



June 14, 2018

**Prescription Drug Costs:  
Can Increased Competition  
Restrain Prices?**

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**ADMINISTRATION**

## Trump Administration



White House Rose Garden Ceremony, May 11, 2018

## American Patients **First**: The Trump Administration Blueprint to Lower Drug Prices and Reduce Out-of-Pocket Costs

### Four main themes

- Increasing competition in drug markets
  - E.g. accelerating approval of generic drugs
- Giving private plans more tools to negotiate discounts for Medicare beneficiaries
  - E.g. covering certain drugs under Medicare Part D instead of Medicare Part B
- Providing new incentives for drug manufacturers to reduce list prices
  - E.g. requiring manufacturers to disclose list prices in direct-to-consumer ads
- Cutting consumers' out-of-pocket costs
  - E.g. requiring prescription drug plans to pass along some of the discounts and rebates from drug manufacturers



## FDA: Leading the Way



FDA Commissioner Scott Gottlieb Wednesday criticized PBMs and payers for **creating “Kabuki” drug pricing schemes** “that obscure profit taking across the supply chain **that drives up costs**; that expose consumers to high out-of-pocket spending; and that **actively discourage competition.**” (March, 2018)

“**Patients shouldn’t face exorbitant out-of-pocket costs**, and pay money where the primary purpose is to help subsidize rebates paid to a long list of supply chain intermediaries,” Gottlieb said at the meeting of America’s Health Insurance Plans (AHIP). “**Sick people aren’t supposed to be subsidizing the healthy.**” (March, 2018)

## FDA’s Drug Competition Action Plan

- Sole Source Markets: **maintain a list of drugs without competition**
- ANDA Process: institute **expedited and priority reviews for generic drug applications** where there is a lack of competition; streamline and accelerate processes
  - Over 1,000 generic drug applications approved in 2017
- Risk Evaluation and Mitigation Strategies: **eliminate misuse of REMS** to block potential generic competitors from obtaining samples needed for FDA-required bioequivalence studies
  - S.974/H.R.2212 CREATES Act of 2017 would support this move
- Citizens Petitions: **evaluate use of citizen petitions** in blocking generic drug entry
- Biosimilars: introduce new **Biosimilar Innovation Plan**; educate providers
  - Of 9 biosimilars approved, only 3 have reached the market
- Orphan Drugs: **close loopholes that allow use of orphan drug designation** unless clinically superior

## Additional Proposal Highlights

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### **CMS Proposals**

- Cap beneficiaries' out-of-pocket costs for prescription drugs under Part D
- Allow Medicaid to have restrict coverage through closed formularies
- Consider changes to Six Protected Classes full coverage policy
- Allow mid-year changes in Marketplace formularies if generic approved
- Increased enforcement of plan sponsors ensuring enrollees pay the lesser of the Part D negotiated price or copay

### **HRSA Proposals**

- Restrict 340B drug discount program
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**CONGRESS**

## Congressional Hearings on the Cost of Prescription Drugs

### Senate:

- Examining the President's Blueprint 'American Patients First' to Lower Drug Prices (June 2018)
- An Examination of the National Academies of Sciences, Engineering, and Medicine Report "Making Medicines Affordable: A National Imperative" (December 2017)
- How the Drug Delivery System Affects What Patients Pay, Part 2 (October 2017)
- How the Drug Delivery System Affects What Patients Pay, Part 1 (June 2017)

### House:

- Examining the Drug Supply Chain (December 2017)
- Examining How Covered Entities Utilize the 340B Drug Pricing Program (October 2017)
- Examining HRSA's Oversight of the 340B Drug Pricing Program (July 2017)

**"President Trump offered little more than window dressing to combat the rising cost of drugs — a problem that is pinching the pocketbook of far too many Americans," Senator Chuck Schumer of New York, the Democratic leader. (May 11, 2018)**



#### **A Better Deal:** *Lowering the Cost of Prescription Drugs*

Prescription drug prices are rising at an unprecedented and unsustainable rate. Americans pay more than double what other nations pay for prescription drugs and per capita prescription drug spending in the United States exceeds that of all other countries.<sup>1</sup> Today, there are no rules in place to stop drug companies from excessively raising prices on middle-class families.

**The American people deserve a Better Deal on the cost of prescription drugs.** Unfortunately, Republicans in Congress are trying to rush through major health care legislation, which the non-partisan Congressional Budget Office has said will actually *raise* the cost of prescription drugs for millions of Americans.<sup>2</sup>

**A Better Deal on drug prices means that we will re-write the rules so the federal government is on the side of consumers and middle-class families.** Over the past few years, we have seen hedge funds and other speculative Wall Street financial firms take stakes in drug companies and then force major price increases on life-saving drugs. The bottom line is that we will crack down on the companies that excessively raise prices on American customers without justification.

#### Specifically, the Better Deal program will:

- Stop outrageous prescription drug price increases
- Negotiate lower prescription drug prices for Medicare
- Require drug manufacturers to publically release hard data and information justifying any significant price increase

### **Democratic Response: Senators Elizabeth Warren (D-MA) and Tina Smith (D-MN)**

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- June 11, 2018: Sent a 12-page letter to HHS Secretary Alex Azar with 38 questions seeking new information to address their concerns about President Trump's "inadequate new proposals to reduce drug prices and his broken campaign promises to "negotiate like crazy" for lower drug prices."
  - May 30, 2018: Sent letters to the top ten drug company CEOs asking if they had voluntarily reduced prices as President Trump and Secretary Azar have suggested they would in response to the Administration's drug pricing blueprint. Not one company had done so - and one of the few companies that gave a clear answer to the senators' letter indicated that they have "some planned price increases later this year."
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### **"HHS Secretary Azar Defends Trump Drug Pricing Plan, Faces Doubts from Senate" (TheStreet)**

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Senate HELP Hearing on June 12, 2018

- Presented American Patients First blueprint
  - Defended lack of progress
  - Focused on need to eliminate rebates from the drug pricing system used by drug companies and pharmacy benefit managers
  - Included ACA focus
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