H.R. 3 – Drug Price Negotiation Bill Summary

Broad Power to Negotiate Lower Drug Prices for All Americans
Every year, the HHS Secretary would be empowered to directly negotiate prices on the top 250 drugs with the greatest total cost to Medicare and the entire U.S. health system without competition from at least two generic, biosimilar or interchangeable biologics on the market – the power to negotiate as many as possible of the most costly 250 drugs each year, year after year. In the first year alone, drugs representing almost half of all Medicare Part D spending, covering tens of millions of patients, would be subject to the negotiation process – including insulins.

To deliver maximum savings for the greatest number of Americans, the price determined by the negotiation process would be available to all purchasers – not just Medicare beneficiaries.

An International Price Index to End Drug Companies Ripping Off Americans
American seniors and families shouldn't have to pay more for the same drug than what big pharmaceutical companies charge people in other countries. To ensure negotiations produce real price reductions, the law sets a maximum price for any negotiated drug with an International Price Index.

Tough Penalties to Keep Drug Companies at the Table & Prevent Interruption to Access
If a drug manufacturer refuses to participate in any part of the negotiation process or does not reach agreement with HHS, they will be assessed a Non-Compliance Fee equal to 75 percent of the gross sales of the drug in question from the previous year.

This steep, retroactive penalty creates a powerful financial incentive for drug manufacturers to negotiate and abide by the final price, while ensuring that patients maintain uninterrupted access to the medicines they need. The penalty gives the HHS Secretary leverage without resorting to a restrictive formulary and without the interruptions of contracting, building and approving a whole new production line.

If a manufacturer agrees to a price and then overcharges Medicare or fails to offer the negotiated price to other payers, the manufacturer will be subject to a civil monetary penalty equal to 10 times the difference.

Reverse Price Hikes Above Inflation Across +8,000 Drugs in Medicare
Year after year, Americans have watched drug companies hike the costs of drugs well above the rate of inflation, subjecting patients to soaring prices even for long-ago discovered drugs that have been on the market for years or decades.

To reverse these unjustified price hikes, all +8,000 drugs in Medicare Part B and D would face a new inflation rebate. If a drug company has raised the price of a drug in Part B or D above the rate of inflation since 2016, they can either lower the price or be required to pay the entire price above inflation in a rebate back to the Treasury.

Reinvesting in Innovation & Historic Improvements to Medicare Benefits
With the savings from negotiating down the unjustified drug prices that are bankrolling stock-buybacks and record-breaking profits, H.R. 3 will reinvest billions of dollars where they belong: in the search for new treatments and cures.

With enough savings, H.R. 3 could also fund transformational improvements to Medicare that will cover more and cost less, including a $2,000 out-of-pocket limit, and even Medicare coverage for vision, hearing and dental.

Why is Bold Legislation to Lower Drug Prices Necessary?
Across America, seniors and families are struggling to afford the prescription drugs they need to stay healthy. Three in ten of all adults reported not taking their medicines as prescribed at some point in the past year because of the cost.[1]

Yet prescription drug companies continue to hike prices without any limit – charging Americans prices that are vastly higher than what they charge for the same drugs in other companies[2], and subjecting the U.S. to unjustified annual price hikes far above the rate of inflation.

- More than 3,400 drugs increased their list prices in the first 6 months of 2019, an increase of 17 percent from the year before.[3]
- From 2011-2016, prescription drug spending in the U.S. grew by more than 2.5 times inflation during that period.[4]

The soaring cost of insulin provides one of the starkest examples of broken drug pricing. More than 100 million Americans are diabetic or pre-diabetic. Diabetes is the disease category with the highest spending – more than $300 billion per year. But although the drug was invented in 1922, its inflation-adjusted per unit price has, at least, tripled between the 1990s and 2014. In the U.S., insulin costs per patient have nearly doubled from 2012 to 2016 ($2,864 vs $5,075).

The soaring price of prescription drugs is crushing Americans at the pharmacy country, driving up health insurance premiums, and creating unaffordable costs for taxpayers who finance Medicare and Medicaid.

Will Lower Drug Prices Hurt Innovation?
It's all too clear that big pharmaceutical companies are raising prices on Americans to pad their profits, not to increase funding for the research and development needed to find new cures and treatments:

- Nine out of 10 big pharmaceutical companies spend more on marketing, sales, and overhead than on research, according to an analysis by the Washington Post.[5]
- In 2018, drug corporations spent $6.5 billion advertising—a 100% percent increase from 2012.[6]

In fact, much of the research and development driving the search for new breakthroughs isn't paid for by drug companies, it's paid for by American taxpayers through federal funding for the NIH and other grants. Based on data from a survey of PhRMA's own member companies, one out of every three dollars spent on drug research comes from American taxpayers.[7][8]

Meanwhile, instead of using their multi-billion dollar windfalls from the giveaways of the GOP tax scam to lower prices, Big Pharma used the money for stock buybacks[9] – further evidence that out-of-control drug prices are padding corporate profits instead of fueling the search for new cures.

H.R. 3 will enable HHS to negotiate for fair prices that reward genuine innovation and recoup research and development costs – but not unjustifiable prices that gouge patients. And with the savings from lowering prices, H.R. will make bold investments in innovation and the search for breakthrough treatments and cures at the NIH.

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[1] https://www.kff.org/health-costs/poll-finding/kff-health-tracking-poll-february-2019-prescription-drugs/
[2] https://www.vox.com/science-and-health/2016/11/30/12945756/prescription-drug-prices-explained
[3] https://www.cbsnews.com/news/drug-prices-in-2019-are-surging-with-hikes-at-5-times-inflation/
[4] Analysis of Centers for Medicare & Medicaid Services, Office of the Actuary prescription drug spending data, Table 11 and BLS data on CPI-U 2011-2016
[5] https://www.washingtonpost.com/news/wonk/wp/2015/02/11/big-pharmaceutical-companies-are-spending-far-more-on-marketing-than-research/?utm_term=.dc7e820c4172
[6] https://www.fiercepharma.com/marketing/kantar-tallies-6-5-billion-for-pharma-ad-spending-2018-abbvie-humira-ranks-as-top
[7] https://www.sciencemag.org/news/2018/09/nih-gets-2-billion-boost-final-2019-spending-bill
[8] · https://www.phrma.org/advocacy/research-development
[9] https://www.axios.com/pharma-share-buyback-tax-reform-40a30b93-6149-4c67-bd65-cd05ee814215.html

H.R. 3 Title Summary

TITLE I – Drug Price Negotiation

Drug Selection Process

Every year, the Secretary would identify the 250 brand-name drugs that lack price competition with the greatest total cost to Medicare and the whole U.S. health system. The Secretary would use data provided by Medicare, Medicaid, as well as commercial insurance to make the determination about aggregate cost. The overwhelming volume of costs in Medicare is disproportionally concentrated in the segment of drugs that would be eligible for negotiation the first year.

Part D Negotiable Drug Spending Rank	Percent of Total Part D Spending
1-25	23%
26-50	9%
51-75	6%
76-100	4%
101-125	3%
126-150	2%

Part B Negotiable Drug Spending Rank	Percent of Total Part B Spending
1-25	66%
26-50	16%
51-75	7%
76-100	5%

An eligible drug that lacks price competition will be defined as a brand-name drug that does not have two or more generic, biosimilar, or interchangeable biologics on the market. Insulins would also be included for negotiation.

In prioritizing drugs for negotiation each year, the HHS Secretary would take into account the drugs for which the greatest savings to taxpayers, patients, and all payers may be achieved. A drug selected for negotiation would continue to be in the program until sufficient competition enters the market.

Negotiation of Maximum Fair Price

The HHS Secretary would directly negotiate with drug manufacturers to establish a maximum fair price. The law establishes an upper limit for the price reached in any negotiation as no more than 1.2 times (or 120 percent) of the volume-weighted average of price of six countries (Australia, Canada, France, Germany, Japan, and the United Kingdom), known as the international index price.

While negotiating the price, the HHS Secretary would take into consideration:

- research and development costs of the drug as well as cost of production;
- information on alternative treatments and the value of the drug; and,
- domestic and international sales information.

If a manufacturer refuses to enter into negotiations after being selected by the Secretary or if the manufacturer leaves the negotiation before a maximum fair price is agreed to, then the manufacturer will be assessed an excise tax equal to 75 percent of annual gross sales in the prior year of the selected drug.

This steep, retroactive penalty creates a powerful financial incentive for drug manufacturers to negotiate and abide by the final price, while ensuring that patients maintain uninterrupted access to the medicines they need. The penalty gives the HHS Secretary leverage without resorting to a restrictive formulary and without the interruptions of contracting, building and approving a whole new production line.

The goal is for the HHS Secretary and the manufacturer to negotiate a mutually agreed maximum fair price that is below the international index price through a voluntary, bi-lateral negotiation process. Once a price is negotiated, the manufacturer may not increase the price faster than inflation in the subsequent years until sufficient price competition enters the market. The Secretary or the manufacturer may request a re-negotiation if new information becomes available after the maximum fair price is agreed to.

Application of Maximum Fair Price to Medicare and Other Payers
The negotiated price would be applied to Medicare, with flexibility for Medicare Advantage and Medicare Part D plans to use additional tools to negotiate even lower prices. A manufacturer would also be required to offer the negotiated price to group health plans, group and individual health insurance plans, VA, and TRICARE. It is at the discretion of these payers whether to accept the negotiated price.

If a manufacturer has agreed to a negotiated price, and then overcharges Medicare or fails to offer the maximum fair price to other payers, the manufacturer would be subject to a civil monetary penalty equal to 10 times the difference between the price charged and the maximum fair price for the drug.

TITLE II – Reducing Out-of-Pocket Costs for Seniors and Modernizing Part D

Title II would simplify the benefit design of Medicare Part D and realign incentives to encourage more efficient management of drug spending. Starting January 1, 2022, it would: (1) change enrollee cost sharing in the initial coverage limit and the coverage gap; (2) cap enrollee cost sharing above the catastrophic out-of-pocket threshold; and (3) change the amount of annual out-of-pocket spending needed to trigger catastrophic coverage. In addition, the provision would modify Part D financing mechanisms to (1) lower federal reinsurance during the catastrophic coverage period; (2) sunset the existing manufacturer discount program in the coverage gap; and (3) institute a new manufacturer discount program in the initial phase and catastrophic coverage phase of the benefit.

To simplify and reduce cost sharing for Part D enrollees, this provision would eliminate the coverage gap and establish 25 percent cost-sharing between the annual deductible and the catastrophic threshold. In this initial phase of the benefit, insurers are responsible for [X] percent and manufacturers are responsible for [X] percent respectively. The provision would also completely eliminate cost-sharing during catastrophic coverage. The catastrophic out-of-pocket threshold would be set at $ [X] in 2022 and indexed to growth in Part D spending. This amount reflects the true out-of-pocket spending enrollees face before reaching catastrophic coverage under Part D today. Additionally, the provision would reduce federal reinsurance payments so that Medicare is responsible for 20 percent, insurers are responsible for [X] percent and manufacturer are responsible for [X] percent, respectively, of total drug spending during catastrophic coverage.

Finally, this provision would sunset the current coverage gap discount program in which manufacturers pay 70 percent of drug costs. Instead, the provision would establish a new manufacturer discount program in which manufacturers provide discounts for drugs and biologics utilized during the initial phase and during catastrophic coverage. Under the provision, manufacturers that choose to have their drugs covered under Part D would enter into agreements with the HHS Secretary to provide [X] percent discounts off negotiated prices during the initial and during catastrophic coverage, including for LIS beneficiaries. Insurers would subtract the anticipated manufacturer discounts from the actuarial value of the Part D benefit when submitting annual bids to CMS.

Manufacturers would provide coverage discounts to applicable beneficiaries, defined as individuals who are: 1) enrolled in a Part D plan; 2) are not enrolled in a qualified retiree prescription drug plan; and 3) have incurred costs for covered part D drugs in a year that are equal to or exceed the annual out-of-pocket threshold. The discounts would be provided for applicable drugs, which are defined as brand-name drugs and biologics and biosimilars on the formulary of a Part D plan or otherwise covered by a Part D plan, including through an enrollee exception or appeal. The discounted prices would be provided at the point of sale at a pharmacy or through a mail-order service. Manufacturers would provide appropriate data to demonstrate they comply with the program.

The coverage discounts would be administered in the same way as the coverage gap discount program is today. CMS would contract with one or more third parties to administer the discounts. If a third party administrator determined a manufacturer was not in compliance, the third party would be required to notify

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the Secretary. The Secretary could collect appropriate data from insurers in a timeframe that allowed for discounted prices to be provided for applicable drugs. Manufacturers would be subject to periodic CMS audits. HHS could impose civil monetary penalties on manufacturers that failed to provide required catastrophic coverage discounts. The penalty would be commensurate with the sum of: (1) the amount the manufacturer would have paid with respect to such discounts under the agreement; and (2) 25 percent of such amount. The Secretary could terminate a manufacturer agreement for a "knowing and willful violation" of program requirements. A manufacturer could request a hearing, which would be allowed with sufficient time for the effective date to be repealed if determined appropriate. A manufacturer would be allowed to terminate an agreement to provide discounts for any reason.

TITLE III – Medicare Part B & D Inflation Rebates

Year after year, Americans have watched drug companies hike the costs of drugs well above the rate of inflation, subjecting patients to soaring prices even for long-ago discovered drugs that have been on the market for years or decades.

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Setting the base year of inflation as 2016 would wipe out the last three years of price hikes in Medicare Part B & D, lowering prices further and for more drugs than the Senate Finance inflation rebate.

TITLE IV – Historic Improvements to Medicare & Additional Investments

With the savings from negotiating down the unjustified drug prices that are bankrolling stock-buybacks and record-breaking profits, H.R. 3 will reinvest billions of dollars where they belong: in the search for new treatments and cures.

With enough savings, H.R. 3 could also fund transformational improvements to Medicare that will cover more and cost less – potentially including Medicare coverage for vision, hearing and dental, and many other vital health system needs.

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