

US presidential candidates' proposals to reduce drug prices

Clinton and Trump seem to agree on at least some ways to bring down the cost of prescription drugs, but Clinton offers more details. Susan Jaffe, *The Lancet's* Washington correspondent, reports.

Medicare officials announced last week that the cost of prescription drugs is still rising; no surprise to most Americans who have paid for a prescription drug lately. Drugs for 38 million older or disabled people enrolled in Medicare's drug benefit cost US\$121 billion in 2014, 17% more than the previous year, even though the number of prescriptions increased just 3%.

The presidential campaign has been preoccupied with the latest headline-grabbing claims from the Republican candidate, Donald Trump, but both he and the Democrats' nominee Hillary Clinton have proposed several ways to make drugs more affordable. Trump rarely mentions the subject since he won his party's nomination in July, unlike Clinton, who has had a long-time interest in health care.

"I'm going to do everything I can to make sure that you have the health care you need at an affordable price and get the cost of prescription drugs down because they are once again getting out of reach", Clinton promised during a speech in Cleveland, OH, last week. She said the cost of Gilead's drug to treat hepatitis C is so expensive that some insurance companies won't pay for it and patients can't afford it.

"You know what is really upsetting about this?" Clinton continued. "That drug company sells that same drug all over the world at a much lower price to everybody else. Now, I am proud that our drug companies invent drugs to cure terrible diseases and treat chronic diseases. I'm proud of that. But let's be clear, your tax dollars help support the research that is used to create those drugs in the first place. Your tax dollars support the Food and Drug Administration [FDA] that tests those drugs to determine whether or

not they are safe and effective to be able to go to market. And then we end up in America paying the highest price for those drugs that we have helped to create. We have got to take this on. And we can do it without hurting research, and discovery and new drugs and new devices."

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Negotiating prices

Clinton and Trump both want the Medicare programme to use its bargaining power to negotiate prices directly with pharmaceutical manufacturers, which Congress prohibited in a 2003 law expanding Medicare to include coverage for drugs prescribed in outpatient settings. Instead, drug coverage is provided through private insurance companies under contract with Medicare who hire pharmacy benefit managers to negotiate prices with drug makers. The federal government reimburses insurers for most of the cost, with patients paying the rest.

The Republican majority in Congress believed that competition in the marketplace would drive down drug prices. It is an idea Republicans value just as much today, even though their candidate believes the federal government could drive a better bargain.

Trump was not clear on how much better in comments earlier this year. At a Republican debate in March, he said Medicare could save

\$300 billion a year through direct negotiations with drug companies. When the debate moderator noted that the federal government's share of the Medicare drug bill was about \$78 billion, Trump said, "I'm not only talking about drugs, I'm talking about other things. We will save \$300 billion a year if we properly negotiate."

If he's correct, Medicare could cut its total annual spending—on hospitals, nursing homes, physicians, drugs, and more—by about 55%. "It doesn't make any sense and it's not mathematically possible", said Tophir Spiro, vice president for health policy at the Center for American Progress. Trump's support for Medicare price negotiation is not mentioned in his health-care reform proposal posted on his campaign website. It is also not included in the Republican Party platform. Sam Clovis, a Trump domestic policy adviser acknowledged that the candidate's view conflicted with his party's position when he spoke to *The Lancet* in March. (The Trump campaign declined to respond to questions for this article.)

Clovis blamed the influence of campaign contributors and powerful

For Trump's health-care reform proposal see <https://www.donaldjtrump.com/positions/healthcare-reform>

For Clinton's fact sheet on lowering drug costs see <https://www.hillaryclinton.com/briefing/factsheets/2015/09/21/hillary-clinton-plan-for-lowering-prescription-drug-costs>



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Panel: Some of Hillary Clinton's additional plans to reduce prescription drug prices

- Limit drug expenses to US\$250 a month for patients who take drugs for chronic or serious health problems, with insurance companies paying the rest.
- Discourage direct-to-consumer drug advertising by ending corporate tax deductions for marketing expenses and require Food and Drug Administration (FDA) approval for these advertisements.
- Require drug manufacturers that receive taxpayer support to develop new drugs also to invest "a sufficient amount of their revenue" in research and development, limiting their "excessive profits" and "unreasonable" marketing expenditures.
- Require drug companies to give Medicare the same rebates available to Medicaid for those low-income Medicare beneficiaries who also receive Medicaid coverage or subsidised Medicare coverage.
- Increase funding for the FDA so that it can speed up approval of cheaper generic drugs, especially generic versions of biologics and other specialty drugs that may have no price competitors.
- Cut the exclusivity period for biologics from 12 years to 7 years.
- Eliminate "pay for delay" tactics used by drug companies to delay the introduction of inexpensive generic alternatives to brand-name drugs.

Washington lobbyists to explain why Congress has not supported price negotiations and another Trump proposal allowing Americans to buy drugs from other countries. "The only special interest not represented in Washington, DC, is the people", he said.

Some critics of Medicare price negotiations with drug manufacturers say that if the companies refuse to lower prices for some drugs, Medicare could refuse to cover them. "Americans need to realise that Medicare price negotiations [include] the implicit threat of blocking access to drugs on behalf of Medicare beneficiaries", said Scott Gottlieb, a physician and resident fellow at the American Enterprise Institute who has worked at the FDA and Centers for Medicare and Medicaid Services.

Spiro said that the government could increase its negotiating power if Medicare adopted a strategy officials use to negotiate drug prices for the Medicaid programme, which provides health insurance for low-income

families. "The drug companies don't walk away from Medicaid because if they do then Medicaid will not cover any of their drugs, not just the drug in question", Spiro said.

The Pharmaceutical Research & Manufacturers of America, a trade group representing brand-name drug companies, claims that Medicare price negotiations would backfire, jeopardising the availability of affordable drugs, driving up premiums, and restricting coverage.

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Drug importation

"Countries in Europe often pay half of what Americans pay for the same drugs", Clinton says in a fact sheet about lowering drug costs posted on her campaign website. She would allow Americans to buy inexpensive drugs for personal use only from foreign countries "whose safety standards are as strong" as those in the USA. The FDA and other agencies would set standards to assure that imported drugs are safe. The proposal is also included in the Democratic Party platform.

But the FDA cannot guarantee the safety of imported drugs the agency has not approved, according to the Pharmaceutical Research & Manufacturers of America. "Due to the FDA's comprehensive drug approval process, medicines on the US market are widely regarded as the safest in the world", a spokeswoman said in a statement.

Americans should be allowed to buy "imported, safe, and dependable drugs from overseas", according to Trump's health-care reform position statement on his website. However, drug importation is not part of the Republican Party platform.

Although some Americans currently buy drugs from Canada and other countries for personal

use, expanded importation is only "a stop-gap measure", said Joe Baker, president of the Medicare Rights Center. "We have the largest economy in the world and we should not have to import drugs from other countries in order to get correct prices", he said. "It's no way to run a country's health-care system, particularly a country as large and sophisticated as the US."

More measures

Clinton has also outlined additional strategies to bring down drug prices (panel). But simply cutting the price is not Clinton's only objective. She also advocates for drug pricing based on effectiveness and argues that prices should "reflect the improved value new treatments provide", according to her drug fact sheet. Value-based pricing is an idea the Obama administration wants to test in Medicare for physician-administered drugs, such as chemotherapy, covered under Medicare's outpatient services. Starting next year, some doctors would be paid an extra 2.5% of the cost of the drug, instead of the usual 6% administrative fee, to reduce any incentive for prescribing drugs that are more expensive to generate more income. In addition to saving money for Medicare, the experiment should lower the patient's share of the cost. In the second phase of the payment project, Medicare would set prices on some drugs based on their efficacy.

"We're trying to find out if we can still provide a lower price overall for these drugs to increase utilisation of cheaper drugs that are just as effective", said Baker, who supports the concept of value-based pricing that includes consumer protections to ensure patients have access to the drugs their doctors prescribe. "We need to make sure we're getting value in the price of our drugs and the clinical effectiveness."

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