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American Retirees Education Foundation

NRLN NATIONAL RETIREE LEGISLATIVE NETWORK

Prescription Drug Price Gouging

Congress Must Take Action to Mitigate Harm to Americans

9/1/2017

EXECUTIVE SUMMARY

Total U.S. prescription sales in the 2016 calendar year were $450 billion, a 5.8% increase compared with 2015, according to the research firm QuintilesIMS. Spending when adjusted for discounts and rebates totaled $323 billion, an increase of 4.8% over 2015. More than half of the increase resulted from price hikes of existing drugs. The Center for Medicare and Medicaid Services (CMS) estimates prescription drug spending will grow an average of 6.3% per year over the 2016-2025.

CMS reported that in 2015 (latest data available) that Medicare Part D spent $137.4 billion on prescription drugs, up from $121.5 billion in 2014. Medicare Part B spent $24.6 billion on prescription drugs in 2015, up from $21.5 billion in 2014. In 2015, the U.S. government paid roughly 43% of all retail prescription drug costs—29% through Medicare, 10% through Medicaid, and the rest through the Department of Defense, the Department of Veterans Affairs, Children's Health Insurance Program (CHIP), and some smaller federal and state programs.

Americans—with 10,000 more people turning age 65 every day in the U.S—are outraged that they are losing access to lifesaving and life-enhancing treatments because they have become less and less affordable. **More than half of Americans say that lowering the cost of prescription drugs is a top priority, according to the results reported in March 2017 on a survey conducted by the Kaiser Family Foundation, a nonprofit, nonpartisan organization focused on health care.**

A Consumer Reports national telephone poll 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 should be no surprise that almost three-quarters of the public thinks that drug costs are too high. Politicians, health care payers, doctors and patients have all criticized drug pricing, saying medicines are out of reach for many patients and straining health care budgets.

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 spent $245,933,749 lobbying in Washington, DC in 2016, making it the biggest spender**. (The insurance industry was second, at $157 million.) In 2016, the industry contributed $59,904,434 in campaign and Political Action Committee (PAC) contributions. During the first half of 2017 its lobbying expenses totaled $144,400,614.

On June 13, 2017, at a hearing conducted by the Senate Committee on Health, Education, Labor and Pensions hearing, a Senator asked the question why companies who make live-saving drugs are constantly incentivized to raise their prices or launch new drugs at radically high prices? Dr. Gerald Anderson, Ph.D., Professor of Medicine, John Hopkins University School of Medicine, responded, "I had the opportunity to meet with drug companies and their investment bankers and I pretty much ask that same question. The simple answer is because they can. Essentially there is not regulation and because they have a monopoly they can set the price at whatever they want to set it.

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."

It is a myth that Pharma deserves to benefit from its heavy R&D load. All tech-type companies manage relatively high R&D burdens but not many S&P 500 companies carry a higher ratio of profit to net income than do the average Pharma companies.

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.

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.

In a Consumer Reports Best Buy Drugs national telephone poll of more than 2,000 adults who take a medication, nearly one-third experienced a price hike in the last year on at least one of their meds. The study found that people were more likely to stop taking their medication; or skip filling prescriptions; or didn't take the prescribed dosage; split pills without contacting their doctor or pharmacist first; took expired meds, or shared prescription drugs with others to save money. Cutbacks weren't limited to refills or dosages. 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.**

PRESCRIPTION DRUG and OVERALL HEALTH CARE PRICING ARE IRRATIONAL AND MUST BE STOPPED BEFORE THEY BECOME THE MOST CRITICAL BURDEN ON OUR U.S. ECONOMY AND ITS

ABILITY TO GROW. CONGRESS MUST COMPREHEND THE DIFFERENCES BETWEEN DRUG PRICE AND COST AT ALL LEVELS AND UNDERSTAND THAT COSTS ARE NOT DRIVING PRICING, GREED IS.

The NRLN Supports Policy Changes and Passage of Bills that Solve this Economic Threat:

<u>The NRLN supports passage of legislation allowing Importation of Safe and Less Expensive Drugs from Canada and for Medicare to be directed to take competitive bids for prescription drugs.</u>

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.

Total prescriptions dispensed in 2016 reached 6.1 billion – up 3.3% over 2015 levels. Since 2007, generic drug availability has mushroomed from less than 20% of drugs dispensed in the U.S. to where today they represent around 80% 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. It's time to start Medicare competitive bidding.

For example, the patent on Crestor expired and competition is salivating to take market share away from the price gouging manufacturer who is now suing the Federal Drug Administration (FDA) to obtain extended patent protection because 800 Americans use Crestor to treat another illness. That is stooping very low to avoid what's good for Americans.

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.

S. 41 and H.R. 242 Medicare Prescription Drug Price Negotiation Act of 2017 would allow for Medicare to negotiate the best possible price of prescription drugs. S. 41 has been in the Senate Finance Committee since January 2017. The House Committees on Energy and Commerce and Ways and Means have had H.R. 242 in their Subcommittees on Health since January 2017. 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.

S. 1688, Empowering Medicare Seniors to Negotiate Drug Prices Act of 2017**,** would allow Medicare to negotiate the best possible prices for prescription drugs to cut costs for nearly 41 million seniors enrolled in Medicare Part D. The bill has been in the Senate Committee on Finance since it was introduced on August 1, 2017.

We strongly urge passage of one of these bils!

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.

S. 92 **and H.R. 1480,** ***Safe and Affordable Drugs from Canada Act of 2017*** would require the FDA to establish a personal importation program to allow individuals to import a 90-day supply of prescription drugs from an approved Canadian pharmacy. **S. 469 and H.R. 1245, the Affordable and Safe Prescription Drug Importation Act of 2017**, would lower cost of prescription drugs by allowing Americans to import safe, low-cost medicine from Canada and would authorize the HHS Secretary in two years to allow importation from other advanced countries. **We strongly urge passage!**

A May 1, 2017, press release from the Kaiser Family Foundation reported majorities of Democrats, Republicans and Independents support actions to lower prescription drug costs, including allowing Americans to buy drugs from Canada. Most say (72%) importing Canadian drugs would lower costs without affecting quality.

A July 31, 2017 *International Business News* article reported that a new analysis by the Congressional Budget Office stated allowing Americans to purchase lower-priced medicines from other countries would save 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.

The Secretary of HHS has the authority under the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 to issue an order to begin legal importation from Canada but refuses to act. Members of Congress should write letters to the Secretary (as the NRLN has) urging her to authorize the importation of safe, lower priced drugs from our northern neighbor. The Secretary should be ordered to do so by President Trump. Has the Executive Branch defaulted to a no position? Congress has failed repeatedly to enact legislation! The Executive and Legislative Branches appear to be accountable only to Pharma's huge sums of money for campaign contributions and lobbying. Both feign concern so as to sound like they care, then they take a snooze.

Lately, both Congress and HHS have run to hide behind a new excuse. They have told the NRLN that insurance companies won't approve importation. To this we say, tell them if they fail to do so they can no longer sell to Medicare. It is time to choose, to side with affected constituents.

In a May 31, 2017, Bill Kadereit, President, National Retiree Legislative Network, and Robert Roach, Jr., President, Alliance of Retired Americans, co-signed a letter to Tom Price, Secretary of HHS, urging him to utilize his existing statutory authority to address the soaring cost of pharmaceuticals by authorizing the importation of prescription drugs from Canada.

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.

In 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.

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. **We applaud his statements!**

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.

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 85-88% 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 is a far cry from the days when Medicare D was enacted but 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.

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.

S. 124, Preserve Access to Affordable Generics Act of 2017 would expand consumers' access to the cost-saving generic drugs and increase 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. The bill has been in the Senate Judiciary Committee since January 2017.

S. 974 and H.R.2212, Creating and Restoring Equal Access to Equivalent Samples ("CREATES") Act of 2017 targets abusive delay tactics that are being used to block entry of affordable generic drugs. S. 974 has been in the Senate Committee on Judiciary since April 2017. H.R. 2212 has been in the House Energy and Commerce Committee's Subcommittee on Health since April 2017.

We strongly urge passage of these bills!

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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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The Terrible Perfect Storm of Rx Prices

Fifty-seven 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 are bottled up in Senate and House committees.

Americans—with 10,000 more people turning age 65 every day in the U.S—are outraged that they are losing access to lifesaving and life-enhancing treatments because they have become less and less affordable. More than half of Americans say that lowering the cost of prescription drugs is a top priority, according to the results reported in March 2017 on a survey conducted by the Kaiser Family Foundation, a nonprofit, nonpartisan organization focused on health care.

Dr. Scott Gottlieb, head of the Food and Drug Administration, told a conference: "The fact is that too many people can't afford the medicines that they need," according to a July 25, 2017 article in the Los Angeles Times.

He noted that in all other developed countries, patients are protected by government authorities overseeing the market for prescription meds, ensuring that prices are reasonable while still allowing drug companies a fair profit. In the United States, profit comes before public interest. There are no limits to how much can be charged for a prescription drug, particularly specialty drugs intended for the costliest illnesses.

As a result, the U.S. is by far the world's biggest spender on pharmaceutical products, shelling out more than $1,026 annually per person, according to a 2015 report from the Organization for Economic Cooperation and Development (OECD). That's double the OECD average of $515 and considerably more than economic peers such as Germany ($678), France ($596) and Australia ($590).

Why hasn't Congress taken action on prescription drug costs, the fastest growing part of the nation's health care budget? Total U.S. prescription sales in the 2016 calendar year were $450 billion, a 5.8% increase compared with 2015, according to the research firm QuintilesIMS. Spending when adjusted for discounts and rebates totaled $323 billion, an increase of 4.8 % over 2015. More than half of the increase resulted from price hikes of existing drugs.

The Center for Medicare and Medicaid Services (CMS) reported that in 2015 (latest data available) that Medicare Part D spent $137.4 billion on prescription drugs, up from $121.5 billion in 2014. Medicare Part B spent $24.6 billion on prescription drugs in 2015, up from $21.5 billion in 2014. CMS estimates prescription drug spending will grow an average of 6.3% per year over the 2016-2025 period, faster than spending on other Medicare-covered benefits. In 2015, the U.S. government paid roughly 43% of all retail prescription drug costs—29% through Medicare, 10% through Medicaid, and the rest through the Department of Defense, the

Department of Veterans Affairs, Children's Health Insurance Program (CHIP), and some smaller federal and state programs.

Average annual growth in total Medicare spending is projected to be 7.1% between 2015 and 2025, faster than the 4.4% average annual growth rate between 2010 and 2015.

CMS reported prices rose substantially in 2015 on some of the Medicare Part D drugs that seniors pay the most for out-of-pocket

Drug	Average benificiary cost share* in 2015	Change in average cost per-unit
H.P. Acthar	$8,007.22	5.07% ▲
Harvoni	**5,497.08**	**-1.35** ▼
Sovaldi	5,204.79	-0.91 ▼
Gleevec	4,418.80	19.46 ▲
Revlimid	4,213.18	8.63 ▲
Letairis	4,017.92	6.65 ▲
Imbruvica	3,849.09	8.64 ▲
Copaxone	3,730.43	-31.61 ▼
Tecfidera	3,554.94	10.27 ▲

Prescription drug spending has increased 10% annually for Blue Cross and Blue Shield members since 2010, amounting to an overall rise of 73%, according to a Blue Cross and Blue Shield Association study published May 3, 2017. The study examined the medical claims of more than 30 million Blue Cross and Blue Shield commercially insured members and more than $208 billion in prescription spending from January 2010 through September 2016.

Branded drugs with no generic alternatives, or single-source drugs, are the main culprit, the study said. They are rising at an average annual rate of 25%, a total of 285% since 2010. These patent-protected drugs now make up 63% of total drug spending, up from 29% of total spending in 2010, despite the fact that they make up less than 10% of total prescriptions filled.

PhRMA's Lobbying of Congress

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 spent $245,933,749 lobbying in Washington, DC in 2016. (The insurance industry was second, at $157 million.) In 2016 the industry contributed $59,904,434 in campaign and Political Action Committee (PAC) contributions. During the first half of 2017 its lobbying expenses totaled $144,400,614.

"Clearly legislation is required, but you and I know that lightning could strike the Capitol dome in the same place not twice but 10 times, and this Congress would not be willing to stand up to the pharmaceutical lobby," said Representative Lloyd Doggett (TX-35) as reported by The Hill newspaper on February 26, 2016. In an opinion piece by Senator Bernie Sanders (VT) on February 6, 2017 he wrote: "The question is: Will Republicans really have the guts to join me and many of my colleagues in standing up to the drug companies to fight for American consumers and end the disgrace of having our country pay by far the highest prescription drug prices in the world?"

Daraprim Price Increase Grabbed Spotlight

Prescription drugs price gouging took center stage in September 2015 with the news media, the public and some members of Congress when Martin Shkreli, then-CEO of Turing Pharmaceuticals, raised the price of **Daraprim**, a specialty drug, from $13.50 to $750 per pill. **Daraprim** is used mainly to treat toxoplasmosis, a parasite infection that can cause serious or even life-threatening problems for babies born to women who become infected during pregnancy, and also for people with compromised immune systems, like AIDS patients and certain cancer patients.

On August 4, 2017, a jury in Brooklyn returned guilty verdicts against Shkreli on two counts of securities fraud and a single count of conspiracy. The most serious count, securities fraud, carries a maximum prison term of 20 years. Although his crimes were unrelated to his time as CEO of Turning Pharmaceuticals his actions as CEO of Turning Pharmaceuticals highlighted the callous and unnecessary price gouging prevalent in the pharmaceutical industry that places Americans – especially retirees – in grave danger due to unaffordability of prescription drugs.

The Shkreli brand of greed and arrogance was on display at a Congressional hearing but so was the propensity for Congress to be shallow and insincere in relating to its constituencies. Elected members of Congress hope that introducing bills and holding a grand stand hearing or two will be enough to placate retirees and the rest of America as Congress does little to actually take action to support controlled drug importation from Canada or to take action to direct Medicare to start up an effective competitive bidding process. It's as though many members of Congress defy Americans to challenge them, maybe they truly believe that taking campaign money and protecting industry contributor's interests over those of constituents and the negative impact on the U.S. economy is OK.

President Trump took office January 2017 complaining that the drug industry was "getting away with murder" by gouging consumers and government programs like Medicare and Medicaid. Though President Donald Trump has repeatedly said he'd bring down prices, a draft executive order on the issue seems to benefit the industry, the New York Times reported on June 20, 2017.

A June 16, 2017 Kaiser Health News article reported that most of the policies in the draft of the executive order would not ease patient costs, and at least one would increase prices.

"This six-page document contains the kind of solutions to the cost-of-drugs problem that you would get if you gathered together all the executives of pharma and asked them 'What sort of token gestures can we do?'" said Vinay Prasad, a professor of medicine at Oregon Health and Sciences University who studies the costs of cancer drugs.

Such measures “would be like a firefighter spraying gasoline on your burning garage,” Prasad said.

Brand-name drug prices — which account for 72% of drug spending — go untouched in the draft, said Fiona Scott Morton, a Yale economics professor and former attorney with the Justice Department’s antitrust division.

Some of the text in the document is lifted directly from policy papers published by the pharmaceutical industry’s powerful lobby — Pharmaceutical Research and Manufacturers Association (PhRMA).

A July 10, 2017 *Pro Publica* article reported that outcome-based contracts in which drug companies agree to refund money if patients don’t respond to medications as expected is raised in the draft of the executive order.

But there is scant evidence this new approach lowers costs. Pharmaceutical companies still set the drug’s list price and have to agree to the criteria upon which they will be measured. Some experts say such arrangements are a ploy to deflect attention from substantive changes that could hurt companies’ bottom lines, such as allowing Medicare to negotiate drug prices. Moreover, the savings don’t always trickle down to consumers.

“Most of them get launched with great fanfare,” said Dr. Steve Miller, the chief medical officer at Express Scripts, which manages the drug benefits of more than 80 million Americans. “But then you never hear anything about it after the launch because most of them collapse under their own weight.”

NRLN grassroots advocates sent letters to President Trump saying there is a "fox" in the White House, Joe Grogan. Until March, Grogan was a lobbyist for Gilead Sciences, the company that priced hepatitis C drugs at $1,000 per pill, and is now associate director of health programs for the Office of Management and Budget (OMB) and a leader on the President’s Drug Pricing and Innovation Working Group that drafted the proposed executive order.

President Trump was informed in the letter of specific bills in Congress that if passed would address prescription drug price gouging better than the draft of the executive order. The President was urged to put pressure on the Representatives and Senators to pass bills to help Americans who need affordable medicines and not issue the executive order.

Bills Held Up in Committees

In the aftermath of the media, public and Congressional firestorm over the huge increase in the price of **Daraprim**, some Senate and House committees have conducted hearings on aggressive drug price increases. Yet, no existing bills to lower the cost of prescription drugs have even had a vote in committees.

S. 41 and H.R. 242 Medicare Prescription Drug Price Negotiation Act of 2017 would allow for Medicare to negotiate the best possible price of prescription drugs. S. 41 has been in the Senate Finance Committee since January 2017. The House Committees on Energy and Commerce and Ways and Means have had H.R. 242 in their Subcommittees on Health since January 2017.

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NRLN Supports Passage of Rx Bills

The National Retirees Legislative Network (NRLN) supports the passage of legislation to allow Medicare to negotiate for lower drug prices and the importation of safe and less expensive drugs from our neighbors to the north. In 2016 and the through July 2017 alone, NRLN members have sent over 11,000 letters to members of Congress urging their support for the passage of these bills. They can't understand why two bills that are obviously in the best interests of Americans can't get passed.

The NRLN acknowledges that drug companies sometimes have to raise prices in reaction to cost and overhead inflation caused by supplier price increases and employee wage and benefit changes. The pharmaceutical industry consistently points to research and development costs as the reason for exorbitant prices. While in some cases this may be the case, it seems obvious that R&D and marketing expense do not increase cost for a product once it has been long established in the market. This serves to put American consumers at risk who will either not buy the drug due to cost concerns or will resort to lower doses than prescribed by their doctors in order to make the medicine last longer.

Spending on Prescription Drugs Reaches $450 Billion

Total U.S. prescription sales in the 2016 calendar year were $450 billion, a 5.8% increase compared with 2015, according to the research firm QuintilesIMS. Spending when adjusted for discounts and rebates totaled $323 billion, an increase of 4.8% over 2015. The Center for Medicare and Medicaid Services (CMS) estimates prescription drug spending will grow an average of 6.3% per year over the 2016-2025 period. More than half of the increase resulted from price hikes of existing drugs. The faster growth rate expected for Part D spending is primarily due to higher costs associated with expensive specialty drugs.

Specialty drugs treat complicated, potentially life-threatening conditions such as cancer, hepatitis, nervous system or blood disorders, and autoimmune conditions. Specialty drugs may also be used to treat more common chronic disease states such as asthma or rheumatoid arthritis. General characteristics of a specialty drug include: a limited distribution network, close patient monitoring, requirements for special handling, a high cost per unit or treatment course, and/or use only in a unique patient population. For 2017, the Centers for Medicare & Medicaid Services (CMS) define a specialty medication as a drug which costs more than $670 per month.

The IMS Institute for Healthcare Informatics reported in April 2017 that spending on specialty pharmaceuticals almost doubled from 2010 to 2015, and spending on this subset of drugs was responsible for 70% of overall drug spending growth during this timeframe. In 2015, spending on these medications reached $150 billion, a more than 20% increase from 2014.1 It is anticipated drug spending will continue to increase and specialty drug sales will reach $402 billion — 47% of prescription drug spending — by 2020.

For example, $39.1 billion was spent in 2015 on cancer drugs alone, followed by $30.2 billion for autoimmune disorders and $18.8 billion for the treatment of hepatitis.

Spending on prescription drugs – especially the newer, breakthrough biometric drugs for the treatment of cancer, autoimmune diseases and Hepatitis-C – continued double digits increases in 2016 for a third year in a row and showed no sign of abating. That means consumers, insurers and federal health care services such as Medicare, Medicaid and the Department of Veterans Affairs were financially squeezed as more and more seniors and veterans had coverage and services.

Major drug firms raked in an additional $25.6 billion (gross) in 2015 simply by raising prices on their brand-name drugs, according to a report by the IMS. The firm estimates that figure to grow to $155 billion over the next five years.

The more the U.S. spends on health care, the less the nation has for everything else, like education, safety, roads, bridges, etc. This is all happening at a time when prescription drugs are becoming a bigger and bigger share of where health care dollars go.

Harvoni was Gilead Sciences' top-selling drug in the U.S. 2015 for hepatitis C, raking in an estimated $14.3 billion in sales before discounts, according to The Wall Street Journal. The average 12-week treatment of **Harvoni** is $95,000 and **Sovaldi** is $84,000, before any discounts. **Epclusa**, which is expected to replace **Harvoni** and **Sovaldi**, will retail for $74,000 for a full treatment, or about $900 per pill Bloomberg News reported.

Since 2005, spending on prescription drugs has steadily risen with just one exception, in 2013, when it actually dipped by 3.2%. The IMS Health report provides only faint hope of a moderation in pricing over the next several years, projecting a mid-single digit growth rate.

Spending on retail-drugs does not include drugs administered at hospitals and doctors' offices, where patients receive many high-cost specialty drugs. This spending is embedded in other categories of health care spending and is not separately reported.

According to the Kaiser Family Foundation, there will be an estimated 49.5% growth of the U.S. senior population by 2030. The expected increase in Part D spending will mean hundreds of dollars more in higher annual premiums and deductibles for beneficiaries over the coming decade. KFF noted one in four Americans report having difficulty affording their medications. Moreover, many specialty drugs are priced higher in the U.S. than they are in other developed countries.

Seniors with Medicare coverage for medication have another worry: hitting the "doughnut hole," the Medicare Part D accounting system that tallies how much money the person and the plan spend together.

In 2017 a senior will hit the doughnut hole if he/she and his/her Part D plan together spends $3,700. Once that happens, all of his/her drugs switch to a complex "cost sharing" formula, paying 45% of a discounted price for branded drugs, or 58% for generics. Costs won't drop back down until he/she is out of the "doughnut hole," when spending reaches $4,950. Under the Affordable Care Act the coverage gap is gradually narrowing but won't be completely closed until 2020. However, it is unknown what will occur if legislation is passed to repeal or repeal and replace the Affordable Care Act.

Drug Companies Spend More Elsewhere than R&D

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 fact, it would seem that the spending drug companies need to recoup with higher prices is at least partly due to how much is spent on direct-to-consumer advertising. The review of the 2015 annual reports of 10 of the world's largest drug companies revealed that all spent more on marketing and administration costs than research and development. Ideally, a drug company will spend a substantial portion of its revenue in R&D seeking new discoveries—finding new medical treatments and cures. Drug company behemoths Johnson & Johnson and Pfizer spent about 13% and 16% on R&D, respectively. At the same time, both companies spent about 30% of revenue on selling, marketing, and administrative expenses.

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.

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 article in Modern Health on March 7, 2017 reported that research published on the Health Affairs blog, the 15 drug companies that made the 20 best-selling drugs worldwide in 2015 made $116 billion in excess revenue from premium drug prices in the U.S. Meanwhile, they spent only $76 billion on global research and development.

The excess revenue comes from drug prices that are much higher in the U.S. than in Canada, Denmark, Ireland and the U.K., the researchers said. Drug prices in those countries for the 15 companies studied were 41% of their U.S. counterparts on average.

U.S patients, businesses and taxpayers would have saved about $40 billion in 2015 if the 15 companies had lowered the premium prices they put on drugs in the U.S. if they were equivalent to global R&D spending, the researchers found.

Some companies, including Biogen and Teva, raked in more than double their global R&D budgets via U.S. premium drug pricing. Biogen made enough from premium pricing of just one product—its best-selling multiple sclerosis drug Tecfidera—to cover all of its R&D spending, and Teva did the same with its multiple sclerosis drug Copaxone.

A few companies, such as AstraZeneca and Novartis, pulled in excess revenue that was roughly the same as their R&D spending.

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 authors contend that many big pharmaceutical companies are living off patents that are decades-old and have little to show in the way of new blockbuster drugs. But their share buybacks and dividend payments inoculate them against shareholders who might be concerned about lackluster research and development.

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.

90% of Seniors Take Prescription Drugs

Around half of all Americans—and 90% of seniors—during any month take a prescription drug. A Consumer Reports national telephone poll found that three-quarters of Americans on Medicare currently take an average of six prescription drugs. Rising prices quickly become overwhelming when people take multiple drugs or take them for chronic conditions for the rest of their lives. Americans pay out-of-pocket for a much greater share of prescription drug costs than hospital costs. These costs will also continue squeezing federal and state budgets as Medicare, Medicaid and various other health care programs pay of prescription drugs.

It should be no surprise that almost three-quarters of the public thinks that drug costs are too high. Politicians, health care payers, doctors and patients have criticized drug pricing, saying medicines are out of reach for many patients and straining health care budgets.

Opioid Epidemic Key National Focus

The opioid epidemic continues to remain a key national focus. Although overall Medicare trend for drugs that treat pain and inflammation has decreased, according to the Express Scripts Trend Report, utilization rates for Medicare remain higher than in any other line of business. Utilization rates for short-term opioid use (17.3%) were higher for Medicare compared to commercial (12.0%) and Medicaid (7.6%). Long-term opioid use was also much higher (17.3%) than for commercial (3.3%) and Medicaid (3.6%). Note that our analysis includes individuals who received opioids for pain associated with cancer.

Dr. Scott Gottlieb, head of the Food and Drug Administration, is a point person for the White House's focus on fighting the opioid epidemic. He says the FDA and other agencies should have been more aggressive over the years in getting ahead of the opioid crisis, calling it the biggest public health crisis they are facing.

"I think what we need to do as a regulatory agency to try to bend the rate of new addiction is make sure that people who are prescribed opioids are being prescribed them for a legitimate medical purpose," he said. "We know if we can reduce overall exposure to opioids, we can also reduce the rate of addiction. It's simple math."

Dr. Gottlieb pointed out that opioids, even when used appropriately, are frequently overused. He focused on the need for more education and the need for the FDA to be "more intrusive" and work together with other agencies, insurance, pharmaceutical companies, and physicians to "stem the tide of new addiction."

Medicare Not Allowed to Negotiate Rx Prices

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.

This is in stark contrast to how drug prices are determined in some other federal programs; for example, the statutory requirement for mandatory drug price rebates in Medicaid, and a requirement that drug manufacturers charge the Department of Veterans Affairs (VA) no more than the lowest price paid by any private-sector purchaser.

For years, the "noninterference" approach seemed effective: Medicare drug costs rose about 1.5% annually on average for most of the last decade. But specialty drugs have contributed to the current huge rise in prices.

Experts disagree on how much money could be saved by allowing Medicare to negotiate for drug prices. When government actuaries last analyzed the proposal in 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: Could Medicare refuse to pay for certain drugs? Could Medicare set up its own formulary, like those used in the private sector?

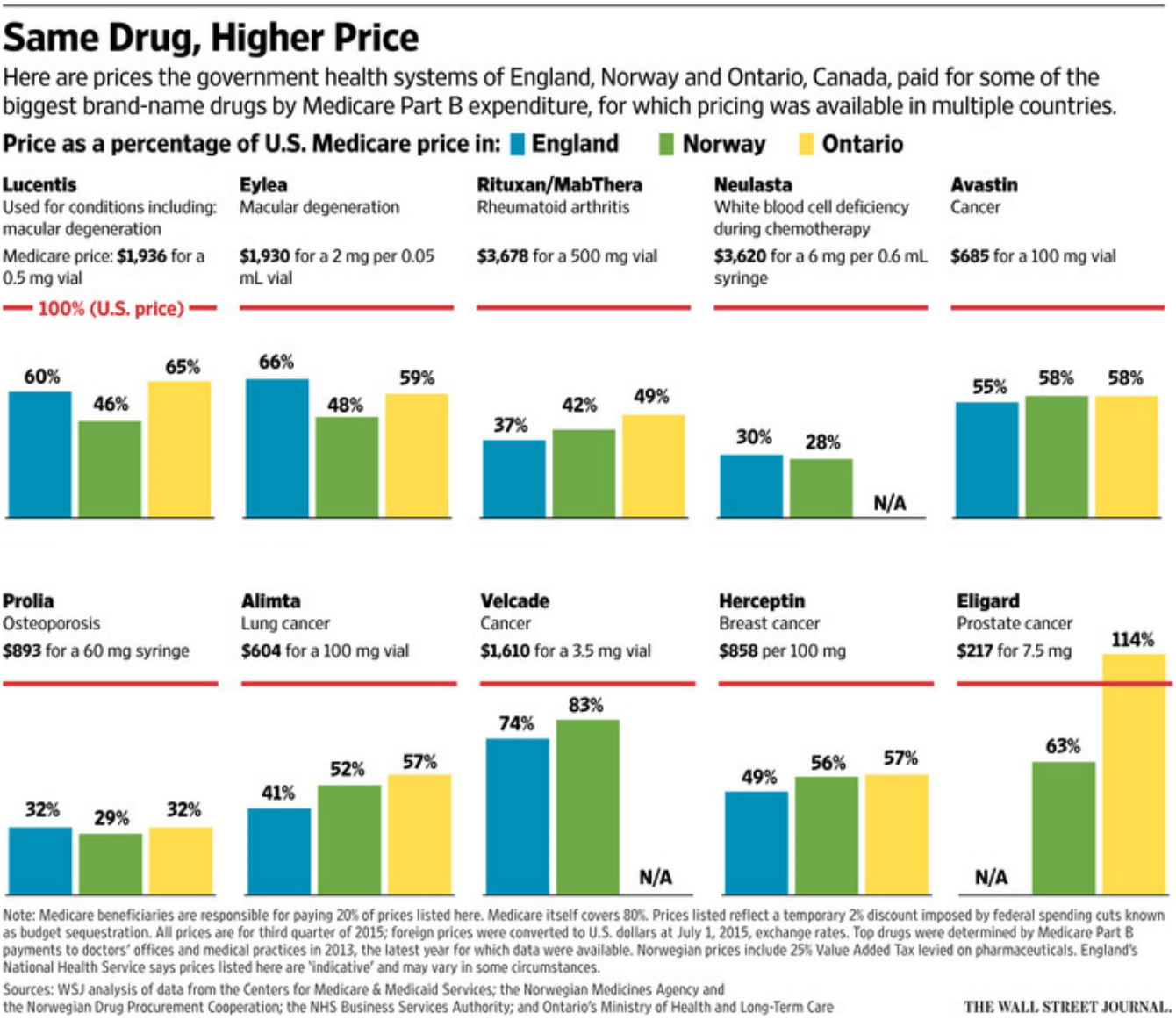
The NRLN believes that members of Congress who oppose Medicare negotiating drug prices should stop using the 10-year-old analysis as an excuse. Depending on which powers would be available, academics have estimated Medicare savings ranging from $15 billion per year to $54 billion per year.

Proof that government price negotiations can work to hold down the cost of drugs is demonstrated by the other two big government programs, Medicaid and the Veterans Health Administration (VHA), which do negotiate discounts. The differences in reimbursements for the same brand-name drugs are stunning: Medicare pays on average 73% more than Medicaid and 80% more than the VHA, according to a study by the School of Public Policy and Administration at Carleton University in Ottawa, Ontario.

As the country's main payer for prescription drugs, by not negotiating for a lower price Medicare is de facto setting the price of prescription drugs, the very thing that many members of Congress oppose. "Medicare is essentially forfeiting its buying power, leaving bargaining to doctors' offices that have little negotiating heft," said Sean Sullivan, dean of the School of Pharmacy at the University of Washington.

Asked to comment on the higher prices Medicare pays compared with foreign countries, the Centers for Medicare & Medicaid Services said: "The payment rate for Medicare Part B drugs is specified in statute."

Pharmaceutical and biotechnology companies in the S&P 1500 earn an average net profit margin of 16%, compared with an average of about 7% for all companies in the index, according to S&P Capital IQ.



Bloomberg News: U.S. Pays a Lot More for Top Drugs than Other Countries

Prices for brand-name drugs are typically higher in the U.S. than other developed countries. The drug industry has argued it's misleading to focus on U.S. list prices that exclude discounts

In an article published on December 18, 2015, Bloomberg News reported that its analysis found that even after discounts struck by drug makers behind closed doors with insurers, prices are higher in the U.S. than abroad. The drugs analyzed were: **Advair** (Asthma Inhaler); **Crestor** (Cholesterol-Lowering Pill); **Gleevec** (Chronic Myeloid Leukemia Pill); **Herceptin** (Breast Cancer Infusion); **Humira** (Rrheumatoid Arthritis Self-Injection); **Januvia** (Diabetes Pill); **Lantus** (Long-Acting Insulin), and **Sovaldi** (Hepatitis C Pill). Of the eight drugs analyzed, seven cost more in the U.S. after estimated discounts than in most other high-income countries.

GlaxoSmithKline Plc's **Advair** asthma inhaler costs at least twice as much in the U.S. compared to other countries analyzed, even after an estimated 50% discount in the U.S. market.

After an estimated discount of 60%, AstraZeneca still charges more than twice as much in the U.S. for **Crestor**, a cholesterol pill, compared to Germany, and in other countries the price is even lower, according to the analysis of IHS data.

SSR Health was not able to estimate discounts for **Gleevec**, Novartis AG's drug for leukemia. Still, the analysis of IHS data found that the U.S. list price for that drug is more than triple the price that Novartis gets in other high-income nations. U.S. price increases for **Gleevec** over the last decade far outpaced "the modest discounts" Novartis has offered, David Whitrap, a spokesman for Express Scripts, said.

The analysis found that Roche Holding AG's **Herceptin**, a breast cancer drug, after rebates of roughly 15%, still cost about 85% more in the U.S. than in other high-income countries, and a third more than in Saudi Arabia, where the price is highest after the U.S.

Humira, AbbVie Inc.'s best-selling rheumatoid arthritis treatment, costs an estimated $2,500 a month in the U.S. after discounts, compared with about $1,750 in Germany, Bloomberg found. In other nations, the drug's price drops even lower.

The list price of Merck & Co.'s diabetes pill **Januvia** is cut in half on average by estimated discounts, according to the SSR Health data. Even so, Merck gets more than twice as much in the U.S. for a monthly supply of the same drug as in Canada, the next most costly place to buy it, Bloomberg found.

Sanofi gives U.S. discounts of about 50% on **Lantus**, a long-acting insulin, SSR Health found. It still costs 30% more in the U.S. than in China, the second-most expensive country.

The U.S. was not an outlier on prices for **Sovaldi**, Gilead Sciences Inc.'s hepatitis C pill. The blockbuster product was only slightly more expensive in the U.S. than most other high-income countries after rebates, and a little less costly than in Saudi Arabia.

In Europe, drug prices are often set by government health systems and decline over time as countries demand additional price cuts, said Floriane Reinaud, a principal analyst at IHS. "In the U.S., list prices are just a little bit crazy, and even with discounts that are tied to that it is still higher than Europe," Reinaud said.

"We can no longer sustain a system where 300 million Americans subsidize drug development for the entire world," said Steve Miller, chief medical officer for Express Scripts Holding Co., the largest U.S. manager of prescription-drug benefits.

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.

HHS Secretary Has Authority for Drugs from Canada

The Secretary of HHS has the authority under the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 to issue an order to begin legal importation from Canada but refuses to act. Members of Congress should write letters to the Secretary (as the NRLN has) urging her to authorize the importation of safe, lower priced drugs from our northern neighbor. The Secretary should be ordered to do so by the President Trump. Has the Executive Branch defaulted to a no position? Congress has failed repeatedly to enact legislation! The Executive and Legislative Branches appear to be accountable only to those who have huge sums of money. Both feign concern so as to sound like they care, then they take a snooze.
Lately, both Congress and HHS have run to hide behind a new excuse. They have told the NRLN that insurance companies won't approve importation. To this we say, tell them if they fail to do so they can no longer sell to Medicare. It is time to choose, to side with affected constituents.

In a May 31, 2017, Bill Kadereit, President, National Retiree Legislative Network, and Robert Roach, Jr., President, Alliance of Retired Americans, co-signed a letter to Tom Price, Secretary of HHS, urging him to utilize his existing statutory authority to address the soaring cost of pharmaceuticals by authorizing the importation of prescription drugs from Canada.

On February 14, 2017, Senators Amy Klobuchar, John McCain and Charles Grassley wrote a letter to Secretary Price asking him to use his authority to fast track the importation of prescription drugs from Canada under certain circumstances as a remedy to recent drastic drug price increases in the United States.

Those circumstances are: If there are significant increases in price for a drug; if the drug is no longer marketed in the U.S.; if there is no direct competitor to a drug marketed in the U.S. and the introduction of a competitor will lower the price for consumers; and if the drug is manufactured in another country by a major company or a generic company that sells drugs in the U.S.

Why hasn't Secretary Price taken action that would save millions of struggling Americans a lot of money with minimal risk?

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.

Harvard Medical School Study on Rx Cost in U.S.

Researchers from Harvard Medical School reviewed medical and health policy literature from January 2005 to July 2016 for articles addressing the sources of drug prices in the United States, the justifications and consequences of high prices, and possible solutions. Their findings published on August 23, 2016 in the Journal of the American Medical Association (JAMA) revealed that FDA regulations and patents protect drug companies from competition, and federal law prevents Medicare from negotiating drug prices. All of this works together to allow drug companies to set their own prices.

The study's lead author Aaron Kesselheim, a professor at Harvard Medical School and the director of Harvard's Program on Regulation, Therapeutics, and Law, said high drug prices are an issue because when people can't afford a medication, they stop taking it.

Kesselheim and his colleagues propose a number of solutions. Those include giving Medicare the power to negotiate prices and removing some of the regulations that keep generics from speedily entering the market.

One source of high drug prices the authors discuss is that Medicare can't negotiate with drug companies. When the Medicare Modernization Act of 2003 established prescription drug benefits in the U.S., the law also prohibited the Department of Health and Human Services from getting involved in price bargaining.

The paper in JAMA describes two forms of legal protection that give brand-name pharmaceuticals an effective monopoly. The first is exclusivity granted by the FDA that gives new small molecule drugs (like aspirin) and biologics (such as antibody or protein drugs) windows of five to seven years and 12 years, respectively, before generic versions can be sold. And patents can protect the active ingredient and chemical structure of a drug — as well as less fundamental aspects like its formulation and coating — for 20 years or more.

Generic manufacturers can sue to challenge these patents, but in a practice called pay for delay, big name pharma companies settle the suits and pay generics manufacturers to wait it out until the patent expires.

Pharma's argument for keeping the regulatory and patent protections in place is that it costs a lot of money to bring a drug to market. Kesselheim noted that there's evidence that lot of the innovation that goes into new drug development actually happens in academia and government laboratories. Although prices are often justified by the high cost of drug development, there is no evidence of an association between research and development costs and prices; rather, prescription drugs are priced in the U.S. primarily on the basis of what the market will bear.

NRLN's Position on Prescription Drug Competitive Bidding

Members of Congress have quoted Congressional Budget Office (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 that 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.

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 85-88% 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 is a far cry from the days when Medicare D was enacted but 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. This data is not speculation or political rhetoric. It's time to start Medicare competitive bidding.

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.

HHS should be authorized to award percentages of the business to up to three vendors so as to maintain continued supply and competition by competing products. This provision does not preclude single sourcing and sourcing decisions shall be the exclusive right of HHS.

Pharmacy Benefit Managers Most Likely Raise Prices

An opinion piece in *The Hill* newspaper on February 14, 2017 titled *Reduce Drug Prices by Eliminating PBM Rebates* reported that pharmacy benefit management (PBM) companies – the businesses that put together the drug benefits for most Americans generated nearly $130 billion in rebates. This is essentially cash that drug companies pay PBMs to reduce the cost of their products.

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."

The hitch is that the biggest PBMs are out to make a buck. They get "rebates" from drug manufacturers — payments based on sales or other criteria, which look suspiciously similar to kickbacks. The rebates, which look suspiciously similar to kickbacks, are not publicly disclosed. Industry analysts estimate that those payments, and other back-room deals, amount to as much as 50% of the list price of insulin.

Heather Bresch, Mylan CEO, who has raised the price of EpiPen 2-Pak from $57 a shot in 2007 to $600 for two auto-injectors became the pharmaceutical villain in August 2016. Mylan, receives less than half the list price for an EpiPen 2-Pak. On the $600 EpiPen, the PBM was likely receiving close to $300 on each prescription, according to an August 31, 2016 article in *The Hill*.

What is known is that business is booming for PBMs. Together, the three biggest benefit managers — Express Scripts, CVS Health and OptumRx. — They control over 80% of the PBM market, involving 180 million insured people.

Top Ten Widely Used Drugs Have Hefty Price Increases

Major drug companies took hefty price increases in the U.S., in some cases more than doubling listed charges, for widely used medications over the past five years, a Reuters' analysis of proprietary data found and reported in an April 5, 2016 article.

Prices for four of the nation's top 10 drugs increased more than 100% since 2011. Six others went up more than 50%. Together, the price increases on drugs for arthritis, high cholesterol, asthma and other common problems added billions in costs for consumers, employers and government health programs.

Sales for the top 10 drugs went up 44% to $54 billion in 2014, from 2011, even though prescriptions for the medications dropped 22%, according to IMS Health data.

At the top of the list was AbbVie Inc. (ABBV.N), which raised the price of arthritis drug **Humeral** more than 126%t, Reuters found. Next were Amgen Inc. (AMGN.O) and Tea Pharmaceutical Industries Ltd (TEVA.TA), which raised prices for arthritis treatment **Enbrel** and multiple sclerosis drug **Copa one** by 118%.

The increases help explain federal data showing overall spending on drugs rose faster than doctor visits and hospitalization over the past five years.

Reuters based its analysis on the top 10 drugs, according to 2014 sales figures from IMS, and on proprietary pricing data provided by Traven Health Analytics.

Memorial Sloan Kettering Cancer Center oncologist Peter Bach said Pharmaceutical "companies have complete control over pricing in the U.S." By Bach's estimate, increases in 2015 on just one drug, Amgen's **Enbrel**, added up to $1 billion to care costs.

Commenting on the Reuters study on "CBS This Morning" Lisa Gill of Consumer Reports said for some consumers, the spike in prices leaves them with difficult decisions.

"They sometimes feel some pocketbook pain coming at the point of when they actually fill the prescription but that pain is very real. When these prices go up, we can see consumers don't fill prescriptions like they should. They don't take them like they should or they do other things. They don't buy groceries, they may not go out to dinner with their families. There are a lot of things they'll cut out in order to try to pay for the medications."

According to a July 15, 2016 New York Times article the two companies that produce **Humira** and **Enbrel** have found common ground in keeping those prices so high. They are deploying new patents to prevent patients from getting two essentially generic versions of the drugs for less money.

"It's a lost opportunity to reduce health care costs," said Fiona M. Scott Morton, a professor at the Yale School of Management. According to her study, biosimilars have been available in Europe for years and have reduced costs for some drugs as much as 80%.

Jacking Up Prices Following an Acquisition

Some major price increases have occurred after a pharmaceutical company has acquired another drugmaker or purchased the rights to a prescription drug.

High prices aren't necessarily the result of the costs of R&D. For example, Gilead didn't discover its blockbuster hepatitis drug, **Sovaldi**. Instead, Gilead purchased Pharmasset the company that developed **Sovaldi** for $11 billion after key clinical trials had been completed. Gilead proceeded to charge $84,000 for a 12-weeks treatment of **Sovaldi** in order to recoup its acquisition costs.

When Rodelis Therapeutics acquired the rights to manufacture **Cycloserine**, which treats multidrug-resistant tuberculosis, the cost went from $500 a bottle to $10,800.

Cycloserine, a drug which treats multidrug-resistant tuberculosis, was acquired by Rodelis Therapeutics, which promptly raised the price to $10,800 for 30 capsules, from $500. But in August 2015 the company agreed to return the drug to its former owner the Chao Center, a nonprofit foundation affiliated with Purdue University.

The foundation now charges $1,050 for 30 capsules, twice what it charged before, but far less than Rodelis was charging.

A patient with multidrug-resistant tuberculosis might take two capsules a day of **Cycloserine**, along with other drugs, for 18 to 24 months, according to the Centers for Disease Control and Prevention. Under the price Rodelis planned to charge, a full course of treatment would have cost more than $500,000 for **Cycloserine** alone. With the new price from the Chao Center, it will be closer to $50,000.

The drug made by generic companies abroad costs only about $20 for 100 capsules.

Cycloserine, which went on sale in 1955 and is also known by the brand name **Seromycin**, was long produced by Eli Lilly and Company, which around 2000 decided to drop the drug, in part because the company was getting out of antibiotics.

Valeant Pharmaceuticals after that company acquired two heart drugs, **Isuprel** and **Nitropress**, from Marathon Pharmaceuticals it promptly raised their prices by 525% and 212% respectively. Marathon had acquired the drugs from another company in 2013 and had quintupled their prices.

In 2014, the drug company Retrophin—run at the time by Martin Shkreli—acquired **Thiola**, a 26-year-old drug that treats a rare condition in which patients constantly produce kidney stones. Retrophin raised the drug's price 1,900%.

In 2015, Valeant Pharmaceuticals International acquired Nitropress and Isuprel, injectable heart medications that are a staple at many hospitals, and raised the list prices more than 200% and 500%, respectively. In 2010, Valeant bought a pair of old drugs that treat Wilson Disease, an obscure disorder in which copper accumulates in the body. The company implemented a series of price increases that ultimately exceeded 2,600%.

Prices of Many Generic Drugs Climb Higher

Generic drugs represent about 80% 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. PPI found that 27% of the most widely used generics have gone up in price, in some cases into the stratosphere. For example: **Doxycycline hyclate** (100 milligrams), a widely used antibiotic, soared from $20 for 500 capsules in October 2013 to $1,849 in April 2014. **Glycopyrrolate** (20 milliliters), used during surgery to prevent slowing of the heart rate, climbed from $65 for 10 vials to $1,277 during the same period. **Pravastatin sodium** (10 mg), a cholesterol medication has surged from $27 to $196 for a one-year supply.

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, with prices, in fact, largely declining over time.

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, MPA, AARP PPI director of health services research and coauthor of the new report, 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.

There are several tactics 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. Some also use pay-for-delay settlements that pay generic drug companies for delaying development.

The National Retiree Legislative Network's (NRLN) position is that it doesn't want to see pay-for-delay cases dragged through the courts for years while Americans—especially retirees—are denied access to cheaper generic drugs. That is why the NRLN continues to lobby Congress to pass legislation that bans pay-for-delay.

Old Drugs Are Reformulated as Costly 'New' Drugs

According to Consumer Reports, reinventing old medications is a tactic called evergreening—where companies change or tweak the formula of a drug by, say, combining two older drugs to form a "new" pill. Or they create 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. That can translate to greater revenue for a pharmaceutical company and higher costs for the consumer.

Thirty products that were reformulations of old drugs hit the market in 2015, according to recent report by the IMS. 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.

Ten years 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 begun 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 in a federal court case that 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."

In the Consumer Reports poll, 77% of people taking a medication said the government should allow more generics onto the market sooner.

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

In 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.

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 such a list could "entice competitors into the market" and ultimately lower costs. **We applaud his statements!**

Consumers pay 94% of the branded 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.

Many Americans Can't Afford the Price of Prescription Drugs

For Americans—especially seniors living on fixed incomes—prescription drug prices have become unaffordable. Americans are rightfully concerned that they are losing access to lifesaving and life-enhancing treatments, simply because they're becoming less and less affordable. Even individuals who have health care insurance or are on Medicare are experiencing either the higher price of drugs or higher copay or both. When Medicare is hit with higher prices of drugs, taxpayers pay for the higher cost. Government programs now pay for half of all prescription drugs.

Some health care industry experts see a prescription drug crisis ahead given the skyrocketing prices of prescription drugs. A case in point, the per year price of Vertex's cystic fibrosis drug **Kalydeco** is $300,000. The prices of older drugs for multiple sclerosis have risen from about $10,000 per year in the late 1990s to more than $60,000 now, according to a study published in the Neurology journal. This has happened even as competition in the market has intensified with the introduction of new products.

Medical organizations, patient groups, health insurance firms and some members of Congress are deeply concerned. With the high cost, too many Americans are cutting dosage of their medicines or have stopped filling prescription. It is estimated that one quarter of prescriptions aren't filled because Americans can't afford them. This places their health in jeopardy. Undoubtedly, this contributes to more hospitalizations resulting in more costs to individuals, health insurance firms, Medicare, Medicaid and even personal bankruptcies.

"Each day, Americans are forced to make difficult decisions about their health. The high price of drugs has created an unfortunate reality — too often for the most vulnerable among us, those decisions are not about wellness but rather choosing between basic necessities and taking their daily prescription medications. Many need those drugs to survive." This was the opening paragraph in an opinion piece in The Hill newspaper on March 9, 2017 by Patricia A. Maryland, Dr.PH, is the President of Healthcare Operations and Chief Operating Officer for Ascension Healthcare, the nation's largest non-profit and largest Catholic health system.

She went on to write: "We must work together to combat the arbitrary and astronomical price increases and prioritize making affordable medications accessible for all. Sadly, drug prices have prevented nearly one in 10 American adults from taking their medications as prescribed, according to the Centers for Disease Control and Prevention's National Center for Health Statistics."

In an article published in July 2015 in the journal Mayo Clinic Proceedings, more than 100 prominent oncologists called for support of a grassroots movement to stem the rapid increases of prices of cancer drugs,

including by letting Medicare negotiate prices with pharmaceutical companies and letting patients import less expensive medicines from Canada.

"There is no relief in sight because drug companies keep challenging the market with even higher prices," the doctors wrote. "This raises the question of whether current pricing of cancer drugs is based on reasonable expectation of return on investment or whether it is based on what prices the market can bear."

Cancer drug prices have increased more than tenfold between 2000 and 2016. The average price of cancer drugs is increasing by about $8,500 a year, far beyond the rate of inflation. Prices for cancer drugs routinely exceed $100,000 a year, and some new ones exceed $150,000. For example, a per year price for Celgen's cancer drug **Reylimid** is roughly $150,000.

Imbruvica, a drug used to treat mantle-cell lymphoma, has a wholesale list price of $116,600 a year for patients. For the higher dose needed by patients it is about $155,400 a year. Producers gave insurers discounts averaging 11% in 2014. Medicare pays most of the cost for more than half of the users of **Imbruvica** through Medicare Part D, but the patients still have an out-of-pocket cost of $7,0000 or more a year.

Keytruda and **Opdivo** help a patient's immune system more effectively seek out and destroy cancer cells. **Keytruda** will set the typical patient back $150,000 annually, while **Opdivo** comes in with an annual wholesale cost of $143,000.

Revlimid is the dominant treatment for front-line and second-line multiple myeloma, a type of cancer that affects a type of white blood cell known as plasma cells. Plasma cells are responsible for fighting the body's infections. **Revlimid** boasts a $100,000-plus annual wholesale cost because of its mammoth market share. Celgene, the manufacturer of **Revlimid**, struck a deal with generic drug manufacturers in December 2014 that protects **Revlimid** from facing a flood of generic entrants until late January 2026, and it gives the drug a very good shot at $10 billion-plus in annual sales by 2020 and beyond.

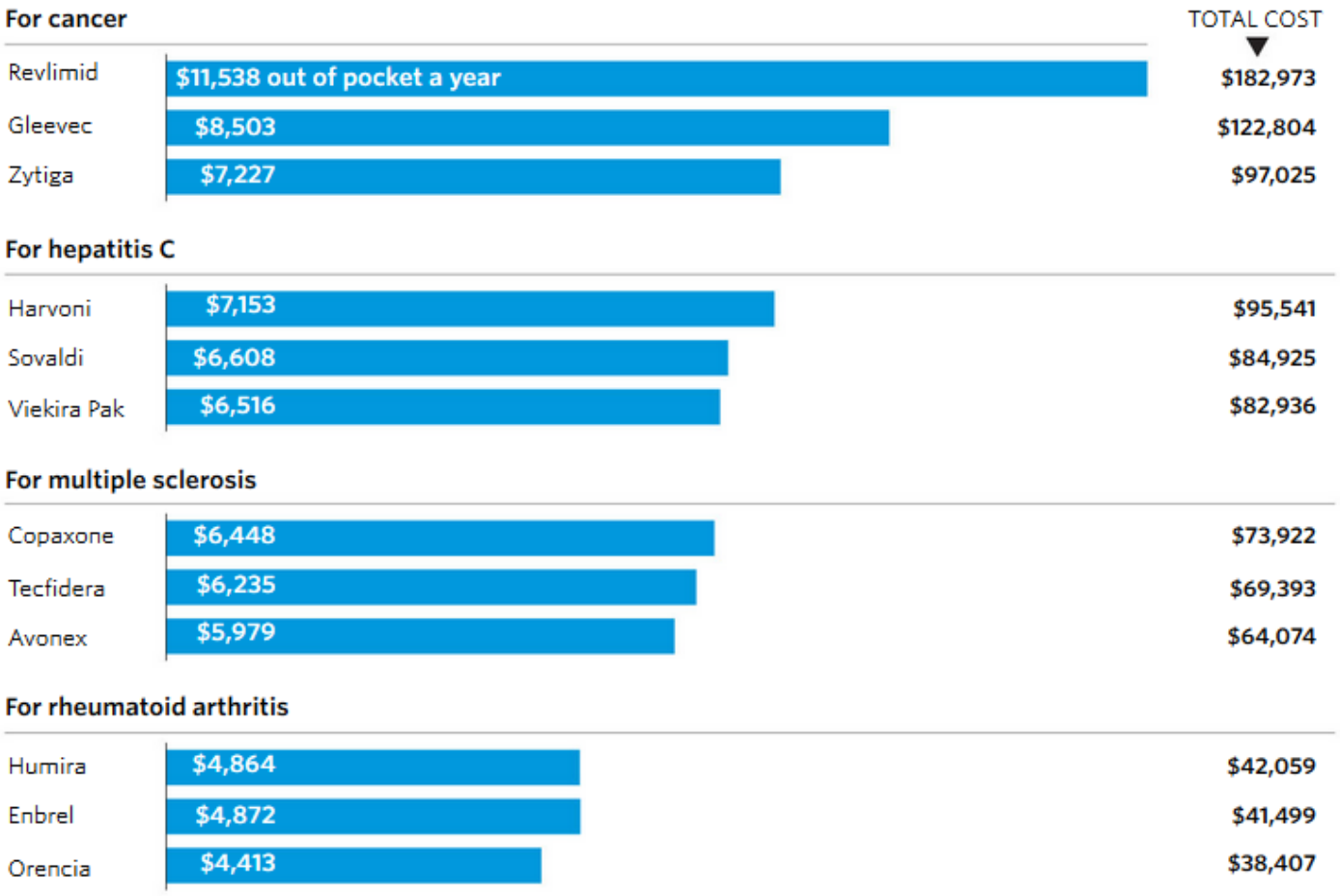
The average household income today for a family of four is about $52,000. Since each American has a 1 of 3 lifetime chance of developing cancer, millions of Americas are at risk of being unable to pay for the prescription medicines to control or hopefully cure their cancer. The high price of cancer drugs is causing harm by shortening the lives of patients who cannot afford the treatment. This is an injustice that creates differential treatment conditioned by financial status.

In a December 31, 2015 article in The Wall Street Journal, Peter Bach, a physician and health-policy researcher at Memorial Sloan Kettering Cancer Center in New York, said: "Drugs are so expensive that once they flow through our ragtag insurance system, we have patients who can't afford them, or they can barely afford them, so they're not getting therapies."

In an August 2015 survey conducted by the Kaiser Family Foundation, a quarter of U.S. prescription-drug users said it was difficult to afford them. In a survey, published in the journal Lancet Haematology in September 2015, 10% of insured U.S. patients with the blood cancer multiple myeloma said they had stopped taking a cancer drug because of its cost.

High Out-of-Pocket Cost for Medicare Patients

A Dec. 15, 2015 article in The Wall Street Journal published the following graph that showed the annual out-of-pocket financial impact on Medicare patients who take expensive prescription drugs. Below are the projected 2016 costs for a dozen commonly use specialty drugs.



Note: Total cost is based on drugs' retail pharmacy prices. Prices are based on default dose and quantity. Analysis includes 20 national and near-national prescription-drug plans. Source: Georgetown/Kaiser Family Foundation analysis of data from Centers for Medicare and Medicaid Services

As Drug Prices Increase, Quality of Life Goes Down

In a Consumer Reports Best Buy Drugs nationally representative telephone poll of more than 2,000 adults who take a medication, 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 with other people, compared to those whose drug costs remained steady.

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.

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.

Express Scripts projects that year-over-year spending through 2019 should increase about 30% for inflammatory conditions such as rheumatoid arthritis, roughly 20% for cancer medications, and about 20% for insulins and other diabetes treatments. This mainly due to price hikes and growing patient populations.

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.

Doctors Who Take Pharma Money More Likely to Prescribe Brand-Name Drugs

An article co-published on March 17, 2016 by NPR, the Boston Globe and Tampa Bay Times reported that a ProPublica analysis has found for the first time that doctors who receive payments from the medical industry do indeed tend to prescribe drugs differently than their colleagues who don't. And the more money they receive, on average, the more brand-name medications they prescribe.

ProPublica matched records on payments from pharmaceutical and medical device makers in 2014 with corresponding data on doctors' medication choices in Medicare's prescription drug program.

Doctors who got money from drug and device makers—even just a meal– prescribed a higher percentage of brand-name drugs overall than doctors who didn't, ProPublica analysis showed. Doctors who received industry

payments were two to three times as likely to prescribe brand-name drugs at exceptionally high rates as others in their specialty.

Doctors who received more than $5,000 from companies in 2014 typically had the highest brand-name prescribing percentages. Among internists who received no payments, for example, the average brand-name prescribing rate was about 20%, compared to about 30% for those who received more than $5,000.

ProPublica's analysis doesn't prove industry payments sway doctors to prescribe particular drugs, or even a particular company's drugs. Rather, it shows that payments are associated with an approach to prescribing that benefits drug companies' bottom line.

"It again confirms the prevailing wisdom … that there is a relationship between payments and brand-name prescribing," said Dr. Aaron Kesselheim, an associate professor of medicine at Harvard Medical School who provided guidance on early versions of ProPublica's analysis. "This feeds into the ongoing conversation about the propriety of these sorts of relationships. Hopefully we're getting past the point where people will say, 'Oh, there's no evidence that these relationships change physicians' prescribing practices.'"

Overall, payments are widespread. Nationwide, nearly nine in 10 cardiologists who wrote at least 1,000 prescriptions for Medicare patients received payments from a drug or device company in 2014, while seven in 10 internists and family practitioners did.

Justifications for High Drug Prices Are Bogus

Drug companies claim that the high prices are due to research and development costs and the arduous Federal Drug Administration approval process to bring a drug to market. A December 9, 2015 article in The Wall Street Journal with the headline *Pharma companies' no. 1 justification for high drug prices is bogus* cited the newspaper's study showing the drug makers' claim is not the case. And much of the basic science research is conducted by government-funded researchers and agencies such as the National Institutes of Health. Experts agree that drug pricing is not research or manufacturing-cost driven, but rather profit-driven.

Marcia Angell, a senior lecturer in social medicine at Harvard Medical School and a former editor in chief of the New England Journal of Medicine, wrote in a Sept. 25, 2015 Washington Post article that there is very little innovation at the big drug firms. Very often, the original discovery occurs in a university lab with public funding from the National Institutes of Health (NIH), then licensed to a start-up company partly owned by the university and then to a large company.

She stated that drug companies' major creative output is trivial variations of top-selling medications that are already on the market (called "me-too drugs"), to cash in with treatments just different enough to justify new patents.

For example, she noted that the first of the statins, drugs that lower cholesterol, was Merck's **Mevacor**, which came on the market in 1987. There followed a whole family of "me-too" statins, including **Zocor** (also made by Merck), **Lipitor**, **Pravachol** and **Crestor**. There is little reason to believe that one is more effective than another at equivalent doses.

She claimed that the major drug companies are hardly strapped for money to cover their R&D: A look at their annual reports shows that they spend more on marketing and administration than on R&D. Pharmaceutical manufacturers are consistently among the most profitable companies.

Ms. Angell pointed out that drug makers are now getting some pushback from the public in response to their claims that they need the money, but they fall back on the rhetoric of the free market. They are investor-owned businesses, after all, they say, and they have a right to charge whatever the market will bear (which for desperately sick patients or their insurers is quite a lot). But the pharmaceutical market is hardly an example of

unfettered capitalism, because the companies are totally dependent on government support. In addition to receiving huge tax breaks and government-granted exclusive marketing rights, they are permitted to acquire drugs that resulted from NIH-funded university research.

Price gouging puts the health of Americans in jeopardy in order to make an unreasonable profit. Sadly, up until now, the voice of the pharmaceutical lobby is Washington has been louder than that of sick patients. The Pharmaceutical Research and Manufacturers of America (PhRMA), spent $18.32 million on lobbying in 2015, more than a 10% increase over the previous year, according to the Center for Responsive Politics. Without any competition or additional regulation of prices, the price of drugs are simply what the manufacturer sets for its monopoly product**.** Drug company profits continue to increase at a faster pace than any other sector of the health care industry.

Pharma Forces Waste and Extra Cost

If you thought the pharmaceutical industry couldn't get any more cynical than the now-infamous Turing Pharmaceuticals price gouging scandals of last year, you would be wrong.

Big pharma is raking in $3 billion in extra profits by forcing doctors and hospitals to waste drugs and to pay for that waste, according to a new study from Memorial Sloan Kettering Cancer Center in New York. While the practice isn't limited to cancer drugs, they were the basis of the study's assessment.

Here's how it works. A pharmaceutical company develops an expensive drug that is administered in a hospital or in a doctor's office. The appropriate dosage of that drug depends on body size. So, a 130-pound woman needs far less than a 250-pound man. But the company sells the drug in a vial of only one size - the size that would be needed to treat the large man, for example. When the woman is treated, a nurse or doctor draws the smaller dosage from the vial, and the remaining medicine is discarded. Yes, an extremely valuable drug is trashed because safety protocols restrict how this kind of medication can be reused. Unconscionably, the patient is charged for the entire contents of the vial. That's where the $3 billion comes in - it is the marginal cost between the amount of drug that is needed and the drug that is sold.

It's not as though the company can't provide the drugs in a greater variety of vial sizes. It does so for the European market, where the regulators are far more diligent. The U.S. regulator, the FDA, does not have the authority to take price or efficiency into account when approving drugs for sale.

All this waste is paid for by the patient and through the tax dollars that support Medicare, Medicaid and the Veterans Health Administration, premiums paid to insurance companies, and of course co-pays of those who need these medications.

As for waste, the authors of the current study suggest that the FDA could, without taking cost into consideration, regulate vial size by issuing specific guidance. Or Congress could mandate that the pharmaceutical companies simply refund the cost of leftover drugs used in government programs. After years of hand-wringing over the skyrocketing cost of health care, one straightforward path to slowing it is available. It should be taken. Fighting waste and abuse by the companies that have their fingers in taxpayers' pockets should be as important as fighting waste and abuse in government.

Congress Should Pass Bills to Reduce Cost of Prescription Drugs

For several years, the National Retiree Legislative Network (NRLN) has been advocating legislation to reduce the cost of prescription drugs. In 2017, there are five bills in the Senate and House that the NRLN supports that, if passed, would result in prescription drug savings to Americans and in some cases also to Medicare.

S. 41 and H.R. 242, Medicare Prescription Drug Price Negotiation Act of 2017.

S. 1688, Empowering Medicare Seniors to Negotiate Drug Prices Act of 2017.

S. 92 and H.R. 1480, Safe and Affordable Drugs from Canada Act of 2017.

S. 469 and H.R. 1245, the Affordable and Safe Prescription Drug Importation Act of 2017.

S. 124, Preserve Access to Affordable Generics Act of 2017.

S. 974 and H.R.2212, Creating and Restoring Equal Access to Equivalent Samples ("CREATES") Act of 2017.

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, all seniors (and all Americans) are being forced to accommodate 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 American economy and thus federal tax revenue that sustains our country. Members of Congress and the White House 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 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 these commonsense bills and stand up for Americans' health and stop the price gouging. There is no time to waste.