AREF
American Retirees Education Foundation

NRLN
NATIONAL RETIREE LEGISLATIVE NETWORK

Prescription Drug Price Gouging

Congress Must Take Action to Mitigate Harm to Americans

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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:

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.

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 bills!

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!

The whitepaper researched and written for the American Retirees Education Foundation (AREF) is the source of information for this Executive Summary. The AREF expands the research and education reach of the NRLN.

For a copy of the whitepaper on this subject, contact Alyson Parker at 813-545-6792 or executivedirector@nrln.org