



Trump unveils plan to cut drug prices

The president's wide-ranging plan to reduce prescription drug prices won't be easy to achieve, experts say. Susan Jaffe, *The Lancet's* Washington correspondent, reports.

A brass band struck up "Hail to Chief" as President Donald Trump entered the White House Rose Garden 3 weeks ago to unveil what he called "the most sweeping action in history to lower the price of prescription drugs for the American people".

They will not have to wait long, he told members of Congress, patients, and other guests gathered under a blazing sun. "We will have tougher negotiation, more competition, and much lower prices at the pharmacy counter. And it will start to take effect very soon."

How soon will depend on what steps the administration takes on its own, through regulations and other mandates, and what changes can only be achieved through new laws enacted by Congress, which will increasingly be preoccupied by November's election. The president's 44-page plan—*American Patients First: The Trump Administration Blueprint to Drug Prices and Reduce Out-of-Pocket Costs*—includes proposals to improve competition and price transparency and end so-called global freeloading by countries who do not pay their fair share for drugs.

But two changes Trump advocated during the presidential campaign are missing. As the Republican candidate for president, Trump disagreed with his party and supported Americans' ability to buy drugs at cheaper prices from other countries. And he also favoured—while the party opposed—allowing the federal government to directly negotiate lower prices with pharmaceutical companies on behalf of some 60 million older Americans in the federal Medicare programme.

The blueprint is mainly a collection of "small ideas", said Joshua Gordon, policy director at the Concord Coalition, a non-partisan advocacy

group for fiscal responsibility. "There is no 'moon shot' here", he said, referring to President John F Kennedy's call to land a man on the moon.

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Despite scepticism and criticism from the Democratic minority in Congress, the president's blueprint has won accolades from Republicans including the only pharmacist among the lawmakers, Earl "Buddy" Carter, of Georgia. He is thrilled, he says, by the initiative, especially because one of its prime targets is independent pharmacy benefit manager (PBM) companies.

Sharing rebates

These middlemen manage drug coverage for insurance companies and negotiate price reductions based on the list price in the form of rebates from pharmaceutical manufacturers and discounts from drugstores. In return for a price cut, the drug can get favourable treatment on an insurance plan's covered drug list, or formulary, so that it is available to patients at a lower cost or without prior authorisation or other restrictions.

"Our plan will end the dishonest double-dealing that allows the middleman to pocket rebates and discounts that should be passed on to consumers and patients", said Trump during his Rose Garden speech.

A trade association that represents PBMs disagrees. Eliminating rebates would leave patients and insurers "at the mercy of drug manufacturer pricing strategies", according to a statement from the Pharmaceutical

Care Management Association. "Simply put, the easiest way to lower costs would be for drug companies to lower their prices."

But so far, drug makers have escaped much of the Trump administration's tough talk.

"Companies were worried about the potential impact of the speech and then realised it won't have much of an impact on their bottom line", said Rachel Sachs, an associate professor of law at the Washington University School of Law in St Louis who studies the interaction of intellectual property law, food and drug regulation, and health law. In response to the blueprint, biotech and pharmaceutical stocks went up, she noted.

The Pharmaceutical Research & Manufacturers of America, a trade group representing brand-name drug companies, has said attempts to lower drug prices could backfire, jeopardising drug development and access to affordable drugs, driving up insurance premiums, and restricting coverage.

Increased competition

"We are getting tough on the drug makers that exploit our patent laws to choke out competition", said Trump in his Rose Garden speech. "Our patent system will reward innovation, but it will not be used as a shield to protect unfair monopolies."

His administration has already taken several steps to improve competition

For *American Patients First: The Trump Administration Blueprint to Lower Drug Prices and Reduce Out-of-Pocket Costs* see <https://www.hhs.gov/sites/default/files/AmericanPatientsFirst.pdf>



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For *Making Medicines Affordable* see <https://www.nap.edu/catalog/24946/making-medicines-affordable-a-national-imperative>

in the drug market, particularly for generics, which usually cost less than brand-name drugs.

The US Food and Drug Administration (FDA) approved more than 1000 generic drugs last year, saving consumers and taxpayers almost US\$9 billion that year, according to the blueprint.

The FDA has posted on its website the names of pharmaceutical companies that have made it difficult for generic competitors to obtain samples of their drugs. FDA Commissioner Scott Gottlieb said a generic drug competitor needs 1500 to 5000 units of the brand drug to develop the generic alternative and conduct the tests required by the FDA to show that it is bioequivalent to the brand drug. The agency received more than 150 complaints from generic drug manufacturers asking for help to obtain these samples.

"We hope that this increased transparency will help reduce unnecessary hurdles to generic drug development and approval", Gottlieb said.

Unlike some changes that would require congressional approval, other proposals could be implemented independently by the administration. "We have seen the FDA moving forward quite quickly on a number of these activities that would promote competition in different ways in the small molecule drug market, in the generic market, in the biosimilar market", said Sachs. "I expect to see more of that."

One of the new proposals in the blueprint would require the FDA to consider requiring drug companies to include the list price in their advertisements.

"Very few people pay, it but that's the only publicly available price", said Gerard Anderson, professor of health policy and management at the Johns Hopkins University Bloomberg School of Public Health.

Drug makers are currently required to include a drug's potential side-effects in its advertising, but if the FDA

requires prices too, Anderson expects drug companies to challenge that new mandate in court. The FDA is charged with reviewing the efficacy and safety of drugs, and has not directly addressed pricing.

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Another proposal recommends that Medicare officials consider banning gag-order clauses in contracts between pharmacists and insurers or pharmacy benefit managers. Such provisions forbid the pharmacist from telling a customer when the pharmacy's cash price is less than paying for a prescription using insurance.

Anderson and his Hopkins colleagues have analysed prescription claims filed by about 130 million privately insured beneficiaries in 2015 and 2016 and found that there was a lower cash price for 60% of generic drugs, and in about 4% of those claims, the cash price saved consumers more than \$40.

Although insurance and pharmacy benefit manager industry groups say gag orders are rare, Anderson said 11 states have recently passed laws or issued regulations to end the practice.

"Global freeloading"

Americans spend more per capita on generic and brand-name drugs than any other country, according to *Making Medicines Affordable: A National Imperative*, a consensus study report published by the National Academies of Sciences, Engineering, and Medicine earlier this year. In 2010, US expenditures were twice as high as the UK's, which was the lowest of seven nations in a study cited in the report. In addition to paying higher prices for drugs, American taxpayers also foot the bill for drug research.

"It's unfair and it's ridiculous, and it's not going to happen any longer", Trump said to applause in the Rose Garden. "It's time to end the global freeloading once and for all." Trump said he would direct the US Trade

Representative to fix "this injustice" with every trading partner. Although details are still scarce, the USA could leverage trade agreements to pressure foreign countries to pay US drug makers more for drugs. The companies could then use that money to lower US drug prices or perhaps to fund a greater portion of research costs.

Even if other countries paid more for drugs, manufacturers would not necessarily reduce prices for Americans, said Susan Helper, Carlton professor of economics at Case Western Reserve University's Weatherhead School of Management in Cleveland. Helper was the department of Commerce's chief economist and the senior economist for President Barack Obama's White House Council of Economic Advisers. "Companies set the price at the profit maximising level and that level would not change based on what happens in some other market."

So far, it is unlikely that many other countries will cooperate. A European Commission spokesman in Washington, DC, claims the USA is responsible for its problem.

"EU member states have government entities that either negotiate drug prices or decide not to cover drugs whose prices they deem excessive", he said. "Drug manufacturers in the USA set their own prices, and that is not the norm elsewhere in the world."

A key US ally was even more emphatic. "The UK Government is committed to ensuring patients have access to the medicines they need and that the cost of medicines remains affordable to the National Health Service (NHS)", said a UK spokesperson at the British embassy in Washington, DC. "The NHS is now, and always will be, a public service free at the point of need; it is not, and never will be, for sale to the private sector, whether overseas or domestic; and no trade agreements will ever alter these fundamental facts."

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