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NRLN NATIONAL RETIREE LEGISLATIVE NETWORK

Congress Continues *'Much Ado About Nothing'* on Reducing Prescription Drug Prices

Talk Is Cheap – Drugs Are Not

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If William Shakespeare were alive today his play, *Much Ado About Nothing*, could be about Congress constantly wrangling over the need to reduce prescription drugs prices but never enacting legislation to accomplish it.

Meanwhile, the National Retiree Legislative Network (NRLN) sees Americans, especially the 65 million Americans on Medicare, being caught in the terrible perfect storm of prescription drug price gouging. Seniors 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.

The pharmaceutical industry began January 2022 as it has in other years by raising prices on prescription drugs. Drug manufacturers raised wholesale prices by a median of 4.9% on more than 450 prescription medicines, an overall annual increase that is comparable to the price hikes seen over the past three years. Additional price increases are expected later in 2022.

According to a Rand Corporation study published on January 29, 2021, the U.S. prices for brand-name drugs are 3.44 times more than those in the other countries. Fortunately, prices for generic drugs are slightly lower in the U.S. than in most other countries. Unbranded generic drugs account for 84% of drugs sold in the U.S. by volume, but only 12% of U.S. spending.

Pharma pretty much disregards the findings of Congressional investigations, hearings and most bills introduced on the need to reduce prescription drug prices.

House Oversight Committee Reports

The Washington Post published a December 10, 2021, article on a nearly three-year investigation into the pharmaceutical industry by the Democratic members of the U.S. House of Representatives Oversight Committee. The study concluded that prescription drug-pricing practices are "unstainable, unjustified and unfair."

The 269-page report is the work of the committee's Democratic majority. The panel's chairwoman, Rep. Carolyn B. Maloney (NY-12), stated in a preamble that the report grows out of a review of 1.5 million pages of internal pharmaceutical company documents and five congressional hearings.

The Oversight Committee's Republicans issued their own 19-page drug-industry report, based on a less exhaustive look at companies known as Pharmacy Benefit Managers (PBMs), which act as go-betweens to manage drug benefits on behalf of private insurers, Medicare drug plans and other payers.

The pharmaceutical industry and other critics have contended for years that PBMs are a major reason for the growth of drug spending because they receive undisclosed rebates based on a medicine's list price, so the higher the price the greater the payment.

"In seeking to cast [brand-name pharmaceutical] companies as the sole villains in the drug cost debate, [Democrats] disregard the benefits they provide the public in the form of treatments and cure" such as vaccines against the coronavirus, says the Republican's report, a sequel to a forum on PBMs that the committee's Republicans convened in November 2021. The middlemen "use their market leverage to increase their profits, not reduce costs for consumers," the GOP report stated.

Pharmaceutical companies, studied by the Democrats on the Oversight Committee, raised prices of common brand-name drugs during the past five years by nearly four times the rate of inflation. The report seeks to debunk industry contentions that companies' price strategy is needed to plow money back into researching and developing new medicines.

The Oversight Committee's Democrats investigation focused on 10 pharmaceutical companies that sell a dozen drugs that it says cost Medicare the most. The review of the companies' practices "confirms that the pharmaceutical industry has targeted the United States for price increases for many years while maintaining or cutting prices in the rest of the world," the report said.

At a Capitol Hill news conference to announce the Democrats' report, House Speaker Nancy Pelosi said the drug industry's "outrageous price hikes" are "a kitchen table issue" and noted that lawmakers of her party have been trying unsuccessfully since 2006 to allow the Medicare program to negotiate prices.

Elijah E. Cummings Lower Drug Costs Now Act

The House passed the **Elijah E. Cummings Lower Drug Costs Now Act** during the 116th Congress, on December 12, 2019. (The bill's title honors Representative Cummings who died on October 17, 2019.) The NRLN supported passage of the bill,

Two key features of the bill were:

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

-- Medicare would be authorized to negotiate prices for 250 commonly used costly medications.

The NRLN hoped that the Senate would pass a bill to reduce the price of prescription drugs and Senate and House bills would go to a conference committee that would produce a bill that both chambers would pass and be signed by the President.

The Senate never passed its own comprehensive drug bill, nor did it vote on H.R.3 passed by the House.

When the current 117th Congress began on January 3, 2021, Bill Kadereit, President, National Retiree Legislative Network, sent a letter to Frank Pallone, Chairman of the House Energy and Commerce Committee, who had introduced H.R.3 in the previous session of Congress. The letter requested that he reintroduce the **Elijah E. Cummings Lower Drug Costs Now Act**. The bill was reintroduced again as H.R. 3 by Chairman Pallone on April 22, 2021.

House Democratic Majority Pursues Different Strategy

Rather than calling H.R.3 up for a vote again in the 117th Congress, the House Democratic leaders decided to insert key elements of the bill into **H.R.5376, Build Back Better Act**, the centerpiece of President Joe Biden's domestic legislative agenda.

Legislative language in H.R.5376 would allow Medicare to negotiate directly with pharmaceutical manufacturers to lower prices for a limited class of as many as 10 expensive drugs, to be chosen later, including medicines for cancer patients, starting in 2025 and increasing to 20 drugs. That would break a

prohibition on such negotiations since Medicare added the Part D drug benefits 15 years ago. The bill also would limit to $2,000 a year the out-of-pocket amount paid by Medicare participants. And for people on Medicare, insulin would cost no more than $35 a month.

The bill's final shape is far more modest than earlier versions, which would have allowed negotiations on the price of up to 250 drugs. Pelosi acknowledged that the negotiating power included in the Build Back Better legislation is "not as robust as I would like." But she said it nevertheless would be historic."

The Build Back Better Act was passed by the House on November 19, 2021, and sent to the Senate.

Senate Boggs Down on Build Back Better Act

In the evenly divided Senate, negotiations between Democratic party leaders and Sen. Joe Manchin, a Democrat, bogged down over the cost of the $1.75 trillion Build Back Better Act. On December 16, President Biden acknowledged that negotiations over his Build Back Better Act would drag on into 2022. Senate Majority Leader Chuck Schumer has pledged to bring the bill to a vote on the floor of the Senate.

Senate Minority Leader Mitch McConnell said the Build Back Better Act, "it will never become law."

NRLN Supports Several Bill to Reduce Drug Prices

Regardless of what happens with the Build Back Better Act, the NRLN will continue to base its lobbying to reduce prescription drug prices on:

1. remove the prohibition on Medicare negotiating prescription drug prices. It should replace it with a competitive bidding mandate to be applied wherever two or more FDA approved generic drugs, or two or more brand drugs, or a generic and brand drugs (upon patent expiration) treat the same medical condition.
2. end pay-for-delay and other brand-name drugmakers' tactics that keep generic drugs off the market.
3. allow individuals to import prescription drugs manufactured at FDA-inspected facilities from licensed Canadian sellers and import drugs from other countries that meet FDA safety standards.

The Rx bills the NRLN supports in the 117th Congress which continues through 2022 include:

H.R.3, Elijah E. Cummings Lower Drug Costs Now Act: The NRLN will advocate strengthening the bill with regard to #1 above. Current law bars Medicare from negotiating drug prices. This is known as the "noninterference" clause in the **Medicare Modernization Act of 2003** (MMA) which stipulates that the HHS Secretary "may not interfere with the negotiations between drug manufacturers and pharmacies and may not require a particular formulary or institute a price structure for the reimbursement of covered Part D drugs." In effect, this provision means that the government can have no role in negotiating or setting drug prices in Medicare Part D.

Passing H.R.3 would eliminate the "noninterference" clause. The NRLN advocates that H.R.3 would be made stronger by changing "negotiating" drug prices to a "competitive bidding" mandate. (**See NRLN's competitive bidding proposal at the end of this white paper**.)

H.R.153, Protecting Consumers Access to Generic Drugs Act of 2021, would prohibit the practice of "pay-for-delay," in which brand name drug companies compensate generic drug makers to delay the entry of generic drugs into the market. This practice leads to decreased competition and increased drug prices for Americans.

H.R.832/S.259, Safe and Affordable Drugs from Canada Act of 2021, would require the Food and Drug Administration (FDA) to set regulations within 180 days of enactment permitting Americans to import prescription drugs from licensed Canadian pharmacies. The bill stipulates there must be a valid prescription issued by a U.S. physician for drugs for personal use and not greater than a 90-day supply.

The drugs must have the same active ingredients, route administration, dosage form and strength as a prescription approved by the FDA.

H.R.2071, Medicare Prescription Drug Price Negotiations Act of 2021, and companion bill **S.833, Empowering Medicare Seniors to Negotiate Drug Prices Act of 2021**, the bills would allow the Secretary of Health and Human Services to directly negotiate with drug companies for price discounts for the Medicare Prescription Drug Program, eliminating the "non-interference" clause that expressly bans Medicare from negotiating for better prices.

H.R.2181/S.920, Affordable and Safe Prescription Drug Importation Act, would instruct the Secretary of Health and Human Services, within 180 days after enactment of this Act, to issue regulations allowing wholesalers, licensed U.S. pharmacies, and individuals to import qualifying prescription drugs manufactured at FDA-inspected facilities from licensed Canadian sellers. After two years, the Secretary would have the authority to permit importation from countries in the Organization for Economic Co-operation and Development (OECD) that meet specified statutory or regulatory standards that are comparable to U.S. standards.

H.R.2883/S.1425, Stop Stalling Access to Affordable Medications, would reduce the incentives for branded pharmaceutical companies to file sham petitions with the Federal Drug Administration (FDA) to interfere with the regulatory approval of generics and biosimilars that would compete with their own products. This is a tactic that delays patient access to more affordable medications. The bill would give the Federal Trade Commission (FTC) enhanced authority to take action against those who file sham petitions.

H.R.2891/S.1428, Preserve Access to Affordable Generics and Biosimilars, would limit anticompetitive "pay-for-delay deals" that prevent or delay the introduction of affordable follow-on versions of branded pharmaceuticals. Pay-for-delay deals – the practice in which drug companies use pay-off agreements to delay the introduction of cheaper substitutes – increase the cost of prescriptions and impose significant costs on our health care system. The bill covers pay-for-delay deals affecting biosimilar and interchangeable biologics in addition to generic drugs.

H.R.3554/S.1909, Pharmacy DIR Reform to Reduce Senior Drug Cost Act, would ensure that all pharmacy price concessions are assessed at the point of sale and eliminate the retroactive nature of direct and indirect remuneration (DIR) claw back fees imposed by Pharmacy Benefit Managers (PBMs). The Centers for Medicare and Medicaid Services (CMS) estimates this change will save Medicare beneficiaries an estimated $7.1 to $9.2 billion in reduced cost sharing. PBMs have increasingly returned to pharmacies days or even weeks after the point-of-sale to demand more in DIR fees. Passage will increase transparency and hold PBMs accountable for retroactively assessing fees on pharmacies.

H.R.4158, Insulin Access for All Act of 2021, would make insulin completely free for individuals enrolled in Medicare or Medicaid who represent some of the most vulnerable populations of diabetics. Also, this bill would eliminate the cost-sharing requirement — including deductibles, copayments, and coinsurance — for insulin under Medicare and Medicaid. Passage is a step towards ensuring that no one is forced to make the life-threatening decision to ration their insulin.

S.1388, Prescription Pricing for the People Act of 2021, would require the Federal Trade Commission (FTC) to study the role and recent merger activity of Pharmacy Benefit Managers (PBMs), including possible anticompetitive behavior. This includes having the FTC to examine the effects of consolidation on pricing and other potentially abusive behavior within the PBM industry and provide policy recommendations to Congress to improve competition and protect consumers. Recent consolidations between PBMs and insurance providers has resulted in vertical integration whereby a small number of companies now manage the vast majority of prescription drug benefits and often own other players in the healthcare industry.

S.1435, Affordable Prescriptions for Patients Act of 2021, would curb drug companies' anti-competitive use of patents to prevent generic and biosimilar competition from coming to market. This bill specifically addresses an anti-competitive tactic known as "product hopping" and an abuse of the "patent dance" process for resolving patent infringement claims for biosimilars.

Pharma's Influence with Members of Congress

Many members of Congress appear to be accountable to the pharmaceutical industry's huge sums of money for campaign contributions and lobbying.

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 companies more than to their own constituents.

Could it be that numerous members of Congress are being overly influenced by the pharmaceutical and health products industry? **According to reports in OpenSecrets.Org, Center for Responsive Politics, the pharmaceuticals and health products industry contributed $44.1 million in campaign and leadership PAC contributions to House and Senate incumbents and challengers in the 2020 election.** In addition, the pharmaceutical and health products **industry spent $266.8 million lobbying in Washington, DC in 2021. The industry in 2021 had 1,616 lobbyists in Washington, DC. Fifty-nine percent of the lobbyists are former government employees.**

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

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

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

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

Attached: NRLN Competitive Bidding Proposal

Congress Should Mandate HHS Competitive Bidding on Prescription Drugs

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

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

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

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

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

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

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

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

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

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