



Insight

Clinton's Generic Drug Price Control Proposal

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Today Hillary Clinton's campaign introduced a new plan targeting generic drug manufacturers, like those in the news recently, who have become increasingly unpopular for raising the price of generic drugs.^[1] The plan is extreme, necessitates high levels of congressional cooperation to achieve legality, and will likely have a chilling effect on future brand name and generic drug manufacturers contemplating entering the market.

Clinton's plan begins with assembling a convention of representatives from various federal agencies who will be tasked with determining when a price increase for 'long-available treatments' is unreasonable (what is 'unreasonable' is undefined). If this unelected group does determine the price is unreasonable, they will have unprecedented powers to lower the cost of the drug.

The group would be given the authority to incentivize new manufacturers to enter the market by having the federal government directly purchase the drug in question and then distribute it to patients at a more reasonable price. This type of action should require an act of Congress to authorize the spending and the agency's powers to manipulate an entire market, though getting this type of legislation passed would be extremely difficult.

There are no details available about how Clinton proposes to accelerate the Food and Drug Administration's (FDA) approval process, which is the primary obstacle generic manufacturers currently face when attempting to offer new competition, nor is there detail about how long the administration would continue its 'direct intervention' in the market once more competition has been introduced.

Clinton's plan would also call for allowing 'emergency importation' of generic and alternative competitors from other countries with high, reliable safety standards. This action would also require a politically difficult amendment to the Food, Drug and Cosmetics Act (FDCA) – one which many patient advocates have been attempting to have passed for years. Allowing for the importation of foreign generics of any off-patent drugs, regardless of their price, from developed countries with reliable safety standards may help reduce the risk of drug shortages and encourage drug developers to focus more on developing innovative drugs.

Finally, Clinton has suggested imposing financial penalties on generic manufacturers, including fines or mandatory rebates paid out to the drug purchasers. Revenue from these fines will be used by the government to purchase drugs from other manufacturers as discussed earlier. This system is modeled on the disastrous Medicaid Drug Rebate Program, which has significant negative outcomes, not least of which was the [340B Drug Program](#).

The most likely outcomes of Clinton's new policy will be that generic drug manufacturing will be a riskier venture for investors, and the potential value of these companies will fall domestically. This could very well exacerbate the problems we already face while further inserting the federal government into drug pricing. There is also no guarantee that the price controls utilized in this plan would not eventually be expanded to innovator drugs, which Clinton's larger health plan contemplates.^[2] This plan would be a significant foray into

government price-setting in the pharmaceutical industry.

[1] <https://www.hillaryclinton.com/briefing/factsheets/2016/09/02/hillarys-plan-to-respond-to-unjustified-price-hikes-for-long-available-drugs/>.

[2] <https://www.hillaryclinton.com/briefing/factsheets/2015/09/21/hillary-clinton-plan-for-lowering-prescription-drug-costs/>.