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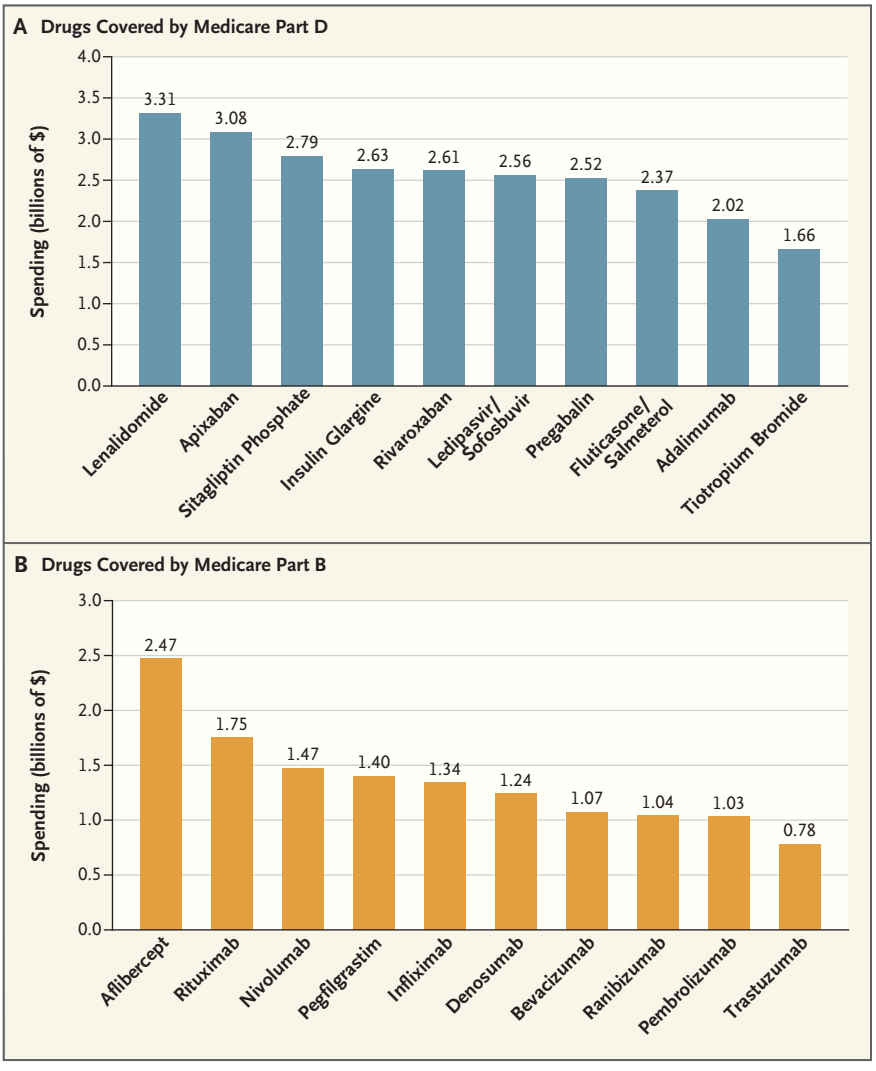
Advancing Legislation on Drug Pricing — Is There a Path Forward?

Stacie B. Dusetzina, Ph.D., and Jonathan Oberlander, Ph.D.

On September 19, 2019, the speaker of the U.S. House of Representatives, Nancy Pelosi (D-CA), released what is now called the Elijah E. Cummings Lower Drug Costs Now Act of 2019 (H.R. 3), aimed at reducing spending on prescription drugs.[1] The bill contains several key but politically divisive provisions targeting prices paid to drug manufacturers and would reform Medicare to reduce both federal spending and beneficiaries' out-of-pocket costs. It would establish a drug-price negotiation process, inflation-based rebates that limit price increases on existing products, and changes to the design of Medicare Part D (the prescription-drug benefit).

The bill authorizes the secretary of health and human services to create a "Fair Price Negotiation Program" that, beginning in 2023, would permit price negotiation for at least 25 drugs each year (increasing to at least 35 drugs each year by 2033).[1] Companies whose products are selected for "negotiation" will in reality face price regulation and a severe penalty for noncompliance. Drugs would be chosen from a candidate set of 250 brand-name drugs that lack generic or biosimilar competition, including the 125 drugs responsible for the highest net spending (after accounting for discounts and rebates) in Medicare Part D and Medicare Advantage and the 125 drugs responsible for the highest net spending in the United States overall. The secretary would also negotiate insulin prices.[1] The bill amends the noninterference clause in the Medicare Modernization Act that has prohibited the secretary from negotiating drug prices in Part D by permitting targeted negotiation for some, but not all, medications.

Of the 250 candidates, drugs would be selected for negotiation on the basis of the potential for price reductions to create savings for the federal government. This determination would be based on considerations including sales volume and the difference between U.S. prices and prices paid in other countries. The 10 drugs accounting for the most spending in 2017 for Medicare Part D (outpatient prescriptions) and Part B (physician-administered drugs) are shown in the graph. The Medicare program and beneficiaries spent nearly $40 billion on these 20 drugs in 2017. Drugs



Drugs Accounting for the Highest Spending in Medicare Part D and Part B, 2017.

Data are from the Centers for Medicare and Medicaid Services Drug Spending Dashboards for Medicare Part D and Part B.

used by many beneficiaries and drugs with very high prices are likely candidates for negotiation under the speaker's bill.[1]

For the selected products, target prices would be determined on the basis of manufacturer-supplied information including research and development costs, manufacturing costs, level of federal investment in drug development, patent and exclusivity status, national sales data, clinical trial data, the presence and comparative effectiveness of therapeutic alternatives, and information on foreign sales.[1] There would also be a legislatively set maximum price that could not exceed 120% of the average net price paid for the same drug in designated countries (Australia, Canada, France, Germany, Japan, and the United Kingdom). When international price comparisons are not possible, drug prices would not be allowed to exceed 85% of the average manufacturer price (the price paid by wholesalers to manufacturers after rebates and most discounts).

Once a product is selected for negotiation, manufacturers would either accept the negotiated price or be assessed a fee equal to 65% of the prior year's gross sales for the drug, a penalty that would increase by 10% for every additional quarter of noncompliance (up to 95%). This "maximum fair price" would be available to all payers, and manufacturers found to be overcharging Medicare or other payers would be penalized.[1]

Beyond these measures, the bill would establish inflation-based rebates for drugs covered under either Part B or Part D with average prices of $100 or more. Manufacturers of drugs or biologic products whose prices have increased faster than inflation since 2016 would either have to reduce their prices (presumably to 2016 levels) or pay the difference in price (multiplied by the number of units sold) to the U.S. Treasury in the form of a rebate.[1]

Finally, the bill would revise the Medicare Part D benefit by capping beneficiaries' out-of-pocket spending at $2,000 per year and simplifying the current benefit structure. For example, it would require manufacturers to discount prices on brand-name drugs by 10% for medications purchased before beneficiaries reach the out-of-pocket threshold and by 30% for those purchased after beneficiaries exceed the out-of-pocket threshold, with funds being used to reduce point-of-sale prices for consumers. It would also reduce Medicare's share of spending when patients reach the out-of-pocket limit (reinsurance) and shift the

burden of high-cost cases to private Part D plans.[1]

Taken together, these policies could have a substantial effect on drug spending. The Congressional Budget Office (CBO) estimates that the H.R. 3 provisions requiring price negotiation for some drugs, limiting U.S. prices relative to international prices, and imposing tax penalties on manufacturers that don't negotiate would reduce federal Medicare spending by $345 billion during 2023 to 2029 (amounting to an estimated savings of 28% in Medicare Part D spending and 5% in total Medicare spending over this period).[2,3] But the CBO's preliminary analysis (which doesn't assess the bill's other provisions) also highlights the trade-offs involved in curtailing drug spending. The CBO predicts that the ensuing lower revenues for the pharmaceutical industry would reduce the number of new drugs that come to market, though the magnitude of that reduction remains highly uncertain.[2] It also anticipates that drug prices in other countries would rise as a result of the bill.

The House bill represents a major departure from the U.S. status quo. The embrace of price controls reverses the hands-off stance toward the pharmaceutical industry taken by both Medicare and the Affordable Care Act. And although Washington has previously leveraged Medicare's purchasing power to constrain program expenditures, giving all payers access to federally obtained discounts on drugs would constitute an important development in system-wide price regulation. U.S. health care has long been the most expensive in the world. But knowledge of that fact has not previously produced action; using international reference prices to reduce U.S. drug payments would break new ground.

An audio interview with Dr. Oberlander is available at NEJM.org

Can the bill pass Congress? There is bipartisan interest in restraining prescription-drug spending, as evidenced by parallel legislation cosponsored by Charles Grassley (R-IA) and Ron Wyden (D-OR) that passed the Senate Finance Committee on a vote of 19 to 9, with 6 Republicans joining 13 Democrats in favor of the bill.[4] That bill, too, would cap beneficiaries' out-of-pocket spending in Medicare Part D and limit increases in drug prices for Medicare, among other provisions. Moreover, President Donald Trump has repeatedly voiced displeasure with the fact that the United States pays higher drug prices than other countries. The aim of reducing U.S. drug prices is in keeping with Trump's agenda of economic nationalism. Indeed, he has proposed an International Pricing Index for Medicare Part B drug spending.[5] Both parties have a political interest in engaging with an issue that resonates with the public. For many insured voters, addressing rising costs is a higher priority than expanding coverage.

Yet there are substantial obstacles to drug-pricing reform. Constrained prices amount to lower income for the pharmaceutical industry, and PhRMA (the Pharmaceutical Research and Manufacturers of America) fiercely opposes these proposals. There are also concerns about the potential effect of price controls on pharmaceutical innovation. Such controls contravene many congressional Republicans' preference for relying on market forces rather than on centralized cost containment. Despite their overlap, the House bill's more aggressive efforts to rein in drug prices for a subset of drugs makes it more contentious than the bill passed by the Senate Finance Committee; Senate Majority Leader Mitch McConnell (R-KY) has already pronounced the House bill dead in the Senate.

The politics of prescription-drug policy are changing because of pressure caused by rising spending, imperiling the deals that have protected the pharmaceutical industry from stronger federal regulation. The growing momentum behind drug-pricing reform means that a compromise that bridges the House and Senate Finance Committee bills and the Trump administration's proposal is possible. But in this polarized political environment, with impeachment proceedings dominating the agenda and a contentious election nearing, securing bipartisan agreement on health policy changes is difficult. Absent congressional action, however, Medicare beneficiaries and taxpayers will continue to shoulder the burden of high drug prices.

Disclosure forms provided by the authors are available at NEJM.org.

From the Department of Health Policy, Vanderbilt University School of Medicine, Nashville (S.B.D.); and the Department of Social Medicine, School of Medicine, and the Department of Health Policy and Management, Gillings School of Global Public Health, University of North Carolina, Chapel Hill (J.O.).

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Which Drug Prices Should Medicare Negotiate? A "Too Little" or "Too Late" Approach

Peter B. Bach, M.D., M.A.P.P.

Americans all along the political spectrum favor allowing Medicare to negotiate the prices it pays for prescription drugs.[1] In September, House Speaker Nancy Pelosi (D-CA) introduced what is now called the Elijah E. Cummings Lower Drug Costs Now Act of 2019 (H.R. 3), and the bill would have Medicare do just that.[2]

Although there are draft pieces of legislation and regulation that take aim at the rising cost of drugs, H.R. 3 is the legislative tip of the spear for price negotiation. If it became law, Medicare would target drugs that claim the largest share of the health care budget and that face limited competition from generics or biosimilars. I propose an alternative set of drugs for price negotiation: those that have too little evidence to support full approval or are too late in their life cycle to justify continued high prices.

My approach may identify some of the same drugs for price negotiation as the ones described in H.R. 3, but the rationale differs. "Too little" and "too late" drugs are those with monopolies that are unjustified by the current incentive framework for innovation, which has three phases. First, a corporation must spend money to prove that its product is safe and effective. Then the corporation is granted a limited period of market exclusivity. Finally, competition enters the market and prices and revenues for the original product fall.

If the pharmaceutical industry opposes H.R. 3 because negotiating down the prices of drugs undermines incentives for innovation, that argument is less compelling for drugs that fall into the too-little and too-late categories.

On the too-little front, the Food and Drug Administration (FDA) grants full approval for drugs when there are convincing data for their safety and efficacy, but it also allows some drugs on the market conditionally on the basis of data indicating that they improve a surrogate indicator of patient benefit, even if there are no data suggesting that they improve clinical outcomes. Despite the conditional nature of approval for drugs entering the market through this accelerated approval pathway, pharmaceutical firms currently charge the same high prices that fully approved drugs capture. Two examples: Lartruvo (olaratumab), an anticancer drug, launched at $17,176 per month in 2016. Exondys 51 (eteplirsen), for patients with Duchenne's muscular dystrophy, launched at an average of $1 million per year per patient in 2016.

Medicare's inability to negotiate prices during the period of conditional approval is detrimental for two reasons. First, required follow-up studies somewhat routinely show that the treatment deserved no reward whatsoever. Lartruvo's negative follow-up trial led to its withdrawal from the U.S. market, but its maker first banked $400 million in U.S. revenues.[3] (Of 198 indications granted accelerated approval since 1992, a total of 115 have ultimately gained full approval, whereas 67 have not and 16 others have been withdrawn.) Second, the innovation incentive is meant to encourage the completion of a drug's development and testing. If the reward is given too early in the process, the incentive dissolves. Required studies of Exondys 51, for example, are 3 years behind schedule.[3]

For many drugs, the FDA has granted conditional approval for some indications and full approval for others, but varying a product's prices according to indication is challenging.[4] To make