



Congress and President Must Act to Reduce Price of Prescription Drugs

Talk Is Cheap – Drugs Are Not!

2/25/2019

EXECUTIVE SUMMARY

In spite of a lot of talk by members of Congress and the President on the importance of making prescription drug prices more affordable, 30 drug companies announced at the beginning of 2019 price increases in the United States on more than 250 drugs. The price increases – the first of more to come in 2019 – ranged from 5% to 9.5% well above the nations rate of inflation.

Americans, Especially Seniors, Caught in Pharma's Perfect Storm

Americans, especially the 58 million Americans age 65 and older and people with disabilities on Medicare, are caught in the terrible perfect story of prescription drug price gouging. They are taking more expensive medications while living on fixed incomes. Even with their Medicare Part D prescription drug plan they are paying substantial out-of-pocket costs. This means that they especially feel the pain of pharmaceutical companies' relentless price increases while bills that would provide lower prices have not been passed by Congress.

The 62 million seniors and people with disabilities who receive Social Security have been especially harmed. Since 1992, the growth in out-of-pocket healthcare costs, including prescription drugs, has outstripped Social Security's cost-of-living adjustments by more than a third.

Total U.S. prescription sales in the 2017 calendar year were \$455.9 billion, according to a May 7, 2018 report by the American Journal of Health-System Pharmacy. On a per capita basis, inflation-adjusted retail prescription drug spending in the U.S. increased from \$90 in 1960 to \$1,025 in 2017, according to a February 14, 2018 report in Health News. In the same report, prescription drugs are expected to see the fastest annual growth over the next decade, rising an average of 6.3% per year, due to higher drug prices and more use of specialty drugs such as those for genetic disorders and cancer.

Per capita prescription drug spending in the United States exceeds that in all other countries – even 40% more than Canada for essentially the same medications – largely driven by brand-name drug prices that have been increasing in recent years at rates far beyond the Consumer Price Index (CPI).

Just because there are more drugs on the American market, that doesn't mean all patients can access them. "To think that patients have full access to a wide range of products isn't right," Aaron Kesselheim, an associate professor of medicine at Harvard Medical School, said in a May 10, 2018 article on Vox.Com. "If the drugs are so expensive that you can't afford them, that's functionally the same thing as not even having them on the market."

Price Increases for Brand-Name Drugs

Brand-name prescription drug prices have doubled between 2008 and 2016 and retail prices for some of the most popular prescription drugs older Americans take to treat everything from diabetes to high blood pressure to asthma increased by an average of 8.4% in 2017, far exceeding the 2.1% inflation rate for other consumer goods and services, according to a September 26, 2018 report from the AARP Public Policy Institute.

A September 26, 2018 Forbes article reported that the Associated Press (AP) analyzed 26,176 changes in list prices for branded drugs from 2015 through mid-September 2018 and concluded drug companies raised prices more frequently than they cut them. In fact, price increases outpaced decreases by 16.5-to-1 in June and July 2018.

In July 2018, Bloomberg introduced a tool to track what has happened to prices for some of the most widely used drugs. The prices for 40 commonly used drugs in six categories—diabetes, cancer, HIV, multiple sclerosis, asthma and chronic obstructive pulmonary disease, and autoimmune diseases such as rheumatoid arthritis and psoriasis—were compared over a three-year period. Starting from June 2015, the indexes tracked the average percent increase in drug prices through late June 2018.

For all six categories of drugs, list prices rose far faster than inflation. Prices for 10 commonly used diabetes drugs rose 25.6%, on average, while average prices for rheumatoid arthritis and other autoimmune treatments rose 40.1%. The latter category includes AbbVie Inc.'s Humira, the biggest-selling drug in the world. Prices for the injection soared 52% on five separate price increases.

Americans Want Action to Reduce Drug Prices

Americans are outraged that they are losing access to lifesaving and life-enhancing treatments because they have become less and less affordable.

Three-quarters of Americans consider the cost of prescription drugs in the United States to be “unreasonable,” despite promises from Congress and the President to rein in prices, according to poll results released on September 13, 2018 by the West Health Institute, a nonpartisan, nonprofit healthcare research organization, and conducted by NORC at the University of Chicago.

In that poll, only 16% approve of how of how Republicans in Congress are addressing high prescription drug prices and only 20% approve of what Democrats in Congress are doing to reduce drug prices. Only 23% of the public approves of how President Trump is dealing with the high cost of prescription drugs.

Also, the survey found that 82% of Americans favor allowing Medicare to negotiate directly with drug companies to get lower prices; 82% support allowing more generics to compete with name brand drugs; 80% want more transparency on pricing from drug companies; 65% want Americans to be allowed to purchase drugs from Canada, and 52% want prescription drug advertising eliminated.

“The rising cost of prescription drugs is a growing economic and public health crisis that hurts the U.S. economy and threatens individual health and financial security, and Americans want solutions. Unfortunately, they don’t feel like they’re getting them from Washington,” said Shelley Lyford, president and CEO of the West Health Institute. “Our representatives in Washington D.C. need to make lower drug prices a reality instead of simply an empty campaign promise.”

A poll conducted by Goldman Sachs (GS) Strategy Group and reported in an article in The Hill newspaper on February 5, 2018 showed 85.5% of registered voters surveyed think lowering the cost of prescription drugs should be a “top priority” or an “important priority” for Congress. The poll also showed three-fourths of registered voters think Congress and President Trump need to do more to lower the cost of drugs.

The Kaiser Family Foundation (KFF), a nonprofit, nonpartisan organization focused on health care, periodically conducts its Health Tracking Poll. Poll results released on March 23, 2018 found that approximately 80% of Americans think that the cost of prescription drugs is unreasonable, and 73% believe that pharmaceutical companies are making too much profit on their products.

Most respondents (72%) said that pharmaceutical companies have too much influence in Washington, 77% said that pharma’s profits are a major factor contributing to the high cost of drugs, and just over half had an unfavorable view of pharmaceutical companies.

Respondents said that the government should negotiate lower prices for the Medicare program (92%);

encourage generic market entry (87%); require manufacturers to disclose pricing information (86%), and allow for importation of cheaper drugs from Canada (72%). With respect to drug importation, more respondents (76%) felt confident that buying imported Canadian drugs would make medicine affordable without sacrificing quality versus buying drugs from Canadian online pharmacies (68%).

More than half of respondents (52%) said that passing legislation to bring down the price of drugs should be a top priority for Congress and President Trump.

The poll results were not unique to 2018. KFF reported poll results in March 2017 that more than half of Americans say that lowering the cost of prescription drugs is a top priority. The KFF poll in October 2016 found that 74% of responders said Congress and the President should make sure that high-cost drugs for chronic conditions are affordable to those who need them and 63% said the government should take action to lower prescription drug prices. A KFF poll of 1,800 Americans in July 2015 showed that allowing Medicare to negotiate lower drug prices is supported by 87% of Americans.

Despite the calls by Americans for actions by the 114th Congress (2015 & 2016), the 115th Congress (2017 & 2018) and two Presidential administrations nothing tangible has been done to curtail prescription drugs prices.

NRLN Advocates Legislation to Reduce Drug Prices

Since 2009 the National Retiree Legislative Network (NRLN) has aggressively advocated federal legislation to curtail rising health care cost through more competition in America's pharmaceutical market through competitive bidding by Medicare for prescription drugs and the importation of safe lower cost prescription drugs from Canada and other nations that meet Federal Drug Administration (FDA) safety standards.

The NRLN supports passage of legislation for Medicare to be directed to take competitive bids for prescription drugs and allowing importation of safe and less expensive drugs from Canada.

NRLN's Position on Prescription Drug Competitive Bidding

Members of Congress have quoted CBO studies to wrongly justify a claim that the CBO and others have said that there would be very little savings if Health and Human Services (HHS) required competitive bidding for Medicare's drug business. These are old irrelevant claims. Other than two letters written in the 2006-2007 period by two incumbent CBO Directors to Oregon Senator Ron Wyden and others, there are no published relevant studies made available to support this claim. It has been said that the Health and Human Services (HHS) Secretary would have to be authorized to set (not competitively bid) prices. In some cases, such as in chronic and fatal disease treatment drugs, this may be even more problematic today.

Total retail prescription drugs filled at pharmacies in 2017 reached 4.063 billion. Since 2007, generic drug availability has mushroomed from less than 20% of drugs dispensed in the U.S. to where today they represent around 90% of the pills, capsule and injected drug units sold. A growing number of these drugs treat the same ailments! And, a growing number will treat even more as drug patents expire. This data is not speculation or political rhetoric.

Current law bars Medicare from negotiating drug prices. This is known as the "noninterference" clause in the **Medicare Modernization Act of 2003** which stipulates that the HHS Secretary "may not interfere with the negotiations between drug manufacturers and pharmacies and PDP sponsors, and may not require a particular formulary or institute a price structure for the reimbursement of covered Part D drugs. In effect, this provision means that the government can have no role in negotiating or setting drug prices in Medicare Part D.

Medicare is required to cover nearly all drugs that the Food and Drug Administration approves. This means that Medicare must cover drugs that aren't an improvement over what currently exists, so long as the FDA finds they're safe for human consumption. Drugmakers know that as long as their products are safe, Medicare must buy them.

CNN Business reported on May 15, 2018 that the Centers for Medicare & Medicaid Services (CMS) spent \$174 billion on prescription medications in 2016, or 23% of its total budget. CMS has not updated its Drug

Spending Dashboard for 2017 or 2018. The Congressional Budget Office (CBO) estimates that spending on Medicare Part D benefits will total \$99 billion in 2019. A 2018 report by the U.S. Senate Homeland Security & Governmental Affairs Committee revealed that the Medicare program pays 61% higher prices for the 20 most commonly prescribed drugs than the Veterans Administration which negotiates for drug prices.

There is only one solution to this problem:

Congress should remove the prohibition on Medicare competitive bidding and replace it with a competitive bidding mandate to be applied wherever two or more FDA approved generic drugs, or two or more brand drugs, or a generic and brand drugs (upon patent expiration) treat the same medical condition.

The following prescription drug bills have been introduced in the 116th and one should be passed:

H.R. 275 and S. 62, Empowering Medicare Seniors to Negotiate Drug Prices Act, and H.R. 448 and S.99, Medicare Drug Price Negotiation Act. Passage of either Act, would direct the Secretary of Health and Human Services (HHS) to negotiate lower prices for prescription drugs under Medicare Part D.

NRLN's Position on Prescription Drug Importation

Countries that practice socialized medicine exact low prices for people served in their countries by demanding below market pricing from American pharmaceutical manufacturers.

As the prescription drug price gouging has taken place, tens of millions of generally law-abiding Americans have committed a technically illegal act in response by purchasing prescriptions, online or otherwise, outside the U.S. Imported pills that are subject to confiscation.

Making it legal to import medication at a lower cost, will break the stranglehold of the drug companies on the throats of American patients.

There are two counter measures to U.S. manufactures being forced to take losses:

A. Pharma companies should exit these markets, thus protecting Americans and our economy from subsidizing socialized medicine.

B. To the extent pharma and Congress don't eliminate this unethical practice of absorption and passing of losses on to Americans and the U.S. economy, Congress must pass laws allowing importation of safe, and lower priced prescription drugs from Canada and elsewhere so that Americans and our economy benefit. Start with Canada NOW.

Congress Has Failed to Pass Drug Importation Bills.

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H.R. 478 and S. 61, Safe and Affordable Drugs from Canada Act, would allow the personal importation of safe and lower priced drugs from approved pharmacies in Canada.

Pay-for-Delay on Generics Must Be Stopped

In a May 4, 2017 article in ModernHealth.Com, Dr. Scott Knoer, chief pharmacy officer of the Cleveland Clinic, said pharmaceutical companies have paid manufactures not to develop generics.

The NRLN urges Congress to pass legislation that bans pay-for-delay. The Supreme Court ruled on a single case that this practice restrained trade but that each case must be dragged through the courts for years while Americans—especially retirees—are denied access to cheaper generic drugs.

Congress should pass this bill:

S. 64, Preserve Access to Affordable Generics and Biosimilars Act, would prohibit the practice of pay-for-delay by brand name drug companies who make deals to delay or keep less expensive generic drugs off the market. In addition, it would prohibit biological product manufacturers from compensating biosimilar and interchangeable companies to delay the entry of biosimilar biological products and interchangeable biological products.

President Trump’s Plan for International Price Indexing

President Trump announced on October 25, 2018 that his administration is moving to stop “global freeloading” by foreign nations when it comes to the price that Americans pay for prescription drugs. Saying that drug companies have “rigged the system” against American consumers by charging higher prices in the U.S. than they do abroad, President Trump proposed creating an “international pricing index” as a benchmark to decide how much the government should pay for prescription drugs covered by Medicare’s Part B outpatient program.

HHS estimates the new pricing index — which the agency says would apply to 50% of the country — would save Medicare \$17.2 billion over five years. Medicare now pays the average sales price of a medicine in the United States, plus a fee based on a percentage of that price. Under the new model, Medicare would pay fees to doctors that are more closely aligned with what other countries pay.

Although President Trump called the proposal “a revolutionary change,” **it wouldn’t affect prescription drugs bought from pharmacies**. It would only apply to infused and injected drugs administered by physicians at doctor’s offices and in hospitals (some of the most expensive drugs older patients get), and only in half the country which has not been identified. It would take effect in late 2019 or 2020.

Prices of Many Generic Drugs Climb Higher

Generic drugs represent about 90% of all prescription filled and have been one of the few bargains for Americans. However, the cost savings on generics are slowing. Pharmaceutical experts have begun to notice something even more disturbing. The prices of many generic drugs that have been around for years have suddenly spiked. AARP’s Public Policy Institute found that 27% of the most widely used generics have gone up in price, in some cases into the stratosphere.

On June 13, 2017 as members of the Senate Committee on Health, Education, Labor and Pensions gathered to discuss the rising cost of prescription drugs, the prices of 14 common medications were increased by some 20% to 85%. The affected drugs would appear to be unlikely candidates for price hikes. All were generic drugs, which lack patent protection and therefore tend to be much less expensive.

NRLN Supports Funding FDA to Speed Approval of Generics

The NRLN supports providing adequate funding to clear the FDA product approval backlog of over 4,000 generics. This would make more affordable alternatives more readily available to patients.

It was reported in a July 25, 2017 Los Angeles Times article that Dr. Scott Gottlieb, head of the Food and Drug Administration, told a conference that since the FDA has no power to dictate price to drug companies the agency will focus on speeding up the approval process for generic drugs so consumers have cheaper alternatives to branded drugs. He also wants to encourage greater competition among drug companies to lower prices.

The FDA has approved more than 1,600 generic drug applications since January 2017 – about a third more than it did in 2015 to 2016. However, more than 700 (about 44%) of those generics weren’t on the U.S. market as of early January 2019, according to an analysis by Kaiser Health News. Also disgusting, 36% of generics that would be the first to compete against a branded drug are not yet for sale. That means thousands or even millions of patients have no option beyond buying branded drugs that can cost thousands of dollars per month.

Consumers pay 94% of the branded drug price on average when one generic firm enters the market, but that drops to 52% with two competitors and to 44% with three, according to an FDA analysis. The savings ripple across the health-care system, and in 2016 generics saved \$253 billion, according to a June 2017 report from the Association for Accessible Medicines.

Experts say a variety of factors are to blame. Generics sellers have fought for years against patent litigation and other delay tactics that protect brand-name drugs from competition. In recent years, vast industry consolidation has reduced the ranks of companies willing to purchase and distribute generics. And, in some cases, makers of generics obtain approvals and ultimately make a business decision to sit on them.

"It's a real problem because we're not getting all the expected competition," Gottlieb said in an interview with KHN, adding that it will be difficult to solve because it has so many causes.

A Grim Scenario

It's a grim scenario some doctors say they are all too familiar with. "As physicians, all too often we are seeing the situation where we prescribe a medication and a patient says 'doc, I just can't afford it.' We hear that all the time," says Wayne Riley, M.D., past president of the American College of Physicians.

Pharmacists are worried too, seeing the everyday effects of not being able to afford medications. Says Beverly Schaefer, RPh, co-owner of Katterman's Sand Point Pharmacy in Seattle, "More and more I'm seeing that consumers are becoming acutely aware of rising drug prices. They are stretching doses, seeking alternatives, asking more questions of their doctor and pharmacist, and sometimes refusing prescriptions or asking for a less expensive treatment option.

It's Time to Pass Bills to Reduce Prescription Drug Prices

Too many Americans are having to choose between paying for food, housing and other necessities, or try to stretch out their drug supply by cutting the prescribed dose or worse, simply going without their medicines.

Retirees, prospective retirees, and most Americans are suffering with prescription drug price gouging. This is at the expense of deferring or passing up altogether the purchase of goods and services that prop up the U.S. economy and thus federal tax revenue that sustains our country. Members of Congress cite internal opinions and old studies that defy logic and reality, and Pharma has far too much influence over public policy on this matter. It is time to change policy, to pass prescription drug importation and Medicare competitive bidding bills and to outlaw pay-for-delay and other obstructing tactics once and for all!

Retirees know that interim steps already suggested by several in Congress would not go anywhere near the realm of government price setting. Retirees also know that the high prices they are paying for prescription drugs only serves to support market entry of those same drugs into countries around the world. It is time for Congress to pass and the President to sign commonsense legislation and stand up for Americans' health and stop the prescription drug price gouging. Talk is cheap, drugs are not. There is no time to waste!



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This whitepaper was researched and written for the American Retirees Education Foundation (AREF). The AREF expands the research and education reach of the National Retiree Legislative Network (NRLN).

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Rx Savings Solution CEO Michael Rea told Reuters News Agency for a January 2, 2019 article: “Requests and public shaming haven’t worked [to lower drug prices]. We expect the number of 2019 increases to be even greater than in past years.”

The early 2019 price increases undercut President Trump’s message that he is cracking down on high drug costs. In August 2018, a number of drug-makers announced price freezes or walked back planned price increases in response to threats from the President on Twitter.

However, at the time industry insiders told the Politico newspaper that the moves by drug-makers were an easy way to give President Trump a symbolic win in the hopes of preventing any meaningful crackdown. The price increases reported in January 2019 lend credence to that analysis.

Pharma had reacted positively to a drug pricing plan unveiled by the administration in May 2018, viewing it as unlikely to have a major impact on prices. The industry began to worry, however, when the administration floated a proposal in October 2018 to tie Medicare prices of certain drugs to an international average. Some members of Congress have voiced opposition to the President’s proposal, saying it would be price fixing.

Americans, Especially Seniors, Caught in Pharma’s Perfect Storm

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AARP's study found that in 2017 the retail price of the popular brand-name drug **Lyrica**, which is used to treat fibromyalgia, a disorder characterized by widespread musculoskeletal pain, increased by 19.3%; the price of diabetes drug **Januvia** increased by 8.2%, and the price of **Benicar**, a widely used medicine for high blood pressure, increased by 17.8%.

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Another drug with an unusually big increase in the period was Bayer AG's liver cancer pill **Nexavar**, whose cost rose 51% on six separate price hikes, to \$155.59 per pill, according to Connecture. **Nexavar** now costs \$18,670 per month for patients who take the typical dose.

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Rather than go into a decade of the NRLN's efforts to reduce the cost of prescription drugs for Americans, especially retirees living on fixed incomes, a review of the bills support by the NRLN in the 114th and 115th Congresses and the past and current Presidential administrations will serve to point out their failures.

The NRLN supports passage of legislation for Medicare to be directed to take competitive bids for prescription drugs and allowing importation of safe and less expensive drugs from Canada.

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"For Medicare, the sky really is the limit," on drug prices, says Jamie Love, who has studied drug pricing and directs the Washington D.C. nonprofit Knowledge Ecology International.

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There is only one solution to this problem:

Congress should remove the prohibition on Medicare competitive bidding and replace it with a competitive bidding mandate to be applied wherever two or more FDA approved generic drugs, or two or more brand drugs, or a generic and brand drugs (upon patent expiration) treat the same medical condition.

The following prescription drug bills have been introduced in the 116th and one should be passed:

H.R. 275 and S. 62, Empowering Medicare Seniors to Negotiate Drug Prices Act, and H.R. 448 and S.99, Medicare Drug Price Negotiation Act. Passage of either Act, would direct the Secretary of Health and Human Services (HHS) to negotiate lower prices for prescription drugs under Medicare Part D.

The **Medicare Prescription Drug Price Negotiation Act** was introduced in 2015 in the 114th Congress (S.31 and H.R. 3061) and again in 2017 in the 115th Congress (S. 41 & H.R. 242) in the House and Senate and was not passed. Passage of the bill would have allowed for Medicare to negotiate the best possible price of prescription drugs. When government CBO staff last analyzed the Medicare prescription drug price negotiation proposal in 2006-2007, they estimated savings would be "negligible." That's in part due to uncertainty about what specific powers Congress would provide Medicare to have in negotiations, more importantly this study used market data that is over ten years old. NRLN original 2007 saving estimate was \$15 billion per year which would have been at approximately \$54 billion per year in 2016.

The NRLN and its members lobbied for the passage of the **Medicare Prescription Drug Price Negotiation Act** during the past two Congresses and is urging its introduction and passage in 2019 in the 116th Congress.

President Trump's plan to lower prescription drug prices announced on May 11, 2018, called "American Patients First" stops short of allowing Medicare to directly negotiate with manufacturers on prices, something he had called for on the campaign trail in 2016. Health and Human Services Secretary Alex Azar, a former Eli Lilly executive, has opposed allowing Medicare bidding for lower drug prices.

NRLN's Position on Prescription Drug Importation

Countries that practice socialized medicine exact low prices for people served in their countries by demanding below market pricing from American pharmaceutical manufacturers.

There are two counter measures to our manufactures being forced to take losses:

A. Pharma companies should exit these markets, thus protecting Americans and our economy from subsidizing socialized medicine.

B. To the extent pharma and Congress don't eliminate this unethical practice of absorption and passing of losses on to Americans and the U.S. economy, Congress must pass laws allowing importation of safe, and lower priced prescription drugs from Canada and elsewhere so that Americans and our economy benefit. Start with Canada NOW.

Congress Has Failed to Pass Drug Importation Bills

The following prescription drug bill has been introduced in the 116th and one should be passed:

H.R. 478 and S. 61, Safe and Affordable Drugs from Canada Act, would allow the personal importation of safe and lower priced drugs from approved pharmacies in Canada.

The **Safe and Affordable Drugs from Canada Act** was introduced in 2015 in the 114th Congress (S. 122 & H.R. 2228) and again in 2017 in the 115th Congress (S. 92 & H.R. 1480) in the House and Senate and was not passed. Passage of the bill would have required the Federal Drug Administration (FDA) to establish a personal importation program to allow individuals to import a 90-day supply of prescription drugs from an approved Canadian pharmacy. The **Affordable and Safe Prescription Drug Importation Act** (S. 469 & H.R. 1245) introduced on February 28, 2017 in the 115th Congress but was not passed. The bill would have instructed the secretary of Health and Human Services (HHS) to put forward regulations allowing wholesalers, pharmacies and individuals to import qualifying prescription drugs from licensed Canadian sellers. After two years, the secretary would have the authority to permit importation from countries in the Organization for Economic Co-operation and Development (OECD) with standards for the approval and sale of prescription drugs that are comparable to those in the United States.

Drug Prices USA vs. Canada

Drug	Use	USA	Canada	Difference
EpiPen	for Anaphylaxis	\$620	\$290	\$330
Crestor	for High Cholesterol	\$730	\$160	\$570
Zetia	for High Cholesterol	\$840	\$183	\$657
Premarin	for Estrogen Therapy	\$421	\$84	\$337
Abilify	for Depression	\$2,626	\$436	\$2,190
Nexium	for Heartburn	\$736	\$214	\$522
Synthroid	for Hypothyroidism	\$101	\$50	\$51
Januvia	for Diabetes	\$1,064	\$255	\$809
Celebrex	for Arthritis	\$895	\$212	\$683
Advair	for Asthima & COPD	\$980	\$212	\$768

Source: Feb. 15, 2018 - https://www.reddit.com/r/coolguides/comments/7xsqfo/drug_prices_canada_vs_usa/

The NRLN and its members lobbied for the passage of the **Safe and Affordable Drugs from Canada Act** and the **Affordable and Safe Prescription Drug Importation Act**. We are advocating the introduction the bills in 2019 in the 116th session of Congress and urging Congress to pass which of the bill that will give Americans the most relief from high prescription drug prices.

The Congressional Budget Office (CBO) analysis showed that passage of the **Affordable and Safe Prescription Drug Importation Act** would have allowed Americans to purchase lower-priced medicines from other countries and saved the federal government alone more than \$6.8 billion over ten years, including a reduction of \$5.1 billion in direct spending and roughly \$1.7 billion in increased revenue.

Drugs Are Imported Without Lower Prices for Americans

PharmacyChecker.com in an August 4, 2017 article stated its research findings showed that 70% of brand name medications sold in the U.S. pharmacies are not made in America. Its research data indicates that when Americans walk into their local pharmacy to fill a prescription, the pharmacist will mostly likely dispense an imported drug – assuming the patient can actually afford it. Around 45 million Americans — 18% of the adult population — said last year they did not fill a prescription due to cost, according to an analysis of data from the Commonwealth Fund by Gabriel Levitt, president of PharmacyChecker.com, whose company helps Americans buy medications online by vetting overseas pharmacies and comparing prices for different drugs.

The PharmacyChecker.com report, noted that the FDA states that 80% of active pharmaceutical ingredients (APIs) found in “American” drugs are imported. The FDA began using that statistic frequently in 2010, usually to note that pharmaceutical imports were growing, emphasizing the need for global engagement in its regulatory efforts.

The FDA also states that 40% of finished prescription drugs found in U.S. pharmacies were imported. PharmacyChecker.com data indicates that number is as high as 70%. The crux of the matter comes down to who controls the importation, which means distribution, of prescription drugs. The answer is the drug companies. Their control means they can protect high drug prices in America. That’s why even medications that are made in America and shipped to Canada and worldwide cost so much more in the USA because re-importation is banned – except by the drug companies themselves!

As the prescription drug price gouging has taken place, tens of millions of generally law-abiding Americans have committed a technically illegal act in response by purchasing prescriptions, online or otherwise, outside the U.S. Imported pills that are subject to confiscation.

Making it legal to import medication at a lower cost, will break the stranglehold of the drug companies on the throats of American patients.

On a positive note, HHS Secretary Alex Azar requested that the FDA establish a working group to examine how to safely import prescription drugs from other countries in an effort to address price hikes of drugs produced by a single manufacturer with no competitor product on the market. Although similar ideas have traditionally been struck down by previous administrations, Azar believes there are certain situations in which importation could make sense, citing the example of the 5000% price hike on the drug Daraprim in 2015 that made then-CEO Martin Shkreli a household name.

NRLN Supports Funding FDA to Speed Approval of Generics

The NRLN supports providing adequate funding to clear the FDA product approval backlog of over 4,000 generics. This would make more affordable alternatives more readily available to patients.

It was reported in a July 25, 2017 Los Angeles Times article that Dr. Scott Gottlieb, head of the Food and Drug Administration, told a conference that since the FDA has no power to dictate price to drug companies the agency will focus on speeding up the approval process for generic drugs so consumers have cheaper alternatives to branded drugs. He also wants to encourage greater competition among drug companies to lower prices.

The FDA has approved more than 1,600 generic drug applications since January 2017 – about a third more than it did in 2015 to 2016. However, more than 700 (about 44%) of those generics weren’t on the U.S. market as of early January 2019, according to an analysis by Kaiser Health News. Also disgusting, 36% of generics that would be the first to compete against a branded drug are not yet for sale. That means thousands or even millions of patients have no option beyond buying branded drugs that can cost thousands of dollars per month.

Consumers pay 94% of the branded drug price on average when one generic firm enters the market, but that drops to 52% with two competitors and to 44% with three, according to an FDA analysis. The savings ripple across the health-care system, and in 2016 generics saved \$253 billion, according to a June 2017 report from the Association for Accessible Medicines.

Experts say a variety of factors are to blame. Generics sellers have fought for years against patent litigation and other delay tactics that protect brand-name drugs from competition. In recent years, vast industry consolidation has reduced the ranks of companies willing to purchase and distribute generics. And, in some cases, makers of generics obtain approvals and ultimately make a business decision to sit on them.

“It’s a real problem because we’re not getting all the expected competition,” Gottlieb said in an interview with KHN, adding that it will be difficult to solve because it has so many causes.

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Commissioner Gottlieb said the agency has published an updated a list of medications that are off patent and have no competition; work to improve generic review times, and seek to “curtail gaming” of regulations by the industry that allows companies to extend patent monopolies. He said the FDA’s list could “entice competitors into the market” and ultimately lower costs. **The NRLN applaud his statements!**

Numerous reports quote that generic prescription drug unit sales have increased from about 20% of all prescription drugs sold in 2003, when the Medicare Modernization Act enabling Medicare D was passed, to around 90% in 2017. American manufactures of brand drugs are expanding their lines of products to include generic drugs and have been buying generic drug companies and generic drug companies have been merging together. This shift to generics is a far cry from the days when Medicare Part D was enacted on December 8, 2003. However, the same players are still in the game and still have control over marketing and pricing dynamics, so it should be no surprise that generic drug prices are rising at more than twice the rate of inflation.

Pay-for-Delay on Generics Must Be Stopped

In a May 4, 2017 article in ModernHealth.Com, Dr. Scott Knoer, chief pharmacy officer of the Cleveland Clinic, said pharmaceutical companies have paid manufactures not to develop generics.

The NRLN urges Congress to pass legislation that bans pay-for-delay. The Supreme Court ruled on a single case that this practice restrained trade but that each case must be dragged through the courts for years while Americans—especially retirees—are denied access to cheaper generic drugs.

Congress should pass this bill:

S. 64, Preserve Access to Affordable Generics and Biosimilars Act, would prohibit the practice of pay-for-delay by brand name drug companies who make deals to delay or keep less expensive generic drugs off the market. In addition, it would prohibit biological product manufacturers from compensating biosimilar and interchangeable companies to delay the entry of biosimilar biological products and interchangeable biological products.

S. 124, Preserve Access to Affordable Generics Act of 2017 would have expand consumers’ access to the cost-saving generic drugs and increased competition between drug manufacturers to end “pay for delay”

deals—the practice of brand-name drug manufacturers using anti-competitive pay-off agreements to keep more affordable generic equivalents off the market.

S. 974 and H.R.2212, Creating and Restoring Equal Access to Equivalent Samples (“CREATES”) Act of 2017 would have targeted abusive delay tactics that are being used to block entry of affordable generic drugs. **S. 974** was passed by the Senate Judiciary on June 21, 2018 but never received a vote on the Senate floor. H.R. 2212 was introduced on April 27, 2018 and referred to the House Energy and Commerce Committee’s Subcommittee on Health. It never received a vote in the subcommittee.

Other Bills the NRLN Has Supported

Other bills to reduce the high cost of prescription drugs that the **NRLN supported in the 115th Congress in 2017 and 2018 included:** (Those with an asterisk were introduced in both the House and Senate)

- S. 124, Preserve Access to Affordable Generics Act
- S. 297*, Increasing Competition in Pharmaceuticals Act
- S. 771*, Improving Access to Affordable Prescription Drugs Act
- S. 974*, Creating and Restoring Equal Access to Equivalent Samples (CREATES) Act of 2017
- S. 1348, Stopping the Pharmaceutical Industry From Keeping Drugs Expensive (SPIKE) Act of 2017
- S. 1688, Empowering Medicare Seniors to Negotiate Drug Prices Act of 2017
- S. 2011*, Medicare Drug Price Negotiations Act
- H.R. 749*, Lower Drug Costs Through Competition Act
- H.R. 934, Personal Drug Importation Fairness Act of 2017
- H.R. 1316, Prescription Drug Price Transparency Act
- H.R. 2051, FAST Generics Act of 2017
- H.R. 2212*, Creating and Restoring Equal Access to Equivalent Samples (CREATES) Act of 2017
- H.R. 4116, Transparent Drug Pricing Act of 2017
- H.R. 4117, Competitive Drugs Act of 2017
- H.R. 4138*, Medicare Drug Price Negotiations Act

Other bills to reduce the high cost of prescription drugs that the **NRLN supported in the 114th Congress in 2015 and 2016 included:** (Those with an asterisk were introduced in both the House and Senate.)

- S. 131 – The Fair and Immediate Release of Generic Drugs Act of 2015
- S. 648 – The Medicare Formulary Improvement Act of 2015 of 2015
- S. 1790 – The Safe and Affordable Prescription Drugs Act of 2015
- S. 1884* – The Medicare Prescription Drug Savings and Choice Act of 2015
- S. 2023* – The Prescription Drug Affordability Act of 2015
- S. 2019 – The Preserve Access to Affordable Generics Act of 2015
- H.R. 2623 – The Personal Drug Importation Fairness Act of 2015
- H.R. 3261* – The Medicare Prescription Drug Savings and Choice Act of 2015
- H.R. 3513* – The Prescription Drug Affordability Act of 2015

HHS Secretary Already Has Authority to Import Canadian Drugs

The NRLN has pointed out in letters to Congressional leaders, President Trump and HHS Secretary Alex Azar that the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 gave the Secretary of HHS the authority to issue an order to begin legal importation from Canada but the power has not been exercised. Members of Congress should write letters to President Trump and Secretary Azar urging him to authorize the importation of safe, lower priced drugs from our northern neighbor. The Secretary should be ordered to do so by President Trump.

Pharma's Influence with Members of Congress

Many members of Congress appear to be accountable only to the pharmaceutical industry's huge sums of money for campaign contributions and lobbying. Many Representatives and Senators feign concern so as to sound like they care, then they take a snooze.

Will Congress take action to lower prescription drug costs, the fastest growing part of the nation's health care budget? As a whole, members of Congress have to prove they are not bound by obligations to pharmaceutical and insurance companies more than their own constituents. **There's nowhere to hide now, it's time to fix it.**

Could it be that numerous members of Congress are being overly influenced by the pharmaceutical and health products industry? According to reports in OpenSecrets.Org, Center for Responsive Politics, the pharmaceuticals and health products industry contributed \$25.6 million in campaign and leadership PAC contributions to House and Senate incumbents and challengers in the 2018 mid-term election cycle. The industry also spent \$216.1 million lobbying in Washington, DC in 2018.

Drug companies seek to maintain their influence and access in the Capitol with campaign contributions and platoons of lobbyists recruited from both parties, according to an October 20, 2018 article in the New York Times.

"Drug companies have been in such a strong position, and they have contributed so generously to people in both parties, they've been pretty well able to block anything," Representative Lloyd Doggett (TX-35) said in the Times article.

Although House Speaker Paul Ryan (WI-01) and Utah Senator Orrin Hatch, Chairman of the Senate Finance Committee where most prescription drug bills were assigned in the Senate, had announced they would retire at the end of the 115th Congress, in the 2017-18 campaign cycle Speaker Ryan received \$228,400 and Chairman Hatch received 238,289 from the pharmaceutical and health products industry, according to OpenSecrets.Com.

In the four 2-year campaign cycles from 2011 through 2018, Speaker Ryan received a total of \$944,416 and Senator Hatch received a total of \$1,060,786 from the pharmaceutical and health products industry, according to OpenSecrets.Com.

Nancy Pelosi (CA-12), the House Speaker for the 116th Congress, received a total of \$135,726 and Iowa Senator Chuck Grassley, who is now the Chairman, Senate Finance Committee, received a total of \$238,880, in the four 2-year campaign cycles from 2011 through 2018, according to OpenSecrets.Com.

In the House, most prescription drug bills are referred to the Ways and Means Committee and/or the Energy and Commerce Committee. As Americans' voices became louder for legislation to address the high prices of prescription drugs and more bills were introduced in the 114th Congress and 115th Congress the pharmaceutical and health products Industry became more generous with its campaign and leadership PAC contributions to the leaders of the two committees.

Election Cycle - Incumbents	2011-2012 112th Congress	2013-2014 113th Congress	2015-2016 114th Congress	2017-2018* 115th Congress	Total
Rep. Kevin Brady (TX-08), Chair, Ways & Means Committee, 2015 - 2018, Ranking Member, 2019-2020	\$54,000	\$126,332	\$258,451	\$287,350	\$726,133
Rep. Richard Neal (MA-01), Ranking Member, Ways & Means Committee, 2017-2018; Chair, 2019-2020	\$102,573	\$101,949	\$103,200	\$252,750	\$560,472
Rep. Greg Walden (OR-02), Chair, Energy & Commerce Committee, 2016-2018, Ranking Member, 2019-2020	\$97,894	\$125,998	\$179,900	\$414,700	\$818,492
Rep. Frank Pallone (MA-01), Ranking Member, Energy & Commerce Committee, 2015-2018; Chair, 2019-2020	\$176,559	\$172,072	\$271,876	\$204,852	\$825,359

*Pharmaceutical & Health Products Industry Campaign and Leadership PAC Contributions from OpenSecrets.Org, Center for Responsive Politics based on data from the Federal Election Commission. 2018 data through Nov. 13, 2018.

It is time for Representatives and Senators to choose, to side with constituents who can't afford their prescription drugs.

As Drug Prices Increase, Quality of Life Goes Down

A Consumer Reports national telephone poll of more than 2,000 adults found that three-quarters of all Americans and 90% of seniors on Medicare, during any month, currently take a prescription drug and on average take six prescription drugs. It found that nearly one-third of people experienced a price hike in the last year on at least one of their medications.

The problem with forking over the additional cash is that it hurt people in other ways. People were more likely to stop taking their medication; they also skipped filling prescriptions, or didn't take the prescribed dosage; split pills without contacting their doctor or pharmacist first, took expired meds or even shared prescription drugs from other people.

Sometimes, the cutbacks weren't limited to refills and dosages. Desperate to afford their prescriptions, the survey found that people sacrificed in other potentially detrimental ways. They skimped on groceries. They also reported relying more heavily on credit cards and putting off paying other bills.

And where people were dealing with high drug costs, other financial setbacks weren't far behind. More than one out of four people whose drug costs spiked also reported experiencing a costly medical event. They were also more likely than those not facing higher costs to report that they couldn't afford medical bills, missed major bill payments, or even lost their health coverage.

A Grim Scenario

It's a grim scenario some doctors say they are all too familiar with. "As physicians, all too often we are seeing the situation where we prescribe a medication and a patient says 'doc, I just can't afford it.' We hear that all the time," says Wayne Riley, M.D., past president of the American College of Physicians.

"Patients and the general public are bewildered and extremely frustrated. More needs to be done to stem the rise in prescription drug prices and costs to patients," Riley added.

Pharmacists are worried too, seeing the everyday effects of not being able to afford medications. Says Beverly Schaefer, RPh, co-owner of Katterman's Sand Point Pharmacy in Seattle, "More and more I'm seeing that consumers are becoming acutely aware of rising drug prices. They are stretching doses, seeking alternatives, asking more questions of their doctor and pharmacist, and sometimes refusing prescriptions or asking for a less expensive treatment option.

In a June 20, 2017 opinion piece in *The Hill* newspaper by David Merritt, executive vice president of public affairs and strategic initiatives for America's Health Insurance Plans, wrote, "Drug prices are not set by the market forces of supply and demand – they are set solely by pharmaceutical companies. The simple truth is, excessive prices raise costs for everyone. More than 22 cents of every dollar spent on insurance premiums goes to pay for prescription drugs – the largest component of insurance costs. So, when the price of prescription drugs goes up, so too does the cost of the insurance that pays for them. It's common sense."

He added, "But no one is holding the pharmaceutical industry accountable for its pricing. Perhaps that's why drug companies see average profit margins that are nearly eight times larger than health insurance plans. Perhaps that's why price hikes accounted for 100% of Big Pharma's earnings growth in 2016.

"Pharmaceutical companies make life-saving medications and breakthrough cures. But it does not give them the right to game the system and gouge hardworking Americans."

U.S. Drug Prices Are Higher Than in Rest of World

In an opinion piece in *The Hill* on January 19, 2018, Dr. Anupam B. Jena, the Ruth L. Newhouse associate professor of health care policy at Harvard Medical School and a faculty research fellow at the National Bureau of Economic Research, wrote, "Americans pay prices for prescription drugs that are two to six times the rest of the world, despite having personal incomes that are on par with many developed countries. For instance, the average price for **Humira** — a top-selling drug to treat rheumatoid arthritis — is nearly \$2,700 per administration in the U.S., more than twice the price in the U.K."

(Scroll Down to USA vs World on Drug Prices)

Medication	Cost Per Pill or Unit		Savings
	USA	Outside U.S.	
Premarin (0.625 mg)	\$6.72	\$0.18 ** United Kingdom	97%
Januvia (100 mg)	\$16.59	\$0.81 ** Turkey	95%
Eliquis (5 mg)	\$8.06	\$1.18 Turkey	95%
Advair Diskus (3 inhalers)	\$1,102.62	\$78.95 ** Turkey	93%
Janumet (50/1000 mg)	\$8.54	\$0.63 ** India	93%
Flovent HFA (3 inhalers, 110 mcg)	\$781.00	\$59.80 ** United Kingdom	92%
Symbicort Inhaler (1 inhaler, 160/4.5 mcg)	\$334.00	\$27.09 ** New Zealand	92%
Vesicare (10 mg)	\$13.14	\$1.12 ** Turkey	91%
Viagra (100 mg)	\$66.50	\$6.17 ** New Zealand	91%
Xarelto (20 mg)	\$16.17	\$1.68 Turkey	90%
Spiriva Handihaler (1 pack, 18 mcg)	\$398.00	\$1.68 ** Turkey	90%
Nuvaring (1 ring, 0.12/0.015 mg)	\$168.94	\$21.30 Turkey	87%
Cialis (5 mg)	\$13.56	\$3.00 ** Turkey	78%
Truvada (200/300 mg)	\$63.53	\$16.11 ** Turkey	75%
Dexilant (60 mg)	\$10.32	\$2.56 Canada	87%
Enbrel (1 carton, four 50 mg)	\$5,008.30	\$1,720.00 Canada	66%
Ventolin HFA (1 inhaler, 18 g of 90 mcg)	\$57.00	\$22.95 ** United Kingdom	60%

*Sources: Price information collected November 2017, U.S. prices from “average retail price” listed on GoodRX.com; Outside U.S. prices are lowest prices listed on PharmacyChecker.com from licensed Pharmacies that sell to Americans and meet the qualifications of the PharmacyChecker Verification Program.

**Generic version(s) available at lower price(s) than listed here.

President Trump’s Plan for International Price Indexing

The above chart reflects why President Trump announced on October 25, 2018 that his administration is moving to stop “global freeloading” by foreign nations when it comes to the price that Americans pay for prescription drugs. Saying that drug companies have “rigged the system” against American consumers by charging higher prices in the U.S. than they do abroad, President Trump proposed creating an “international pricing index” as a benchmark to decide how much the government should pay for prescription drugs covered by Medicare’s Part B outpatient program.

HHS estimates the new pricing index — which the agency says would apply to 50 percent of the country — would save Medicare \$17.2 billion over five years. Medicare now pays the average sales price of a medicine in the United States, plus a fee based on a percentage of that price. Under the new model, Medicare would pay fees to doctors that are more closely aligned with what other countries pay.

Although President Trump called the proposal “a revolutionary change,” it wouldn’t affect prescription drugs bought from pharmacies. It would only apply to infused and injected drugs administered by physicians at doctor’s offices and in hospitals (some of the most expensive drugs older patients get), and only in half the country which has not been identified. It would take effect in late 2019 or 2020. The drug industry and some members of the President’s party in Congress oppose the “international pricing index” as price fixing.

Pharma’s Research and Development Spending

Pharmaceutical companies spent \$71.4 billion in 2017 on drug research and development. The FDA approved 46 new drugs in 2017.

A March 2, 2017 article titled *R&D Costs for Pharmaceutical Companies Do Not Explain Elevated U.S. Drug Prices* reported on Health Affairs’ empirical testing of Pharma’s claim that the higher prices they charge in the U.S. provide them with the funds they need to conduct their high-risk research. “We found that the premiums pharmaceutical companies earn from charging substantially higher prices for their medications in the U.S. compared to other Western countries [two to five times the prices in Europe] generates substantially more than the companies spend globally on their research and development. This finding counters the claim that the higher prices paid by U.S. patients and taxpayers are necessary to fund research and development.

Drug companies spend up to twice as much or more on marketing and promoting their products—including advertising—as they do on research and development. That’s according to an analysis published in the *Annals of Internal Medicine* in March 2016. Says Wayne Riley, M.D., immediate past president of the American College of Physicians (ACP), one of the largest physician groups in the U.S. and the organization that did the review: “Pharmaceutical companies may price drugs at will, and in truth, it’s not clear what that price is based on.”

In addition, American taxpayers shouldered a substantial burden of those costs. About 38% of all basic science research is paid for with tax money through federal and state governments, according to a 2015 study published in the *Journal of the American Medical Association*.

An academic study shows, big pharmaceutical companies have spent more on share buybacks and dividends in a recent 10-year period than they did on research and development. The working paper, published on July, 13, 2017 by the Institute for New Economic Thinking, is entitled “U.S. Pharma’s Financialized Business Model.”

The paper’s five authors concluded that from 2006 through 2015, the 18 drug companies in the Standard & Poor’s 500 index spent a combined \$516 billion on buybacks and dividends. This exceeded by 11% the companies’ research and development spending of \$465 billion during these years.

The drug industry doesn’t play by the same rules as any other market, where exorbitant prices dissuade customers, says Kevin Riggs, M.D., a researcher at the Johns Hopkins University, where he focuses on health care costs. “A drug company can increase the price of a product many times over, and people will still buy it because they need it,” he says. “At the end of the day, they largely charge whatever the market will bear—and with lifesaving medication, that’s a lot.”

Many policy makers have expressed concerns about government involvement in this issue because it establishes a precedent in government-set price controls that are antithetical to America’s free market system. **The NRLN strongly believes in our country’s free market system. Nonetheless, there are many steps that Congress could consider in the area of pharmaceutical drugs that fall well short of government price setting that would be highly appropriate.** Keep in mind that we are talking about prescription drugs and not discretionary consumer products like televisions and smartphones.

Prices of Many Generic Drugs Climb Higher

Generic drugs represent about 90% of all prescription filled and have been one of the few bargains for Americans. However, the cost savings on generics are slowing. Pharmaceutical experts have begun to notice something even more disturbing. The prices of many generic drugs that have been around for years have suddenly spiked. AARP's Public Policy Institute found that 27% of the most widely used generics have gone up in price, in some cases into the stratosphere.

On June 13, 2017 as members of the Senate Committee on Health, Education, Labor and Pensions gathered to discuss the rising cost of prescription drugs, the prices of 14 common medications were increased by some 20% to 85%. The affected drugs would appear to be unlikely candidates for price hikes. All were generic drugs, which lack patent protection and therefore tend to be much less expensive.

One drug, which saw an 85% increase in its price, is used to treat tuberculosis. An anti-seizure drug's price rose 63%. A drug for attention-deficit hyperactivity disorder was increased by 47%. Between 2010 and 2015, more than 300 generic drugs had at least one "extraordinary" price increase of 100% or more, according to a Government Accountability Office report in 2016.

"Unfortunately, it's becoming clear that we can no longer rely on decreases in generic drug prices to offset unrelenting price increases for brand name and specialty drugs," Leigh Purvis, AARP Public Policy Institute director of health services research, said in a statement. Purvis added, "This shift has serious implications for older adults and the entire health care system."

Wayne Riley, M.D., immediate past president of the American College of Physicians (ACP), one of the largest physician groups in the U.S. said in a Consumer Report article, "It's those huge price hikes in everyday drugs that are having the greatest impact on consumers. Patients who have been taking generics for years are suddenly finding that their medication is unaffordable."

Why are some generics, including pills that have been around for decades, suddenly so expensive? An important reason is that mergers and acquisitions in the generic drug industry have reduced the number of competitors. For example, between 2002 and 2013 the number of manufacturers making **Oral Digoxin**, a heart drug, fell from eight to three and the cost soared by 637%. Other competitors can enter the market but it can take a year or more to get Food and Drug Administration approval to make a generic and to ramp up manufacturing. Until then, prices can remain high. Pay-for-delay in bringing generic drugs to the market remains an issue.

One of the most egregious examples is **Plavix**, an anticlotting medication prescribed to prevent stroke. When the patent was challenged, the company that makes the drug agreed to pay a generic manufacturer tens-of-millions of dollars not to enter the market. The U.S. Supreme Court has ruled that brand-name drug makers can be sued for violating antitrust laws if they make a deal to pay a potential competitor to delay selling a generic version of a brand-name medicine. The high court's opinion stated that "large and unjustified reverse payments" [pay-for-delay] from a brand-name to a generic drug company can trigger an antitrust lawsuit. The outcome of each lawsuit will depend on the facts in the case.

"We know that branded companies are using our rules that are intended to protect consumers, or meant to make the regulatory process more predictable, and taking advantage of these rules in order to deliberately forestall the entry of expected generic drug competition," FDA Commissioner Dr. Scott Gottlieb said at the "Hatch-Waxman Amendments: Ensuring a Balance Between Innovation and Access" meeting on July 18, 2017.

The Truth in Rx website states that many patients rely on generic drugs as an affordable option for their medication needs. They expect when a generic version becomes available for a brand name drug, its price will be lowered and continue to offer them cost savings over time. In reality, generic drug prices can shoot back up, sometimes surpassing the cost of the brand name medication. The expectation of generic drugs being inexpensive relies on reasonable competition in the marketplace. When one-third of generic drugs are produced by three or fewer manufacturers, there is nothing stopping pharmaceutical companies from indiscriminately raising the price, even for generic drugs that have been available for decades.

Investigation of Generic Drugs ‘Cartel’

A December 9, 2018 Washington Post article reported what started as an antitrust lawsuit brought by states over just two drugs in 2016 has exploded into an investigation of alleged price-fixing involving at least 16 companies and 300 generic drugs, according to Joseph Nielsen, an assistant attorney general and antitrust investigator in Connecticut who has been a leading force in the probe.

“This is most likely the largest cartel in the history of the United States,” Nielsen said. He cited the volume of drugs in the schemes, that they took place on American soil and the “total number of companies involved, and individuals.”

In just one instance of extraordinary cost spikes, the price of a decades-old drug to ease asthma symptoms, **Albuterol**, sold by generic manufacturers Mylan and Sun, jumped more than 3,400%, from 13 cents a tablet to more than \$4.70. The example is documented in a lawsuit brought against the generic industry by grocery chains, including Kroger.

“Everyone is paying the price,” Nielsen said. He offered a single word to explain the behavior: “Greed.”

While precise estimates of alleged overcharges have not been released, generic-industry sales were about \$104 billion in 2017. Excessive billings of even a small fraction of annual sales over several years would equal billions of dollars in added costs to consumers, according to investigators.

Generic manufacturers reject the accusations. They contend officials lack evidence of a conspiracy and have failed to prove anti-competitive behavior.

But investigators say voluminous documentation they have collected, much of it under seal and not available to the public, shows the industry to be riddled with price-fixing schemes. The plaintiffs now include 47 states. The investigators expect to unveil new details and add more defendants in coming months, which will put more pressure on executives to consider settlements, according to the Post article.

“It’s particularly ironic since the whole idea of generic drugs was we would get a lower price,” said Henry Waxman, the Democratic former California Congressman who co-wrote the 1984 law establishing the Food and Drug Administration’s rules for generics. “If generic versions are higher than need be through rigged systems, that undercuts the whole idea.”

Generics account for 90 percent of the prescriptions written in the United States but just 23% of costs, according to the industry trade group, the Association for Accessible Medicines. But for some generic manufacturers, the anti-competitive agreements drove up prices on most, if not all, of the products they sold, according to the states.

Officials say they have documented price increases of up to 2,000%. Throughout 2013 and 2014, soaring generic prices sparked consternation at drugstores and among state and federal lawmakers. Independent pharmacists said they were dismayed to learn of the price-fixing allegations.

“It makes me angry,” said Eric Belldina, an operator of pharmacies in Masontown and Morgantown in West Virginia. “Most people think when their prices go up it’s because of a raw-ingredient shortage, not thinking the companies are sitting down, saying, ‘Hey, let’s do this.’”

Old Drugs Are Reformulated as Costly New Drugs

There are several tactics name brand drug companies use to maintain their market share. They can employ what’s known as “evergreening,” where branded manufacturers develop a slightly different version of their drug to earn a new drug approval, which extends their patent without leaving a window to obtain samples for bioequivalence testing needed for generic drug approvals. Certain branded drug developers seek approval for their drugs to treat a rare disease and benefit from orphan drug exclusivity rights.

According to Consumer Reports, reinventing old medications can take the form of creating an extended-release version, or change the delivery method—for example, instead of a tablet or an injectable, the new version is inhaled. When that happens, the federal government may grant the drug company a new patent, which could be worth up to 20 years of protection for its drug, meaning it may not have any generic drug competitors during that period of time. That can translate to greater revenue for a pharmaceutical company and higher costs for the consumer.

George Slover, senior policy counsel for Consumers Union, the advocacy arm of Consumer Reports, said, “Evergreening keeps drug prices high for consumers because it makes it harder for lower-cost generic alternatives to enter the market and give consumers a choice.”

Consider if Apple decided to charge \$10,000 for a 20-year-old computer. What if Samsung priced a 20-year-old TV at \$6,000 and cited the “high cost of innovation?” It would be ridiculous not because their costs of innovation aren’t high—but because it’s understood that consumers, in a free market, have no need to accept unaffordable prices.

A decade ago, consumers were on the verge of getting a lower-priced, generic version of the brand name antibiotic **Doryx** (doxycycline). But the drug’s manufacturer, Warner Chilcott, stopped making the drug in its original capsule form and instead began producing it as a tablet. This seemingly minor change meant that generic manufacturer, Mylan, was blocked from being able to market the matching generic tablet it had been developing.

That tactic, called “product hopping,” is a strategy drug makers have been using in recent years to stall the development of generic versions of a medication so they can keep brand-name drug prices high. But it is coming under fire from the Federal Trade Commission and several consumer groups, which charge it’s a violation of antitrust law that bilks consumers of millions of dollars in high drug prices.

People are far more likely to fill an inexpensive generic prescription because skyrocketing drug prices and insurance fees have made brand-name medicines increasingly unaffordable.

Christopher Kelly, a spokesperson for the Federal Drug Administration, told Consumer Reports the “FDA doesn’t have a way to control what a company ultimately decides to charge under our present authorities.” Kelly noted that the FDA pays particular attention to new generic drug applications from companies that would prevent shortages of medically necessary drugs. But “the pricing and decisions that companies make regarding pricing is an area currently outside FDA purview, and we have no enforcement capability in this area.”

Pharmacy Benefit Managers Raise Prices

A November 26, 2018 article in the Washington Post examined the role of Pharmacy Benefit Managers (PBMs) in increasing the cost of prescription drugs. Health plans pay their PBMs based on the extent of the discount that a PBM can negotiate with individual drug companies. In theory, this should encourage the PBM to drive prices down. After all, entities should bargain hard when their pay is tied to how much of a discount they can negotiate.

The problem is that drug companies raised their prices so they could give a greater discount. This increases how much of a “discount” the PBM can claim to have negotiated, and the payout to the PBM. It is a little like a department store raising prices right before a sale so the sale discount looks more appealing.

All of this might not be so bad if no one paid the high list price. But many people do. Many plans make patients pay full drug costs until they meet their deductible, and other plans require coinsurance — both of which are based on the list price. Many people still do not have coverage for prescription drugs, even if they have health insurance. Thus, people are forced to pay the full price at various times. Worse yet, the entire structure encourages drug companies to compete not by cutting prices but by offering higher prices.

Pharmaceutical companies offer the same types of rebate deals to hospitals, to clinics that administer medication and to doctors who deliver medication such as injections or infusions in their offices. The hospital or other facility charges the patient a higher list price and then receives a rebate later from the drug company, ultimately pocketing the difference. And they also provide other types of payments under labels like “administrative fees” and “data fees.”

A Health Affairs article on July 31, 2018 cited the 2017 Economic Report on U.S. Pharmacies and Pharmacy Benefit Managers, within the PBM industry, approximately 70–75% of all prescription claims are handled by the top three PBM companies: Express Scripts, CVS Caremark, and OptumRx. Total profits for the “big three” were a little more than \$17 billion. When the remaining smaller players were added the total was an estimate of \$22.6 billion in gross profits for the PBMs.

PBMs pass the rebates directly to insurance companies and some businesses that contract with the PBM. The health plans use their cut for anything they want. Very little, if any, of that money, goes to the patients whose prescriptions make the rebate revenue happen. The PBMs and insurers make the sickest patients pay between 30% and 100% of the retail (not rebated price) of medicines depending on the drug plan.

Additionally, the PBMs set up the drug benefit to maximize these rebates. That is, it will cover drugs that generate more rebates and discourage patients from taking others that produce less profit. That’s a big reason why many sick people must fail on one or more drugs before being able to get a drug that works covered.

Robert Goldberg, PhD is Vice President of the Center for Medicine in the Public Interest, “Unless we end the rigged system of rebates, insurers, PBMs and drug companies will find themselves threatened with more government regulation. PBMs deserve the criticism they are receiving but every industry is involved. It’s time for them to stop manipulating drug benefits for their own self-interest. Our health and lives depend on it.”

PBMs say they share the rebates with employers and health plans, and insurers claim that money helps limit premium price hikes. But that often isn’t the case, said James Robinson, director of the Berkeley Center for Health Technology.

"In most cases, the value of the rebate goes to the PBM, which shares it with clients and does not go to the patient," he said. "Then you have a situation where specialty drug prices are higher and the sickest patients are paying the most."

PBMs benefit from both the rebate model and gag clauses because they make money off the status quo, said Kenneth Thorpe, a professor of health policy at Emory University.

Express Scripts Looks to Limit Rebate Model

Modern Healthcare article on November 13, 2018 reported that Express Scripts will push patients, employers and insurers in 2019 to switch to lower-cost generic drugs rather than rebated brand-name drugs as it tries to wean off of the rebate model.

Express Scripts will add approved lower-cost generics to its National Preferred Flex Formulary and exclude the branded drug, and possibly other drugs in the therapy class, from its coverage. Cash-paying patients can have immediate access to lower-priced medications while employers and health plans can still choose between the lower-priced option or the original brand, the company said.

Trump Administration Targeting PBMs Rebate Game

An October 23, 2018 Forbes article reported the Trump administration is seeking to end the PBM rebate game. On July 18, 2018, the U.S. Department of Health and Human Services submitted to the White House a proposed rule entitled “Removal of Safe Harbor Protection for Rebates to Plans or PBMs Involving Prescription Pharmaceuticals and Creation of New Safe Harbor Protection.”

While the exact contents of HHS’ proposed rule remain unknown, it’s clear that HHS Secretary Alex Azar aims to disrupt the rebate ecosystem and refocus PBMs on what should be their true mission: driving a hard bargain with drug companies so that patients can gain access to life-extending medicines with the lowest possible cost.

PBMs enjoy a “safe harbor” from federal anti-trust rules and other regulations that allow them to extract these rebates from drug companies. Azar and President Trump seek to change that.

Legislation Signed Prohibiting ‘Gag Clauses’ for Pharmacies

President Trump signed into law on October 10, 2018 bipartisan legislation passed by Congress to eliminate what are known as pharmacy “gag clauses,” where pharmacists are forbidden from telling consumers they could get a less expensive medicine by buying it without using their health insurance. The law kicked in immediately for private insurance and will take effect for Medicare Advantage and Medicare Part D plans in 2020.

The Trump administration also has proposed increasing price transparency in prescription drug advertisements. There has been pushback from the pharmaceutical industry and some members of Congress.

Employer Health Benefits Declining for Retirees

Planning for retirement is tough enough, and it gets even tougher when promised retirement health care benefits from a former employer are changed or eliminated. According to an April 14, 2016 Reuters article, a growing number of U.S. employers are capping their risk of rising health insurance costs by sending retirees into private exchanges to buy coverage - often with little advance warning.

Two-thirds of employers provided retiree health coverage as recently as 1988, according to the Kaiser Family Foundation. This was usually supplemental coverage to pay for prescription drugs, cap out-of-pocket expenses or to cover Medicare’s deductibles and co-pays. By 2016 that number had dwindled to just 23%.

Among the employers that still cover retirees, a growing number are shifting retirees into insurance exchanges. Similar to a shift from a defined benefit to a defined contribution, the expense risk is shifted from employer to retiree.

Aon Hewitt, a consulting firm that operates exchanges for employers, reports that 35% of public and private sector employers are using healthcare exchanges for all or some of their Medicare-eligible retirees. Of those that are not, 17% say they will do so in the future, and another 46% are considering it.

Aon data shows that 59% of companies sending retirees into exchanges do not index the subsidy; 28% index at their own discretion and only 13% automatically adjust the subsidy amount annually.

It's Time to Pass Bills to Reduce Prescription Drug Prices

Too many Americans are having to choose between paying for food, housing and other necessities, or try to stretch out their drug supply by cutting the prescribed dose or worse, simply going without their medicines.

Retirees, prospective retirees, and most Americans are suffering with prescription drug price gouging. This is at the expense of deferring or passing up altogether the purchase of goods and services that prop up the U.S. economy and thus federal tax revenue that sustains our country. Members of Congress cite internal opinions and old studies that defy logic and reality, and Pharma has far too much influence over public policy on this matter. It is time to change policy, to pass prescription drug importation and Medicare competitive bidding bills and to outlaw pay-for-delay and other obstructing tactics once and for all!

Retirees know that interim steps already suggested by several in Congress would not go anywhere near the realm of government price setting. Retirees also know that the high prices they are paying for prescription drugs only serves to support market entry of those same drugs into countries around the world. It is time for Congress to pass and the President to sign commonsense legislation and stand up for Americans' health and stop the prescription drug price gouging. Talk is cheap, drugs are not. There is no time to waste!