Statement for the House of Representatives Committee on Energy and Commerce

May 4, 2021

Negotiating a Better Deal: Legislation to Lower the Cost of Prescription Drugs

Submitted by
National Association of Health Underwriters

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I am writing on behalf of the National Association of Health Underwriters (NAHU), a professional association representing over 100,000 licensed health insurance agents, brokers, general agents, consultants and employee benefits specialists. The members of NAHU work daily to help millions of individuals and employers of all sizes purchase, administer and utilize health plans of all types. Our members have daily first-hand experience with how Americans are struggling with pharmaceutical prices. As such, we have a great interest in legislation that could lower prescription drug prices and reduce out-of-pocket costs for patients.

Prescription drug prices in the United States are significantly higher than 32 other nations, averaging 2.56 times greater for generic drugs and 3.44 times greater for brand-name medications. [1] These high drug costs have forced consumers to make difficult choices, like spending less on groceries, putting off a doctor's visit, or even declining to fill a necessary medication prescribed by their physician.[2] Accordingly, NAHU believes that extensive public policy action needs to occur to reduce the cost of prescription pharmaceuticals in the United States. Our comments today are primarily focused on H.R. 3, also known as the Elijah E. Cummings Lower Drug Costs Now Act.

One of the main provisions of H.R. 3 would allow the the secretary of Health and Human Services to negotiate prescription drug prices for the Medicare program and its beneficiaries. The secretary would be required to negotiate a minimum of 25 drugs in 2023 and at least 50 drugs in 2024, with international prices from six comparable high-income nations (Australia, Canada, U.K., France, Germany, and Japan) determining the minimum and maximum prices for the negotiation process. The minimum price would be the lowest price of the drug in any of those six nations, while the maximum price would be 120 percent of the average international market price across the comparable countries. Following negotiation with Medicare, H.R. 3 would extend this negotiated price to commercial plans as well.

Regarding an international pricing index, the Trump Administration proposed a similar system of international reference pricing to cap rates paid for physician-administered drugs under Medicare Part B. This regulation was structured as a seven-year Medicare demonstration project and as a mandatory model tying U.S. prices for affected drugs to those paid in a group of developed countries. This regulation, unlike H.R. 3, would only apply to Part B prices.[3]

NAHU, generally speaking, supports granting the Medicare program the ability to negotiate with pharmaceutical companies. Many comparable countries already enter such a negotiation process. According to a 2019 CBO analysis, these negotiation provisions, if enacted, would lower spending by about $456 billion.[4] However, NAHU has several concerns in this area, including possible negative impacts of price-setting on innovation and the potential for cost-shifting from Medicare to commercial plans.

[1] Mulcahy, Andrew W., et al, International Prescription Drug Price Comparisons: Current Empirical Estimates and Comparisons with Previous Studies. Santa Monica, CA: RAND Corporation, 2021.
[2] Gill, Lisa. The Shocking Rise of Prescription Drug Prices. Consumer Reports. 26 November 2019.
[3] Centers for Medicare and Medicaid Services. Most Favored Nation (MFN) Model. 27 November 2020. Accessed 3 May 2021.
[4] Congressional Budget Office. H.R. 3, Elijah E. Cummings Lower Drug Costs Now Act. 10 December 2019.

The CBO recently released a report analyzing the research and development (R&D) process in the pharmaceutical market, where they noted that the amount of money that is devoted to R&D is directly determined by the projected revenue from a new drug and policies that influence the supply and demand for said drugs.[5] When the anticipation of future profits is higher, companies tend to invest more in R&D and produce more new drugs, but if expectations about prices and profits are lower, companies tend to invest less in R&D, ultimately leading to fewer drugs developed. By capping the price of certain high-cost drugs at 120 percent of the average international market price, regardless of any changes in demand, NAHU is concerned that H.R. 3 will lead to a decrease in R&D spending, a decrease in innovation and therefore a decrease in the number of drugs that American consumers have access to.

H.R. 3 would also penalize manufacturers that do not comply with these provisions, subjecting them to an excise tax ranging from 65 percent to 95 percent of gross sales of the drug. Because of this penalty, in combination with establishing a maximum potential price and then extending these prices to commercial plans, NAHU is uncertain whether the negotiation process outlined in this bill may effectively lead to the federal government setting prices in the private market. Price-setting can be a dangerous precedent to set in this area, and we are apprehensive about potential ramifications of these price controls and the implications it has for regulation of the health insurance market moving forward.

We would like to direct the committee's attention to the German negotiation model. For context, most German citizens obtain health insurance from one of 110 competing, non-governmental "sickness funds," with the premiums paid by employers and employees and with governmental subsidies for the unemployed and retired. These nonprofit health plans participate in the national system of employer-sponsored payment, risk adjustment, and centralized price negotiations with physicians, hospitals, and pharmaceutical manufacturers.[6] In Germany, health plans reward innovative drugs that provide genuine clinical breakthroughs through a clinical comparative effectiveness review by the non-governmental nonprofit Institute of Quality and Efficiency in Healthcare (IQWiG). If the IQWiG determines that a new drug provides a major or considerable added benefit for patients, then that sets the basis for negotiations with the Federal Joint Committee, a private organization governed by the associations of sickness funds, physicians, hospitals, and patient advocates. This classification allows manufacturers to get higher prices for more innovative drugs.[7]

If parties cannot reach agreement in the negotiation, the drug's price is reviewed by an arbitration panel with representatives from both entities, who reach a decision based on comparable international prices. And in the interest of price transparency, every negotiated or arbitrated price is public knowledge, so consumers understand the process used to determine the price.[8] While we are not suggesting that the U.S. adopt every aspect of the German model, it is important to understand how their system manages to keep prices lower than American prices without stifling innovation in the process.

[5] Congressional Budget Office. Research and Development in the Pharmaceutical Industry. April 2021.
[6] The Commonwealth Fund. Drug Price Moderation in Germany: Lessons for U.S. Reform Efforts. 23 January 2020.
[7] Lauterbach, Karl, et al. Germany's Model For Drug Price Regulation Could Work In The US. *Health Affairs*. 29 December 2016.
[8] National Coalition on Health Care. National Coalition on Health Care Policy Priorities U.S. Drug Pricing and the German Model. 7 August 2020.

Another major provision of H.R. 3 is the creation of "reverse price hikes," new inflation rebates that would apply to over 8,000 prescription drugs available in Medicare Part B and D. This would limit annual price increases for drugs covered under Part B and under Part D to the rate of inflation as measured by the consumer price index. We appreciate the logic behind this proposal, since drug companies have hiked the costs of drugs well beyond the rate of inflation, even for drugs that have been on the market for some time. One prominent example of this is the life-saving EpiPen, an allergy shot used during serious allergic reactions; the drug company Mylan increased the EpiPen's cost from roughly $60 in 2007 to over $700 in 2016 for a pack of two units. Additionally, a precedent has already been set regarding capping certain drug prices in Medicare. Several NAHU members who work with Medicare beneficiaries have reported positive feedback regarding the new $35 insulin price cap in certain Medicare plans. Per CMS estimates, Medicare beneficiaries who use insulin and join one of the participating plans could see an average out-of-pocket savings of $446 per year, or 66 percent.[9]

However, we still harbor concerns with the inflation rebates outlined in H.R. 3. By tethering this provision to the consumer price index alone, this stipulation essentially caps drug prices without consideration for R&D and manufacturing costs. As was mentioned earlier, the amount of money that a manufacturer devotes to R&D is directly determined by the projected revenue from a new drug and policies that influence the supply and demand for the drug. If an economic event occurs that has a drastic impact on drug manufacturing costs, then there may be a legitimate market-based rationale to why a drug price may increase beyond the rate of inflation in a short period of time.

Furthermore, NAHU is concerned that this would result in cost-shifting, ultimately increasing prices for those on commercial plans. On the medical side, Medicare sets reimbursement rates lower than private payers and the costs are shifted to the private market; since Medicare pays providers an average of 80 percent of the cost of care delivered,[10] providers routinely make up for this short-fall by charging private plans more.[11] Any legislation aimed at lowering drug costs must consider the potential for this cost-shifting to occur in the pharmaceutical market as well.

In addition to these major provisions, H.R. 3 would also establish a hard cap on out-of-pocket spending for Medicare beneficiaries that would initially be set at $2,000 per year. For catastrophic costs, the proposal would reduce Medicare payments from 80 to 20 percent, increases plans' share from 15 to 50 percent, and requires drug manufacturers to pay that 30 percent difference. H.R. 3 would also phase out the coverage gap and require manufacturers to pay 10 percent of costs. Once again, a primary concern of ours is the potential for plans to make up the lost revenue by shifting the cost from the Medicare market to the individual and employer markets.

While we have reservations about many provisions in H.R. 3, there are already proposals in existence that NAHU supports that would eliminate anti-competitive practices and ensure a freer, fairer market. For example, eliminating "pay-for-delay" deals between pharmaceutical companies in which one company pays a generic competitor to delay research, production, or sale of a competitive drug. The FTC estimates that ending these pay-for-delay agreements

[9] Centers for Medicare and Medicaid Services. President Trump Announces Lower Out of Pocket Insulin Costs for Medicare's Seniors. 26 May 2020.
[10] Centers for Medicare and Medicaid Services. How to Use the Searchable Medicare Physician Fee Schedule (MPFS). March 2021.
[11] Milliman. Why hospital cost shifting is no longer a viable strategy. June 2010.

would save $3.5 billion each year for patients, insurers, and government programs.[12] This provision is included in the Protesting Consumer Access to Generic Drugs Act, which is also being considered during this hearing. This could level the playing field in the pharmaceutical market, and allowing for increased competition earlier in the lifespan of a drug may decrease costs to the point where many of the issues H.R. 3 seeks to address may be resolved.

We appreciate the opportunity to provide these comments and would be pleased to respond to any additional questions or concerns of the committee. If you have any questions about our comments or if NAHU can be of assistance as you move forward, please do not hesitate to contact me at either (202) 595-0639 or jtrautwein@nahu.org.

Sincerely,

Janet Stokes Trautwein
CEO, National Association of Health Underwriters

[12] Federal Trade Commission. Pay for Delay. Accessed 3 May 2021.