



Congress Must Act to Reduce Price of Prescription Drugs

Talk Is Cheap – Drugs Are Not!

2/24/2020

Talking Points

- Few issues have been debated more on Capitol Hill over the past year than prescription drug prices. Despite a lot of talk about making prescription drug prices more affordable, a comprehensive bill has not been passed by both the House and Senate. Talk Is Cheap – Drugs Are Not!
- Americans, especially the 58 million Americans age 65 and older and people with disabilities on Medicare, are caught in the terrible perfect story of prescription drug price gouging. They are taking more expensive medications while living on fixed incomes. Even with their Medicare Part D prescription drug plan they are paying substantial out-of-pocket costs. This means that they especially feel the pain of pharmaceutical companies' relentless price increases while bills that would provide lower prices have not been passed by Congress.
- The 63 million seniors and people with disabilities who receive Social Security have been especially harmed by high drug prices. Since 1992, the growth in out-of-pocket healthcare costs, including prescription drugs, has outstripped Social Security's cost-of-living adjustments by more than a third.
- MarketWatch reported on January 2, 2020 that more than 60 pharmaceutical companies started the new year by raising the price of hundreds of drugs by an average of 5.8%. Pfizer Inc. led the way, including increasing prices by over 9% on more than 40 products.
- The average inflation rate 2019 was 1.8% according to U.S. Labor Department data published on January 14, 2020. The Kiplinger forecast on January 15, 2020 was the inflation rate is likely to run about 2.2% through 2020. Why do drug prices need to be raised so much more than inflation rate?

NRLN's Position on How to Reduce Prescription Drug Prices:

- Legislation should remove the prohibition on Medicare negotiating prescription drug prices and replace it with a competitive bidding mandate (see 2 attached proposals) to be applied wherever two or more FDA approved generic drugs, or two or more brand drugs, or a generic and brand drugs (upon patent expiration) treat the same medical condition. Passage of **H.R. 275 and S. 62, Empowering Medicare Seniors to Negotiate Drug Prices Act**, or **H.R. 448 and S.99, Medicare Drug Price Negotiation Act**, would direct the Secretary of Health and Human Services to negotiate lower Medicare Part D prices.
- Legislation should end pay-for-delay and other brand name drugmakers' tactics that keep generic drugs off the market. Passage of the Creating and Restoring Equal Access to Equivalent Samples (CREATES Act) in the fiscal year 2020 appropriations bill was a step in the right direction. It will make it easier for generic manufacturers to obtain samples of brand-name drugs necessary to develop generic versions. Additional action should be taken to pass **H.R. 2375 / S. 64, Preserve Access to Affordable Generics and Biosimilars Act**, or **H.R. 1499, Protecting Consumer Access to Generic Drugs Act**. Both bills would prohibit brand-name drug companies from pay-for-delay and other tactics against generic drugs.
- Legislation should allow importation of safe and less expensive drugs from Canada. Passage of **H.R. 478 and S. 61, Safe and Affordable Drugs from Canada Act**, would allow the personal importation of safe and lower priced drugs from approved pharmacies in Canada.

It appears to the NRLN there are only two bills currently receiving significant attention in Congress:

- **H.R. 3, Elijah E. Cummings Lower Drug Costs Now Act** (also referred to as the Speaker Pelosi bill) was introduced by Representative Frank Pallone (NJ-06) Chairman of the Energy and Commerce Committee and passed by the House on December 12, 2019.
- **S. 2543, Prescription Drug Pricing Reduction Act** (also referred to as the Grassley-Wyden bill) was introduced by Iowa Senator Chuck Grassley, Chairman, and Oregon Senator Ron Wyden, Ranking Member, Senate Committee on Finance. The Finance Committee approved the bill on September 25, 2019. Senators Grassley and Wyden updated the bill on December 6, 2019.
- The NRLN urges Senate Majority Leader Mitch McConnell (Kentucky) to call up **S. 2542** for a vote on the Senate floor.
- The NRLN hopes **S. 2542** will be passed and go to a conference committee with **H.R. 3** and result in a compromise bill that both the House and Senate will pass and the President will sign.

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

For more information on this subject, contact Alyson Parker at 813-545-6792 or executivedirector@nrln.org



Congress Should Mandate HHS Competitive Bidding on Prescription Drugs

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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 healthcare security for seniors, their kids, grandkids 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; particularly the cost of healthcare, 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 for the industry's abusive pricing.

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 generic drug product approval 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 2nd 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 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 to 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 in 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. The entire NRLN whitepaper on Prescription Drug Prices can be requested from Alyson Parker, NRLN Executive Director, at executivedirector@nrln.org or call 813-545-6792.

General Business Model to be Applied by HHS for Competitive Bidding	Proposed Negotiating Model for Drug Price Discounts
<p><i>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.</i></p>	<p><i>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.</i></p>
<p>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.</p>	<p>Identify medical condition: Diabetes. Drug needed: Insulin.</p>
<p>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.</p>	<p>Establish Insulin formulary. Identify brand-name and generic producers (if any) of Insulin.</p>
<p>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 percent of business to award two or more suppliers.</p>	<p>HHS Secretary (or his staff) initiates negotiations with drug makers for price discounts.</p>
<p>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.</p>	<p>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.</p>
<p><u>Negotiable Terms:</u> 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.</p>	<p>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.</p>