AREF

American Retirees Education Foundation

NRLN NATIONAL RETIREE LEGISLATIVE NETWORK

Congress and President Must Act to Reduce Price of Prescription Drugs

Talk Is Cheap – Drugs Are Not!

5/1/2020

EXECUTIVE SUMMARY

For all the bipartisan talk on drug prices by members of Congress and by the President, there has been little, or nothing done to stem the increases in prescription drug prices and lower out-of-pocket costs. Prices were increased on 500 medications on January 1, 2020. On average, the increase was about 5%, well above the projected 2020 rate of inflation of 2.1 to 2.3% and the actual 1.8% inflation rate in 2019.

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

Americans, especially the 64 million Americans age 65 and older and people with disabilities on Medicare, are caught in the terrible perfect storm 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 enacted.

The 69 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 calendar year 2018 totaled $476.2 billion (latest data available) and were projected to grow by 5.4% in 2019 according to data by the U.S. National Library of Medicine National Institute of Health. Americans spend the most of any country on prescription drugs.

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 for some of the most popular prescription drugs older Americans take to treat everything from diabetes to high blood pressure to asthma have doubled between 2008 and 2019.The skyrocketing cost of brand-name prescription drugs in the U.S. can be blamed primarily on price increases, not expensive new therapies or improvements in existing medications as drug companies frequently claim, a study shows. The study published in the March 2020 issue of the Journal of the American Medical Association, found that the cost of brand-name oral prescription drugs rose more than 9% a year from 2008 and 2016, while the annual cost of injectable drugs rose more than 15%.

"The main takeaway of our study should be that increases in prices of brand-name drugs were largely driven by year-over-year price increases of drugs that were already in the market," says Inmaculada Hernandez, an

assistant professor of pharmacy at the University of Pittsburgh, and the lead author of the study.

The researchers used the wholesale acquisition cost data for more than 27,000 prescription drugs. They then compared new and existing drugs and separated the data into brand-name, generic and specialty categories to come up with cost increase estimates.

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.

The Kaiser Family Foundation Health Tracking poll released on November 20, 2019 reported support for the following:

- Cost of prescription drugs is unreasonable (79%)
- Pharmaceutical companies have too much influence in Washington, DC (72%)
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- Bi-partisan majorities support two other Medicare changes:
- Placing an annual limit on out-of-pocket drug costs for Medicare beneficiaries (76%)
- Lowering what Medicare pays based on prices in other countries (65%)

Among seniors, nearly all of whom are covered by Medicare, the majority support the following:

- Allowing the government to negotiate prices (82%),
- Setting an out-of-pocket spending limit (68%)
- Setting prices based what people in other countries pay (60%)

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. It has recommended 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.

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 supported by the NRLN in the 116th Congress

and current Presidential administration will make the NRLN's point.

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 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.

Current law bars Medicare from negotiating drug prices. This is known as the "noninterference" clause in the **Medicare Modernization Act of 2003** (MMA) which stipulates that the HHS Secretary "may not interfere with the negotiations between drug manufacturers and pharmacies, 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.

The MMA non-interference clause adopts the drug and healthcare insurance industries' for-profit Price Benefit Manager (PBM) business model into a public non-profit dynamic and guarantees higher prices. The Obama administration, AARP and the AFL-CIO sacrificed the American supply- line and pricing models to gain passage of the 2010 Affordable Care Act (ACA). What a shame! This last-minute political deal must be undone!

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. Drug-makers know that as long as their products are safe, Medicare must buy them.

"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.

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. 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 (VA) which negotiates for drug prices.

The VA requires drug companies to only charge the lowest price they offer to anyone in the private sector. Medicaid mandates that drug companies provide drug price rebates. It is no wonder medications offered through these federal programs are cheaper than Medicare.

Legislation should remove the prohibition on Medicare negotiating prescription drug prices. It should 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. (**See NRLN's competitive bidding proposal at the end of this white paper**.)

Passage of **H.R. 275 and S. 62, Empowering Medicare Seniors to Negotiate Drug Prices Act,** or **H.R. 448 and S.99, Medicare Drug Price Negotiation Act.** would direct the HHS Secretary to negotiate lower Medicare Part D prices.

We need competitive bidding the American business model way, not by the unique standards of control by the prescription drug or healthcare insurance industries. Negotiations as to service and quality terms and the

number of suppliers awarded business by Stock Keeping Units (SKUs) come after bidding, not at the beginning of this process. Our politicians just don't get it. Party politics and individual reelection needs predominate judgment.

NRLN's Position on Prescription Drug Importation

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.

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. The imported pills 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.**

Legislation should allow importation of safe and less expensive drugs from Canada. Passage of **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

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.

Legislation should end pay-for-delay and other brand-name drugmakers' tactics that keep generic drugs off the market. Passage of the Creating and Restoring Equal Access to Equivalent Samples (CREATES) Act in the fiscal year 2020 appropriations bill was a step in the right direction. It will make it easier for generic manufacturers to obtain samples of brand-name drugs necessary to develop generic versions.

Additional action should be taken to pass **H.R. 2375 / S. 64, Preserve Access to Affordable Generics and Biosimilars Act,** or **H.R. 1499, Protecting Consumer Access to Generic Drugs Act.** Both bills would prohibit brand-name drug companies from pay-for-delay and other tactics against generic drugs.

Two Bills Receiving Significant Attention

H.R. 3, Elijah E. Cummings Lower Drug Costs Now Act (also referred to as the Speaker Pelosi bill) was introduced by Representative Frank Pallone (NJ-06) Chairman of the Energy and Commerce Committee. It was passed by the House on December 12, 2019 and sent to the Senate.

H.R. 3 would:

-- Cap Medicare recipients' out-of-pocket costs for medicines at $2,000 a year.

-- Medicare would be authorized to negotiate prices for 250 commonly used costly medications, using a formula based on lower prices paid in other economically advanced countries.

-- Drugmakers that refuse to negotiate would be hit with steep sales taxes for the medication at issue.

-- Require pharmaceutical manufacturers to pay rebates to Medicare if the price of their drugs increased faster than inflation.

-- U.S. prices for drugs would be tied to a benchmark index of prices in other developed countries.

-- Private health insurance plans would be able to receive Medicare's discounted prices.

-- Congressional Budget Office estimates the price negotiations provisions of Pelosi's bill would save $456 billion over 10 years.

-- Use about $360 billion of its projected 10-year savings from lower drug costs to establish Medicare coverage for dental care, hearing, and vision, filling major gaps for seniors.

-- Make it easier for beneficiaries to enroll in Supplement (Medigap) insurance or to switch from Medicare Advantage to traditional fee-for service Medicare and would increase the number of low-income seniors eligible for Medicare subsidies.

S. 2543, Prescription Drug Pricing Reduction Act (also referred to as the Grassley-Wyden bill) was introduced by Iowa Senator Chuck Grassley, Chairman, and Oregon Senator Ron Wyden, Ranking Member, Senate Committee on Finance. The Finance Committee approved the bill on September 25, 2019. Senators Grassley and Wyden updated the bill on December 6, 2019.

S. 2543 would:

-- Limit out-of-pocket medication costs faced by seniors to $3,100, starting in 2022.

-- Limit price hikes in Medicare to the rate of inflation.

-- Require drug companies to provide a new discount of 7% on brand-name drugs in the initial phase of the benefit and reset the brand catastrophic discount to 14%.

-- Direct insurers to offer a cap on the amount of out-pocket-costs that a beneficiary has to pay in any one month; spreading high out-of-pocket costs over multiple months to protect against the burden of a significant one-time expense.

-- Require Medicare Part D plans and their Pharmacy Benefit Managers (PBMs) to include concessions and fees they negotiate with a pharmacy in the price beneficiaries pay at the pharmacy counter, reducing out-of-pocket expenses and prohibiting retrospective recoupment of payments to pharmacies as to provide more financial predictability.

-- Require rebates from drug manufacturers whose prices increase faster than inflation.

-- For Medicare Part D and Part B drugs, include incentives for physicians to implement more usage of biosimilars by increasing the physician add-on payment from 6% to 8% for the first 5 years after market introduction.
-- Require augmenting the star rating system for Medicare Advantage to recognize improvements in patient access to biosimilars.

-- CBO projects the bill would save $94 billion over the next decade, reduce out-of-pocket spending by $72 billion and reduce premiums by $1 billion.

-- Does not allow Medicare to negotiate prescription drug prices.

The NRLN urges Senate Majority Leader Mitch McConnell to call up S. 2542 for a vote on the Senate floor.

The NRLN hopes S. 2542 will be passed and go to a conference committee with H.R. 3 and result in a compromise bill that both the House and Senate will pass, and the President will sign.

As the nation moves further into the 2020 election year for the office of President, all Representatives and 35 Senators, it remains very uncertain whether a comprehensive bill to reduce the price of prescription drugs will be enacted. If no legislation is passed in 2020, the powerful pharmaceutical industry lobby in Washington wins again.

President Trump's Plan for Drug Importation

President Trump supports the passage of **S. 2542.**

President Trump announced on December 18, 2019 a notice of proposed rulemaking (NPRM) that, if finalized, would allow for the importation of certain prescription drugs from Canada. In addition, the Administration is providing draft guidance on how manufacturers could import drugs originally intended for sale in another country that are manufactured in accordance with the FDA-approved application.

According to an HHS news release issued on the President's announcement, the NPRM would allow states and certain other non-federal government entities to submit importation program proposals to the FDA for review and authorization. An importation program could be co-sponsored by a pharmacist, a wholesaler, or another state or non-federal governmental entity. These programs would also have to demonstrate significant cost reductions to the American consumer.

Eligible prescription drugs would have to be relabeled with the required U.S. labeling prior to importation and undergo testing for authenticity, degradation, and to ensure that the drugs meet established specifications and standards.

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. He said 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 doctors’ 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 2020.

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 push back from the pharmaceutical industry and some members of Congress.

NRLN Supports Speedy Approval of Generics

In fiscal year 2019 (ended September 30), the FDA approved a total of 1,171 generic drugs, an all-time record. That follows a record 971 approvals in fiscal year 2018 and a record 937 approvals in Fiscal Year 2017.

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 Association of Accessible Medicines reported that generics saved Americans $293 billion in 2018. This represented $2,254 in average savings per Medicare beneficiary.

Unfortunately, only 25% of the first generics approved by the FDA become available on Medicare Part D formularies. 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.

Prices of Many Generic Drugs Climb Higher

Generic drugs represent about 90% of all prescriptions 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.

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 should 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.

Wayne Riley, M.D., 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.”

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."

Consumers abandon hundreds of thousands of prescriptions each year at the pharmacy, often because of high prices, jeopardizing their health and often leading to higher costs down the road, studies show, according to Kaiser Health News, 2019.

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 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 to 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 $29.3 million in campaign and leadership PAC contributions to House and Senate incumbents and challengers in the 2019 – 2020 election cycle. In addition, the pharmaceutical and health products industry spent $296.7 million lobbying in Washington, DC in 2019. The industry had 1,466 lobbyists in Washington, DC in 2019.

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

Too many Americans are having to choose between paying for medicines or 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 serve 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 white paper 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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"What makes these – and all – price hikes stand out is drug prices are out of control, and Big Pharma continues to raise the prices for all Americans," Kristine Grow, senior vice president of communications for the trade group America's Health Insurance Plans (AHIP). "Not only does that mean higher prices at the pharmacy counter, it also means higher premiums and other healthcare costs for everyone."

Out-of-pocket costs for prescription drugs are rising, not only driven by pharmaceutical companies but also in part by deductibles that have risen faster than incomes over the past decade, according to a study released in November 2019 by the Commonwealth Fund, a New York–based think tank focusing on healthcare.

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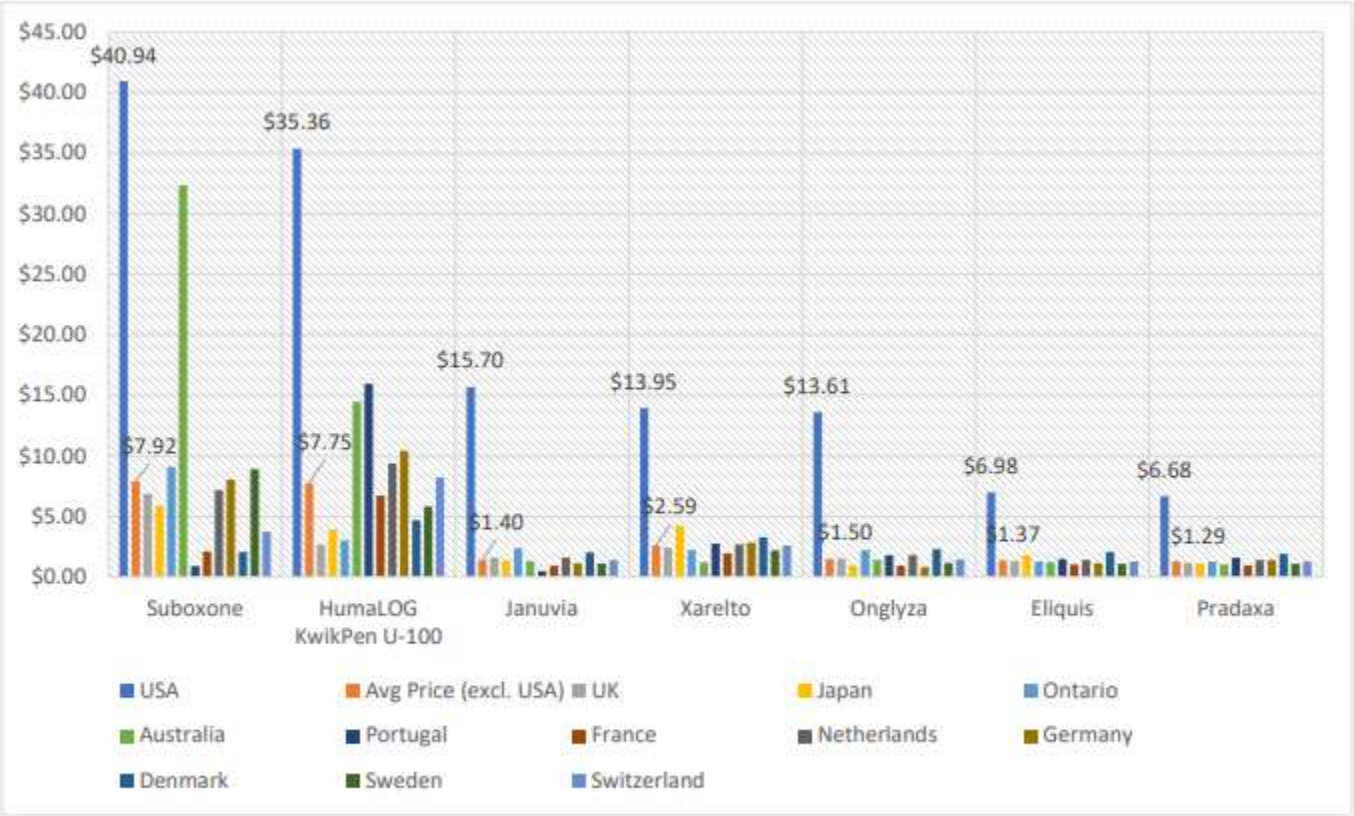
Per capita prescription drug spending in the United States, about $1,200, exceeds that in all other countries – even 40% more than Canada for essentially the same medications – largely driven by brand-name drug prices that have been increasing in recent years at rates far beyond the Consumer Price Index (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."

The House Ways and Means Committee issued its report in September 2019 on U.S. vs. International Prescription Drug Prices. It found that U.S. Drug Prices were nearly four times higher than all 11 other countries - United Kingdom (UK), Japan, Ontario, Australia, Portugal, France, the Netherlands, Germany, Denmark, Sweden, and Switzerland. The U.S. could save $49 billion annually on Medicare Part D alone by using average drug prices for comparator countries.

Drug List Prices for Medications in All 12 Countries, 2018



SOURCES and NOTES: *Authors' analysis of price data for 2018, collected from recognized price sources. There were 10 drugs whose prices were listed in recognized drug price databases for all 12 countries studied. We chose to compare these drugs separately in Figures 14 and 14.B to cross-compare their drug prices in each country.*

More drug price comparisons are available at:
https://waysandmeans.house.gov/sites/democrats.waysandmeans.house.gov/files/documents/U.S.%20vs.%20International%20Prescription%20Drug%20Prices_0.pdf

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Gerard Anderson, professor of health policy and management at Johns Hopkins University, says price increases on existing drugs not only benefit drug makers, but also insurers, who can make more money through rebates on higher priced drugs.

"Research and development are only about 17% of total spending in most large drug companies," Anderson says. "Once a drug has been approved by the FDA, there are minimal additional research and development costs so drug companies cannot justify price increases by claiming research and development costs."

The Associated Press (AP) has analyzed 32,795 U.S. list price changes of brand-name prescription drugs from January 1 through July 31 in the years 2015 through 2019. In the first seven months of 2019 there were 4,483 price hikes. There were 37 price hikes for every decrease in the first seven months of 2019.

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The KFF poll results were not unique to 2019. 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 a 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."

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 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.

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 supported by the NRLN in the 116th Congress and current Presidential administration will make the NRLN's point.

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 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 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.

Current law bars Medicare from negotiating drug prices. This is known as the "noninterference" clause in the **Medicare Modernization Act of 2003** (MMA) which stipulates that the HHS Secretary "may not interfere with the negotiations between drug manufacturers and pharmacies, 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.

“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.

The MMA non-interference clause adopts the drug and healthcare insurance industries’ for-profit Price Benefit Manager (PBM) business model into a public non-profit dynamic and guarantees higher prices. The Obama administration, AARP and the AFL-CIO sacrificed the American supply- line and pricing models to gain passage of the 2010 Affordable Care Act (ACA). What a shame! This last-minute political deal must be undone!

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. 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 (VA) which negotiates for drug prices.

The VA requires drug companies to only charge the lowest price they offer to anyone in the private sector. Medicaid mandates that drug companies provide drug price rebates. It is no wonder medications offered through these federal programs are cheaper than Medicare.

Legislation should remove the prohibition on Medicare negotiating prescription drug prices and replace it with a competitive bidding mandate. (**See NRLN’s competitive bidding proposal at the end of this white paper**.) 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.

Passage of **H.R. 275 and S. 62, Empowering Medicare Seniors to Negotiate Drug Prices Act,** or **H.R. 448 and S.99, Medicare Drug Price Negotiation Act.** would direct the HHS Secretary to negotiate lower Medicare Part D prices.

A major issue of ours that escapes under the radar is that for high-priced, chronic and life-threatening diseases, over 95% of all prescriptions filled in the U.S. are for generic drugs and that the same people who price high dollar brand drugs also price generics. Large brand companies are buying up generic firms and have entered the generic market organically.

We need competitive bidding the American business model way, not by the unique standards of control by the prescription drug or healthcare insurance industries. Negotiations as to service and quality terms and the number of suppliers awarded business by Stock Keeping Units (SKUs) come after bidding, not at the beginning of this process. Our politicians just don’t get it. Party politics and individual reelection needs predominate judgment.

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. The imported pills 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.

Legislation should allow importation of safe and less expensive drugs from Canada. Passage of **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.

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/

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 most likely dispense an imported drug – assuming the patient can actually afford it. Around 45 million Americans – 18% of the adult population – said they did not fill a prescription due to cost, according to an analysis of data from the Commonwealth Fund.

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!

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.

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 authorization of the importation of safe, lower priced drugs from our northern neighbor. The Secretary should be ordered to do so by President Trump**.**

Pay-for-Delay on Generics Must Be Stopped

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.

Legislation should end pay-for-delay and other brand name drugmakers' tactics that keep generic drugs off the market. Passage of the Creating and Restoring Equal Access to Equivalent Samples (CREATES) Act in the fiscal year 2020 appropriations bill was a step in the right direction. It will make it easier for generic manufacturers to obtain samples of brand-name drugs necessary to develop generic versions.

Additional action should be taken to pass **H.R. 2375 / S. 64, Preserve Access to Affordable Generics and Biosimilars Act,** or **H.R. 1499, Protecting Consumer Access to Generic Drugs Act.** Both bills would prohibit brand-name drug companies from pay-for-delay and other tactics against generic drugs.

Two Bills Receiving Significant Attention

H.R. 3, Elijah E. Cummings Lower Drug Costs Now Act (also referred to as the Speaker Pelosi bill) was introduced by Representative Frank Pallone (NJ-06) Chairman of the Energy and Commerce Committee and passed by the House on December 12, 2019 and sent to the Senate.

H.R. 3 would:

-- Cap Medicare recipients' out-of-pocket costs for medicines at $2,000 a year.

-- Medicare would be authorized to negotiate prices for 250 commonly used costly medications, using a formula based on lower prices paid in other economically advanced countries.

-- Drugmakers that refuse to negotiate would be hit with steep sales taxes for the medication at issue.

-- Require pharmaceutical manufacturers to pay rebates to Medicare if the price of their drugs increased faster than inflation.

-- U.S. prices for drugs would be tied to a benchmark index of prices in other developed countries.

-- Private health insurance plans would be able to receive Medicare's discounted prices.

-- Congressional Budget Office estimates the price negotiations provisions of Pelosi's bill would save $456 billion over 10 years.

-- Use about $360 billion of its projected 10-year savings from lower drug costs to establish Medicare coverage for dental care, hearing, and vision, filling major gaps for seniors.

-- Make it easier for beneficiaries to enroll in Supplement (Medigap) insurance or to switch from Medicare Advantage to traditional fee-for service Medicare and would increase the number of low-income seniors eligible for Medicare subsidies.

S. 2543, Prescription Drug Pricing Reduction Act (also referred to as the Grassley-Wyden bill) was introduced by Iowa Senator Chuck Grassley, Chairman, and Oregon Senator Ron Wyden, Ranking Member, Senate Committee on Finance. The Finance Committee approved the bill on September 25, 2019. Senators Grassley and Wyden updated the bill on December 6, 2019.

S. 2543 would:

-- Limit out-of-pocket medication costs faced by seniors to $3,100, starting in 2022.

-- Limit price hikes in Medicare to the rate of inflation.

-- Require drug companies to provide a new discount of 7% on brand-name drugs in the initial phase of the benefit and reset the brand catastrophic discount to 14%.

-- Direct insurers to offer a cap on the amount of out-pocket-costs that a beneficiary has to pay in any one month; spreading high out-of-pocket costs over multiple months to protect against the burden of a significant one-time expense.

-- Require Medicare Part D plans and their Pharmacy Benefit Managers (PBMs) to include concessions and fees they negotiate with a pharmacy in the price beneficiaries pay at the pharmacy counter, reducing out-of-pocket expenses and prohibiting retrospective recoupment of payments to pharmacies as to provide more financial predictability.

-- Require rebates from drug manufacturers whose prices increase faster than inflation.

-- For Medicare Part D and Part B drugs, include incentives for physicians to implement more usage of biosimilars by increasing the physician add-on payment from 6% to 8% for the first 5 years after market introduction.

-- Require augmenting the star rating system for Medicare Advantage to recognize improvements in patient access to biosimilars.

-- CBO projects the bill would save $94 billion over the next decade, reduce out-of-pocket spending by $72 billion and reduce premiums by $1 billion.

-- Does not allow Medicare to negotiate prescription drug prices.

The NRLN urges Senate Majority Leader Mitch McConnell to call up S. 2542 for a vote on the Senate floor. President Trump supports the passage of S. 2542.

The NRLN hopes S. 2542 will be passed and go to a conference committee with H.R. 3 and result in a ~~comprise~~ compromise bill that both the House and Senate will pass and the President will sign.

As the nation moves further into the 2020 election year for the office of President, all Representatives and 35 Senators, it remains very uncertain whether a comprehensive bill to reduce the price of prescription drugs will be enacted. If no legislation is passed in 2020, the powerful pharmaceutical industry lobby in Washington wins again.

President Trump's Plan for Drug Importation

President Trump announced on December 18, 2019 a notice of proposed rulemaking (NPRM) that, if finalized, would allow for the importation of certain prescription drugs from Canada. In addition, the Administration is providing draft guidance on how manufacturers could import drugs originally intended for sale in another country that are manufactured in accordance with the FDA-approved application.

According to an HHS news release on the President's announcement, the NPRM would allow states and certain other non-federal government entities to submit importation program proposals to the FDA for review and authorization. An importation program could be co-sponsored by a pharmacist, a wholesaler, or another state or non-federal governmental entity. These programs would also have to demonstrate significant cost reductions to the American consumer.

Eligible prescription drugs would have to be relabeled with the required U.S. labeling prior to importation and undergo testing for authenticity, degradation, and to ensure that the drugs meet established specifications and standards.

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. President Trump said that drug companies have "rigged the system" against American consumers by charging higher prices in the U.S. than they do abroad. He 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 doctors' 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 2020. The drug industry and some members of the President's party in Congress oppose the "international pricing index" as price fixing.

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.

NRLN Supports Speedy Approval of Generics

In fiscal year 2019 (ended September 30), the FDA approved a total of 1,171 generic drugs, an all-time record. That follows a record 971 approvals in fiscal year 2018 and a record 937 approvals in Fiscal Year 2017.

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 Association of Accessible Medicines reported that generics saved Americans $293 billion in 2018. This represented $2,254 in average savings per Medicare beneficiary.

Unfortunately, only 25% of the first generics approved by the FDA become available on Medicare Part D formularies. 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.

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 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 to 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 $29.3 million in campaign and leadership PAC contributions to House and Senate incumbents and challengers in the 2019. In addition, the pharmaceutical and health products industry spent $296.7 million lobbying in Washington, DC in 2019. The industry had 1,466 lobbyists in Washington, DC in 2019.

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.

To learn how much U.S. Representatives and Senators take as campaign contributions from the Pharmaceutical and Health Products Industry go to the NRLN website at:
https://www.nrln.org/Pharma%20Contributions%20to%20Congress%20%202019-20%2003-09-20.htm

The NRLN has compiled the data from OpenSecrets.Org, Center for Responsive Politics.

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; and 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."

David Merritt, executive vice president of public affairs and strategic initiatives for America's Health Insurance Plans, says, "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."

Consumers abandon hundreds of thousands of prescriptions each year at the pharmacy, because of high prices, jeopardizing their health and often leading to higher costs down the road, studies show, according to Kaiser Health News, 2019.

Pharma's Research and Development Spending

A March 9, 2020 article by Statistics reported that the U.S. Pharmaceutical Industry spent $79.6 billion on research and development in 2018.

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~~ 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 and 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 prescriptions 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.

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 should 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., 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," former FDA Commissioner Dr. Scott Gottlieb said.

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 manufactures, there is nothing stopping pharmaceutical companies from indiscriminately raising the price, even for generic drugs that have been available for decades.

Generic Drugs Price Fixing

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.”

Sandoz, part of Novartis AB which is one of the world’s largest drugmakers, has agreed to pay $195 million penalty to settle federal charges for its role in the price-fixing scheme. Former Sandoz senior executive Hector Armando Kellum pleaded guilty in February 2020 to conspiring with other companies to fix prices, rig bids and apportion customers for generic drugs. He is awaiting sentencing.

Executives at two other drug companies have pleaded guilty as part of the federal investigation, and another was indicted in early 2020.

“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% 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.

“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 drugmakers 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.”

Controversy Over Rebates to PBMs

Pharmacy Benefit Managers (PBMs) are companies that manage prescription drug benefits on behalf of health insurers, Medicare Part D drug plans, large employers, and other payers. By negotiating with drug manufacturers and pharmacies to control drug spending, PBMs have a significant behind-the-scenes impact in determining total drug costs for insurers, shaping patients’ access to medications, and determining how much pharmacies are paid. PBMs have faced growing scrutiny about their role in rising prescription drug costs and spending.

Drug manufacturers argue that the growing rebates they pay PBMs are forcing them to raise list prices for their products. According to a recent analysis, reported on April 22, 2019 by the Commonwealth Fund, manufacturer rebates to PBMs increased from $39.7 billion in 2012 to $89.5 billion in 2016, partially offsetting list price increases. PBMs counter that they have been passing along a larger share of the rebates to insurers.

There is a lot of debate over whether PBMs should be able to keep the rebates they receive from drug manufacturers, which generally aren’t publicly disclosed. Some believe PBMs should be compelled to “pass through” all or a larger portion of these savings to health insurers and other payers. If PBMs were required to do this, insurers could use the savings to further reduce people’s premiums and cost-sharing payments. A recent study found that the share of rebates PBMs passed through to insurers and payers increased from 78 % in 2012 to 91% in 2016. But many small insurers and employers say they do not receive this share of savings.

A separate controversy involves a PBM practice known as “spread pricing,” whereby PBMs are reimbursed by health plans and employers a higher price for generic drugs than what the PBMs actually pay pharmacies for these drugs. The PBMs then keep the difference. Again, a lack of transparency allows this to happen: the payment schedules PBMs generate for pharmacies are kept confidential from health plans.

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.

Proposed Reforms to Regulate PBMs

Some policymakers have considered three principal reforms to regulate PBMS:

-- Require greater transparency around rebates. Federal and state policymakers likely need more data

on the rebates PBMs receive to gain a more complete understanding of pharmaceutical spending and where reforms may be needed.

-- Ban spread pricing. Policymakers could ban the practice to ensure that payers and employers are not overpaying PBMs for prescription drugs. A more limited proposal would mandate that PBMs update their cost schedules with pharmacies to reflect price increases for generic drugs.[7]

-- Require PBMs to pass through rebates to payers or to patients. To preserve some of their incentive to negotiate price reductions with drugmakers, PBMs could be required to pass through 90% of their rebate savings to payers. Alternatively, PBMs could be required to pass through rebates to patients. The federal government has, in fact, proposed requiring PBMs contracted with Medicare Part D plans to pass through to patients at least one-third of the rebates and price concessions they receive.

Some experts think that PBMs also need to reorient their business model away from securing rebates and more toward improving value in pharmaceutical spending. For example, health plans and PBMs could do more to support physicians in prescribing the most cost-effective medications on their patients' formularies. And PBMs could base formulary decisions and price negotiations on a drug's health benefits as well as its effect on the total cost of patient care.

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 medicines or for food, housing and other necessities, or they 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!

Attached: NRLN Competitive Bidding Proposal

Congress Should Mandate HHS Competitive Bidding on Prescription Drugs

The NRLN is unique in that that our members have retired from over 300 U.S. companies and public entities. A significant number of the NRLN's board members and total membership are experienced senior and mid-level executives, corporate pension plan managers; HR; PR; R&D; product and process quality engineers; manufacturing managers and purchasing staff members. Other members bring hands on experience in producing, delivering and installing American goods and services at high quality world-class standards.

We are dedicated to objectively using our experiences in a business-like manner in support of non-partisan public policy that protects income and health care security for seniors, their children, grandchildren and all consumers. Our legislative agenda is directed to protecting seniors from losing more benefits and from the effect of a rising cost of senior living. This includes, in particular, the cost of health care, including prescription drugs, and the effect cost of living will have by the year 2060 when one in four Americans (25%) will be over age 65.

The prescription drug industry's influence is evident in various forms -- repeated campaign contributions, pressure on HHS regulatory rules and self-serving industry data sent to members of Congress. The "non-interference" clause that bans Medicare from competitive bidding for prescription drugs has resulted in an unwarranted shifting away from the basics of World-Class business operational practices. The current prescription drug procurement model economically disadvantages Americans who are paying abusive prices.

The prescription drug market was different in 2003 when the Medicare Modernization Act (MMA) became law. Then, generics drugs filled a small portion of physicians' prescriptions. Today they fill 90% of them. The pressure to fund FDA to accelerate approvals of generics has brought price relief only as patents expire.

As patents expire, industry tactics turn to unreasonable requests to extend patents, pay-for delay (still not prohibited by law), brand companies buying generic companies, and generic companies buying other generic companies. Pricing strategies drive revenue and profit by company. So, it's no wonder that generic prices are on the rise 6-7% or more annually. Why? No competitive bidding! Pricing is bifurcated between very expensive brand drugs and generics, but pricing policy alternatives have not caught up.

Branded drug pricing issues in general center around very expensive drugs for which there are few or no generics. Where there are no generics to treat a medical condition, a new set of policies are needed to address the drug manufacturers second generation patents. But where generics can solve a health problem without violating patents or where patents are licensed to generic manufactures, the only long-term permanent Medicare solution to this bifurcated pricing problem is an HHS competitive bidding program.

The path to business excellence in any business starts with competitive production or purchasing of products and services, always in a competitive Request for Quote (RFQ) / Bidding system and through managing efficient delivery and service from suppliers. That's what HHS and FDA should value as their job. Legislation should be passed to free HHS to do competitive bidding. HHS may already have an effective purchasing staff core in place now. The job is not complex, and delivery can be contracted to those who do it best. The 2003 MMA terms instituted non-standard prescription drug industry policies and practices that disguise non-value-added costs, e.g., pharmacy benefit managers (PBMs) and other practices that have made pricing obtuse. Nowhere is this more apparent than in the relationship between HHS as it serves Medicare beneficiaries. Congress must enact policy that mandates HHS implement a competitive bidding model that will permit direct purchasing of prescription drugs from manufacturers. Competitive bidding will not create bigger government; it will make HHS more efficient and save Medicare billions annually!

It is very important to recognize that there will always be final purchasing contract negotiations regarding details of the allocation of purchase volume, final price schedules at various volume levels, quality standards, delivery service, drop shipping details, etc., between and among sellers and HHS as the buyer. However, the model is a competitive bidding model and if termed a negotiating model there will always be unwarranted assertions of coercion and price fixing by big government, etc., that are politically expedient even if they would be inaccurate.

NRLN's attached model describes conditions that address the bifurcation issue and highlights the standard competitive bidding process used by U.S. companies and how readily it can be adapted to manage procurement of prescription drugs by HHS. The model would fit global procurement should Congress approve prescription drug importation from Canadian and other foreign suppliers that meet FDA quality standards.

General Business Model to be Applied by HHS for Competitive Bidding	Proposed Negotiating Model for Drug Price Discounts
NRLN advocates removal of "MMA" "non-interference clause," and replacing it with a competitive bidding model to be applied whenever (1) two or more FDA approved generic drugs or (2) two or more brand drugs or (3) a generic and brand drug (upon patent expiration) treat the same medical condition.	***H.R. 448 / S. 99, Medicare Drug Price Negotiation Act would allow the Secretary of Health and Human Services to directly negotiate price discounts with drug companies for Medicare, eliminating the "non-interference clause" that bans Medicare from negotiating for better prices.***
Establish formulary specifications; determine annual demand, quality systems definitions, monthly scheduled release quantities, Manufacturers FOB drop sites, and billing date and other terms. A boiler plate / bid request.	Identify medical condition: Diabetes. Drug needed: Insulin.
Identify suppliers capable of producing the generic or brand drug. Solicit bids from potential suppliers, a request for quote (RFQ) that includes generic specifications, volume level(s) to quote and capability of meeting time frame for shipments and billing requirements.	Establish Insulin formulary. Identify brand-name and generic producers (if any) of Insulin.
Select the top two or three bids (best prices) with capability of delivery on time. Examine capacity, service and quality capabilities; verify on site if new business - use FDA to qualify manufacturers. Determine % of business to award two or more suppliers.	HHS Secretary (or staff) initiates negotiations with drug makers for price discounts.
Award business to two or more suppliers with the capacity to meet demand levels needed to assure continued supply in the event one supplier cannot perform over a short period. Develop price, quality, service and overall performance ratings of each supplier annually. Change suppliers to gain compliance if warranted.	Prescription drug manufacturers decide whether or not to agree to an HHS'–requested discount. If a manufacturer will not agree to provide a discount, there is no reduction in price. If they agree, today's channel model prohibits consumers from getting discounts. In a bid model HHS accepts bids that include discounts by volume level only.
Negotiable Terms: Sellers to HHS may not offer a lower price to its other Medicare D RX buyers at the volume levels agreed to with HHS. HHS will sell to contracted distributors, resellers or retail customers on their terms as needed. **IT'S IMPORTANT** to know there will always be purchasing agreement closing negotiations over final allocation of volume, final price schedules at volume levels, quality, delivery service, drop shipping details etc. between and among sellers and HHS as buyers. However, the model is a competitive bidding model and if termed a negotiating model there will always be unwarranted assertions of coercion and price fixing by big government etc. that are politically expedient but inaccurate.	What distinguishes a **Negotiation Model from a Competitive Bid model** is that the former is not anchored by required specifications (formulary in RX drug nomenclature) developed by the buyer only. Determination of quality and service terms, and price terms at two or more bidding levels prior to initial bids are the buyers exclusive right and is not required or negotiable. The seller should not be involved until he decides to bid in accordance with opening bid terms. Negotiations should not be allowed until after selected initial bidders are determined by HHS.