defining the Problem

Every American deserves access to affordable medicine. Unfortunately, out-of-control drug prices prevent many families from getting the medicines they need. No one should ever have to choose between paying for necessities and taking the medicine that will improve their health – or even save their life.

While pharmaceutical companies make life-saving treatments and cures, it does not give them the right to price gouge hardworking families to pad their own bottom lines. Over the past five years, brand name drug prices have increased at 10 times the rate of inflation – creating a health crisis that leaves one in four Americans unable to afford the medications they need. Despite immense public scrutiny, pharmaceutical companies continue to prioritize profits over people. In January alone, over three dozen companies raised the prices of hundreds of medications. That's because, for decades, America's prescription drug system has lacked the competition and transparency needed to drive down the price of prescription drugs.

For example, while generic and biosimilar drugs offer many patients an affordable alternative to expensive name-brand medications, federal laws that exist today give drug companies monopoly market power and allow for exclusivity patents that last for decades. As

of September 2018, the FDA has approved 12 biosimilars but consumers have been able to access only four, according to a study by Matrix Global Advisors. Often, pharmaceutical companies work to further extend these patents for trivial updates, such as pill color and packaging, simply for the purpose of keeping generic makers out of the market – forcing patients to resort to name-brand drugs they may not be able to afford or, worse, forcing patients to forgo the treatment they need altogether.

Moreover, pharmaceutical companies are not required to be transparent about how and why they set or increase their list prices on medicines families need. Every person deserves the right to know about all of their health care options and how much drugs cost.

The unsustainable cost of prescription drugs not only puts pressure on the health care system, but increasingly patients, employers and providers are paying prices that are too high.

By The Numbers



60 percent of Americans and 90 percent of seniors take prescription drugs. (Brady Dennis, "Nearly 60 Percent Of Americans — The Highest Ever — Are Taking Prescription Drugs," Washington Post, 11/3/15)



One in four Americans cannot afford to use their medications at the recommended level and end up "underusing" or skipping dosages. (Monica Chin, "1 In 4 Americans Refuse Medical Care Because They Can't Afford It," New York Post, 6/7/17)



88 percent of Americans say prescriptions costs should be a priority issue for Congress. ("High Prices, Broken Promises: New Poll Finds Few Americans Approve How President Trump And Congress Are Addressing 'Unreasonable' Prescription Drug Costs" NORC at the University of Chicago, 9/13/18)



10 Times: Over the past five years, brand name drugs have increased at 10 times the rate of inflation. (Wayne Drash, "Medicare Drug Prices Soar At 10 Times Rate Of Inflation, Report Says," CNN, 3/26/18)



45 Percent: Top pharmaceutical players can have net margins of between 35 to 45 percent. (Julianne Slovak, "The Average Profit Margin Of Pharmaceuticals, AZ Central, 5/14/18)



Nine out of 10 of the biggest drug makers spent 50 percent more on advertising their products than researching and developing new ones. (Aimee Picchi, "Drug Ads: \$5.2 Billion Annually -- And Rising," CBS News, 3/11/16)



\$174 billion: the amount The Center For Medicare And Medicaid spent on prescription drugs in 2016 – a \$65 billion increase over the \$109 billion spent in 2012. (Tami Luhby, "Check Out How Much Medicare Spends On Drugs," CNN, 5/15/18)



74 times: Sanofi has filed patent applications for its insulin drug Lantus 74 times, one and a half times the amount it filed in the European patent office and three times the amount filed in the Japanese office, in order to extend its market exclusivity to 37 years, or nearly double the intended time under U.S. patent laws. ("Overpatented, Overpriced: Lantus Special Edition," Initiative for Medicines, Access and Knowledge, 11/1/18)



247: the number of patent applications that have been filed on Humira in the U.S. with the aim of delaying competition for 39 years. ("Overpatented, Overpriced: Special Humira Edition," I-MAK, 9/17)

Examples of Out-of-Control Drug Prices

The price of Humira, the world's biggest drug by sales, has had its price increased by nearly 100 percent since 2012 from **\$19,000 to \$38,000.**

(Danny Hakim, "Humira's Best-Selling Drug Formula: Start At A High Price. Go Higher," The New York Times, 1/6/18)

The price of Evzio, a drug used for emergency treatment of known or suspected opioid overdoses, is up almost **600 percent from its 2014 price.**

(Ken Alltucker, "Drug Company Raised Price Of Lifesaving Opioid Overdose Antidote More Than 600 Percent," USA Today, 11/19/18)

Cancer drug Gleostine has had its price increased **nine times and by 1,400 percent since 2013.**

(Peter Loftus, "Cancer Drug Price Rises 1,400% With No Generic To Challenge It," The Wall Street Journal, 12/25/17)



Proposals for Change

CSRxP has developed market-based reforms that restore a functioning market by increasing transparency, promoting competition and innovation, and that result in value.



Transparency

Patients deserve open and honest drug pricing – clear and transparent information about the true costs of treatment, how manufacturers set prices, and the actual cost of bringing drugs to market, particularly for high-cost drugs. Improving pricing transparency will enable patients to become actively involved in their healthcare decision-making and put pressure on big pharma to lower the prices of their excessively costly drugs.



Releasing details of a drug's unit price, cost of treatment and projection on federal spending before FDA approval. Given the significant impact pharmaceuticals have on overall health care spending, manufacturers should be required to: list prices in all forms of direct-to-consumer (DTC) advertising; disclose information on the estimated unit price for the product and the cost of a course of treatment; provide a projection of federal spending on the product.



Annually reporting increases in a drug's list price. Reporting requirements are already in place for other entities such as health plan issuers, hospitals and nursing facilities, and this level of transparency should simply extend to the pharmaceutical sector as well. Congress should enact the Fair Accountability and Innovative Research (FAIR) Drug Pricing Act to require drug manufacturers to report to the Department of Health and Human Services (HHS) expensive drugs with significant price increases. Furthermore, the HHS should provide an annual report to the public to include the top 50 price increases per year by branded or generic drugs; the top 50 drugs by annual spending and how much the government pays in total for these drugs; and historical price increases for common drugs, including those covered by Medicare Part B.



Disclosing true R&D cost for drugs. Drug manufacturers should publicly disclose research and development costs, including the portion of research funded by the National Institutes of Health (NIH), research funded by other academic entities and research conducted by another manufacturer.



Medicare and Medicaid Drug Spending Dashboards updates. HHS should frequently update the Medicare and Medicaid Drug Spending Dashboards that show spending by these federal health programs on prescription drugs.



Real-time prescribing information. HHS should encourage the use of real-time benefit inquiry software so that patients and prescribers know cost-sharing at the point of prescribing.

Competition

Pharmaceutical companies today abuse the patent system to prevent more affordable drugs from disrupting their monopolies over the drug marketplace. Bringing more competition to the prescription drug market will give consumers more choices and more control – resulting in lower prices and improved access.



Speeding FDA approval of generic drug applications – especially for lifesaving drugs. The FDA faces a backlog of nearly 4,000 generic drug applications, yet approval times can be three or more years. The FDA should be provided with sufficient resources to reduce the backlog of generic drug applications – particularly for lifesaving drugs and drugs with limited or no generic competition.



Curbing unfair extensions of product monopolies. Market exclusivity protections should be awarded only to those products that are actually innovative and treat true orphan diseases with small patient populations, so that drugs do not maintain unfair market monopolies.



Thwarting abuse of the patent system. In many cases, drug producers will file over 100 patent applications for the same drug in order to keep generics off the market, allowing them to continue their price-gouging tactics. Anti-competitive abuses of the patent system by drug manufacturers should be stopped by having appropriate federal agencies apply scrutiny to potential patent abuses and enacting the Preserving Access to Cost-Effective Drugs (PACED) Act to prevent drug manufacturers from transferring their patents to Native American tribes with sovereign immunity.



Reducing drug monopolies by incentivizing competition for additional market entrants. Several FDA programs are intended to expedite review of new drugs that address unmet medical needs for serious or life-threatening conditions. Incentives should drive competition for expensive treatments where no competitors exist and encourage a second or third market entrant.



Strengthening post-market clinical trials and surveillance. Currently, expedited drug approvals often involve small clinical trials with a narrow patient population and trials are not regularly reported publicly. Once a drug enters the market, research into the long-term efficacy and side effects should continue with specific timelines and reporting requirements. Even if a product is not approved, manufacturers should be required to report data for all trials that summarize non-identifiable demographics and participant characteristics, primary and secondary outcome results, and adverse event information.



Targeting exclusivity protections to the most innovative products. Currently, pharmaceutical manufacturers can extend market exclusivity protections by seeking approval for a “new” product that is essentially the same as the original. Prohibiting such tactics will bring consumers more options and lower prices more quickly. Anti-competitive pricing schemes should be closely monitored by federal agencies and prosecuted if violations of antitrust laws are found.



Restraining misuse of REMS. Currently, the FDA requires manufacturers to submit detailed Risk Evaluation and Mitigation Strategies (REMS) to weigh a drug's risks and benefits. While this type of information can create additional safety information for patients and safeguards for providers, manufacturers often manipulate REMS to block generic manufacturers from obtaining samples of brand drugs under the guise of addressing patient safety concerns. This practice can stifle the introduction of generic competition, thus preventing lower price options from being available. In order to halt REMS abuse, Congress must enact either the Creating and Restoring Equal Access to Equivalent Samples (CREATES) Act or the Fair Access to Safe and Timely (FAST) Generics Act.



Promoting uptake of biosimilars. Policies should be implemented to promote a robust biosimilars market, including lowering the period of market exclusivity for expensive biologics from 12 years down to seven years and having the FDA and the Centers for Medicare and Medicaid Services (CMS) engage in extensive education campaigns to inform patients, providers, and payers about the value of biosimilars.



Enabling Medicare Part D plans to use full commercial negotiating tools to lower drug costs. CMS should extend more flexibility to private health insurers operating Medicare Part D plans so that Medicare beneficiaries can take full advantage of the commercial negotiating tools used to lower drug prices for consumers.



Preserving the Medicare Part D “donut hole” agreement. Congress should preserve the Medicare Part D “donut hole” agreement reached in the Balanced Budget Act (BBA) of 2018, so that drug manufacturers continue to pay their fair share of costs of the coverage gap.

Value

Patients deserve reliable information regarding whether a drug's "therapeutic outcome" – or its health benefit – is in line with its price. This information is critical to moving America's prescription drug market toward a system that empowers doctors and patients to choose medications based on the value they provide – not the "value" set by drug manufacturers.



Increasing funding for public and private research on drug pricing and value.

Policymakers should increase funding for private and public research efforts such as the Institute for Clinical and Economic Review (ICER), a non-profit organization that evaluates evidence on the value of medical tests and treatments. Investments in objective information is critical for physicians, patients and payers as more and more high-priced drugs are introduced into the health care system.



Requiring drug makers to compare cost and outcomes of new versus existing drugs.

Through comparative effectiveness research (CER) studies, manufacturers would have to demonstrate their product is better than others, so that physicians and patients can make smart decisions about the value of different treatments, particularly those with very high costs. Many other countries currently require drug manufacturers to provide CER studies. They should be expanded in the U.S. to reduce spending on unnecessary or ineffective treatments.



Expand value-based pricing in public programs. Federal programs like Medicare and Medicaid purchase prescription drugs for their beneficiaries, but most are not structured to accommodate value-based payment models. Steps should be taken to ensure these programs can best take advantage of recent developments in value-based purchasing to ensure all parts of the U.S. health care system can benefit from market-based negotiating efforts to lower drug prices.





What They're Saying

Tackling Out-Of-Control Drug Prices Has Bipartisan Support



President
DONALD TRUMP

“One of my greatest priorities is to reduce the price of prescription drugs. In many other countries, these drugs cost far less than what we pay in the United States ... That is why I have directed my administration to make fixing the injustice of high drug prices one of our top priorities. Prices will come down.”

“Hopefully we can all work together next year to continue delivering for the American people, including ... lowering the cost of prescription drugs.”



Senator
DICK DURBIN (D-IL)

Health care is too expensive for too many working families, and the skyrocketing cost of prescription drugs drives the problem, causing higher out-of-pocket costs at the pharmacy and ever-rising monthly premiums ... By requiring drug companies to tell us their prices and cracking down on gimmicks used to reduce competition ... We can create a more transparent and affordable system for consumers.



House Speaker
NANCY PELOSI (D-CA)

[Lowering prescription drug prices] will be one of our first legislative priorities in the majority.



Senior Vice President of Public Policy Analysis and Development, American Hospital Association
ASHLEY THOMPSON

The higher prices that drug manufacturers demand have caused immense hardships for many patients, their families, and the providers who care for them ... It is time for drug companies to stop attacking others and come to the table with solutions on how to rein-in out-of-control drug prices for patients.



Senator
AMY KLOBUCHAR (D-MN)

The rising cost of prescription drugs in our country is an urgent problem ... Competition, not anti-consumer actions from pharmaceutical companies, should determine prescription drug costs.



Senate Majority Leader
MITCH MCCONNELL (R-KY)

... I can't imagine [lowering prescription drug prices] won't be on the agenda.



Senator
SUSAN COLLINS (R-ME)

Drug companies should not be able to increase their prices dramatically by thousands of percent overnight without any justification or development of the drug to improve its effectiveness.



Health and Human Services Secretary
ALEX AZAR

Patients deserve to know what a given drug could cost when they're being told about the benefits and risks it may have. They deserve to know if the drug company has pushed their prices to abusive levels.



Senator
CHUCK GRASSLEY (R-IA)

On my watch, I'll continue working across the aisle to lower drug prices, restore competition and increase transparency in the pharmaceutical industry. I welcome the incoming Democratic House Majority to join our efforts on behalf of the American taxpayers and consumers.



FDA Commissioner
SCOTT GOTTLIEB

Too many Americans struggle with the high cost of drugs. In some cases, patients go without needed medicines. This is why drug pricing is a matter of public health.



Representative
ELIJAH CUMMINGS (D-MD)

We have to bring the drug companies in here and let them explain to us that when they say they are doing R&D does that mean advertisement, does that mean giving doctors extra money to prescribe their medications? ... We have to figure all of that out, and once we do, we will figure out how to attack it.



Representative
FRANK PALLONE (D-NJ)

It's time to find workable solutions that will encourage the development of affordable and high-quality drugs and incentivize the lower prices and transparency in the pharmaceutical marketplace, while also monitoring steep prescription drug price increases when they arise.



CEO, AARP
JO ANN JENKINS

One of the main reasons prescription drug prices are so high is that pharmaceutical companies are allowed to set prices with no transparency. That's how they like it. Meanwhile, those companies spend billions on advertising and lobbying to protect their monopolies and control the price of drugs to keep charging all of us more. This has to stop.



President, The Foundation for
Research on Equal Opportunity
AVIK ROY

Nobody forces drug companies to charge high prices ... [I]n the absence of competition, manufacturers frequently charge the highest prices they believe they can justify in the court of public opinion.



the campaign for
SUSTAINABLE Rx PRICING

The Impact Of Skyrocketing Drug Costs On Everyday Americans

“**[Twenty-five million people hesitate to take their medications in order to control their medical costs.** This can lead to even worse financial outcomes as patients avoid preventive care and instead use expensive ambulance and ER care as their health worsens.”

(“NerdWallet Health Finds Medical Bankruptcy Accounts For Majority Of Personal Bankruptcies,” NerdWallet, 3/26/14)



A Pennsylvania man regularly drives from his home in Philadelphia to Canada to pick up a prescription to treat his son's immune disorder.

Since his health insurance does not cover prescription drugs, he must choose between paying \$50,000 a year for the drug from a drug discount website or paying \$15,000 a year for the same drug in Canada.

("The Price They Pay," The New York Times, 3/5/18)

An Indiana woman "had to refinance her home last year to afford ... copays for a drug to treat ... a type of blood cancer."

("Patients Who Can't Afford Medications Pin Hopes On Trump," CNN, 5/10/18)

An Army veteran in Kansas was forced to split his medications because he couldn't afford the proper regimen. "In between jobs and without insurance' he 'had to resort to dangerous measures when it came to managing his daily medications.' For months 'he couldn't afford his HIV medication, drugs that cost upward of \$2,000 each month.' 'I would skip doses or take the medicine every other day.'"

("The Costly Risks Of Not Following Prescription," Fox News, 2/13/15)

A Wisconsin family with health insurance recently "drained their savings," gave "up family vacations, and sold a motorcycle, a car, furniture and other belongings" to cover out-of-pocket costs for drugs to treat multiple sclerosis.

("The Price They Pay," The New York Times, 3/5/18)

A California man suffering from cancer decided to skip treatment because he could not afford the co-payments for the prescription drugs.

"With new cancer drugs commonly priced at \$100,000 a year or more" his "story is becoming increasingly common."

("As Drug Costs Soar, People Delay Or Skip Cancer Treatments," National Public Radio, 3/15/17)

A Minnesota man died in 2017 after he could not afford to pay for insulin.

"He didn't qualify for public health insurance programs and couldn't afford to buy coverage. But many people with health insurance are having problems paying for their diabetes supplies because so many plans require significant out-of-pocket spending before coverage kicks in."

("Her Son Couldn't Afford Insulin And Died. Now She's Fighting Big Pharma," Minnesota Public Radio, 5/11/18)

A Pennsylvania woman with "diabetes, lupus, asthma, COPD, vertigo and fibromyalgia" has to pick and choose which disease to treat at any given time.

"She doesn't take all of her medications. 'I can't afford them, and I can't get them any other way,' she says, 'so it's always a choice which do I need worse, what's hurting worse, what do I need this month, what can I handle without.'"

("Getting Around High Prescription Drug Prices," WTAJ, Accessed 6/5/18)