



## Congress and President Trump take on high drug prices

Proposals from the White House and Congress to lower prescription drug costs, which both rejected more than a decade ago, are making a comeback. Susan Jaffe reports.

The Trump administration's Department of Health and Human Services (HHS) is the first federal health agency to claim they are "open" to the idea of importing cheaper drugs from Canada and overseas. And both Republicans and Democrats in Congress now advocate familiar strategies to rein in drug price increases.

Americans pay more per capita for prescription drugs than any other country, according to a National Academies of Sciences, Engineering, and Medicine study published last year. And in an opinion poll earlier this month by the Kaiser Family Foundation, 70% of the American public says lowering those costs should be a top priority for Congress.

Last week, Democratic majority leaders in the US House of Representatives introduced massive legislation to overhaul how the government pays for drugs for the 60 million older or disabled adults in the Medicare programme. Among other measures, Medicare officials would be authorised to negotiate lower prices for at least 25 and up to 250 of the most expensive brand-name medicines. The price for each drug would be based on no more than 120% of the volume-weighted average of its cost in Australia, Canada,

France, Germany, Japan, and the UK. Drug companies would face hefty financial penalties if they did not charge private insurers the same lower prices Medicare would pay.

But the legislation introduced by House Speaker Nancy Pelosi, a California Democrat, was quickly rejected by the minority Republican members of a House committee even before it holds a hearing on the bill. The Republicans claimed Pelosi was pursuing "a socialist proposal to appease her most extreme members".

When the Republican-controlled Congress debated the 2003 legislation that added drug coverage to Medicare, lawmakers included a provision expressly prohibiting the government from negotiating prices with the drug industry. Instead, it gave the job to the private insurance companies Medicare paid to offer drug policies to beneficiaries. Market competition would pressure insurers to keep drug costs low to attract more members. And yet people with Medicare have said they cannot always afford their prescriptions because their insurance plan often does not stretch far enough.

The Pelosi bill removes that ban and is expected to be approved by the Democratic majority in the House. It is likely to languish in the Republican-controlled US Senate.

A bill championed by the Senate Finance Committee chairman, Chuck Grassley of Iowa, and the committee's senior Democrat, Ron Wyden of Oregon, takes a more moderate approach to controlling drug prices. It continues the ban on government price negotiations. But if drug companies raised prices at a rate greater than inflation, they would have to pay the difference in the form of rebates to the US Treasury.

### White House strategy

Fully aware that no legislation can become law without the president's signature, Senate Republican Leader Mitch McConnell of Kentucky has been reluctant to allow a vote on any legislation President Donald Trump does not support. Given Trump's continued high popularity among Republican voters, Republican lawmakers risk alienating those supporters by criticising the president. "I still await guidance from the White House as to what [Trump] thinks he's comfortable signing", McConnell said last week, about stalled gun control legislation. "If and when that happens, then we'll have a real possibility of actually changing the law."

The congressional strategies the president favours to cut drug prices are also difficult to assess.

During the 2016 presidential race, candidate Trump supported government-negotiated drug pricing, but he did not include it in last year's *American Patients First: The Trump Administration Blueprint to Lower Drug Prices and Reduce Out-of-Pocket Costs*. The blueprint also omitted his campaign promise to allow Americans to buy less expensive prescription medicine, from other countries. Both changes were a departure from long-held Republican Party positions.

Instead, Trump's blueprint recommended that drug companies include prices in their television adverts. Manufacturers won a court decision that blocked his order. Another administration rule required them to redirect rebates paid to pharmacy benefits managers—the middlemen who help to administer drug insurance—and pass those savings to patients instead. That idea backfired when it became clear that the private companies could not be relied on to



Nancy Pelosi presents her proposals for lowering drug prices

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redirect the rebates to consumers, as the government wished.

After these setbacks, Trump administration officials announced in late July they would propose a regulation allowing importation of certain drugs from Canada. HHS Secretary Alex Azar, a former pharmaceutical executive, reminded reporters that HHS and the Food and Drug Administration (FDA) have had the authority for decades to allow drug imports but did not believe until now it “could be done safely, effectively and at lower cost to American consumers”.

“What we’re saying today is we’re open”, he continued. “And we’re laying out the criteria by which entities like states, wholesale distributors and pharmacies could convince us that they have a workable plan that protects the integrity and safety of the American drug supply chain, protects American patient safety, [and] will deliver lower costs for consumers.”

However, biological products like insulin, which can be purchased in Canada at 10% of the typical US cost, are excluded from the proposal, as are controlled substances, infused and injectable drugs, and drugs inhaled during surgery. That still leaves thousands of medicines HHS could approve for importation.

HHS and FDA officials would not indicate when the proposal will be issued. But Colorado, Florida, Maine, and Vermont have already enacted drug importation laws and await FDA approval to proceed. Dozens more states are also considering some kind of drug pricing legislation.

For high-cost drugs, states could save as much as 40% on average, said Trish Riley, executive director of the National Academy for State Health Policy.

Florida’s law lists several drugs for importation from Canada that have experienced shortages in Canada, said Joelle Walker, a spokeswoman for the Canadian Pharmacists Association, which represents about half of the 42 000 pharmacists in the country.

“The proposals in the US are based on the assumption that Canada has an unlimited supply of medications and that’s simply not the case”, she said. That supply is intended to meet the needs of a country that has ten times fewer residents than the USA, she added.

Health Canada is also not keen on sharing its prescription drugs with its neighbour. “The Government of Canada does not support actions that could endanger the health and safety of Canadians by threatening the supply of prescription

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drugs in Canada”, said a Health Canada spokesman. “If the USA moves forward with its proposed actions, Health Canada is prepared to take action should there be a threat to the health and safety of Canadians.”

Another part of the Trump importation proposal would allow drug manufacturers to import their FDA-approved products from other countries at lower prices than in the USA.

“Depending on drug companies to undercut their own market by importing cheaper versions of their own products” is not realistic, said Peter Maybarduk, director of Public Citizen’s Access to Medicines programme.

Depending on Canadian drugs is not much better, he said. “You can’t fix US drug pricing by hitching it to imports from a much smaller country. We actually have to fix US drug pricing.”

The trade association representing brand-name pharmaceutical makers also does not have much faith in drug importation, which would inhibit medical innovation and subject more Americans to the risks of counterfeit medicines, said Holly Campbell, a spokeswoman for Pharmaceutical Research and Manufacturers of

America. “Instead of importation schemes, we should pursue practical policy solutions that will lower medicine costs for patients.”

### Little consensus

Compelling drug companies to negotiate with the government or adopting a pricing scheme based on prices other countries negotiated “is not a true negotiation”, Joel White, president of the Council for Affordable Health Coverage, told reporters last week. The group is a coalition of employers, insurers, patient groups, pharmacy benefit managers, insurance agents, and physician organisations.

Under the Pelosi legislation, companies could be penalised between 65% and 95% of their gross sales if they refuse to negotiate lower prices. The fees are intended to be “painful” and not something that can be simply dismissed as part of the cost of doing business, Pelosi told reporters last week.

“That’s not a take it or leave it proposition”, said White. “It’s a take it or die proposition.”

Democrats in the Progressive Congressional Caucus criticised the Pelosi legislation’s limit on price negotiations. “Why cap the annual number of negotiated drugs at 250 if the goal is for HHS to negotiate on as many as possible?”, they said in a statement.

The 250 limit is designed to get the “best possible” results using existing HHS resources, and if more are needed, “then we should make that available”, Pelosi said. “I want the biggest number we can possibly get, but I don’t want to promise something that we won’t have—a deliverable within the next year.”

The timing is no coincidence. As the November, 2020, presidential and congressional elections draw closer, the Republican and Democratic leaders recognise that whoever can bring down soaring drug prices will earn voters’ grateful support.

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