

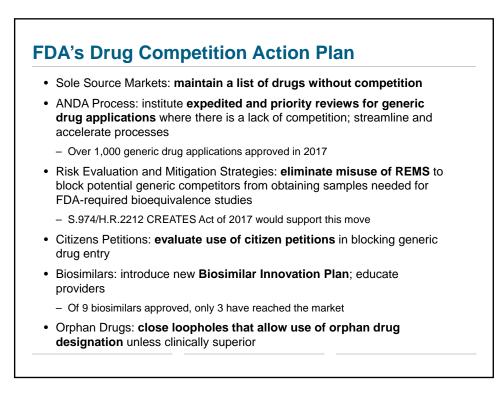


FDA: Leading the Way



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-ofpocket 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)



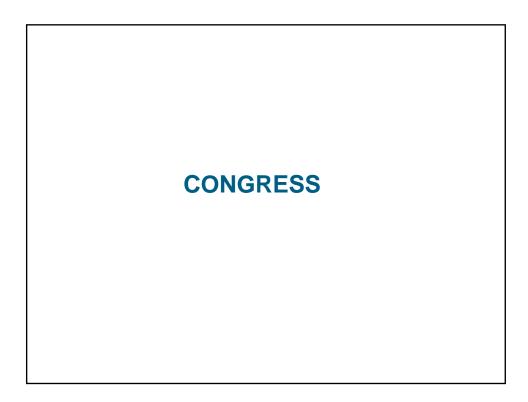
Additional Proposal Highlights

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



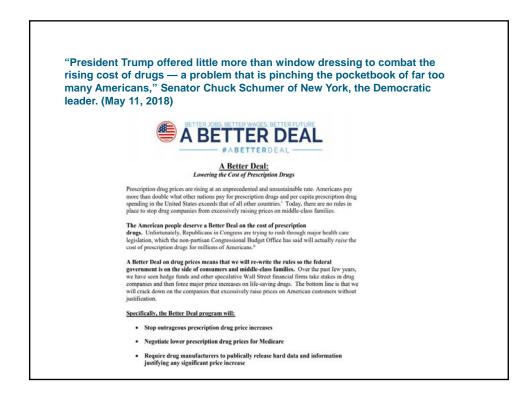
Congressional Hearings on the Cost of Prescription Drugs

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:

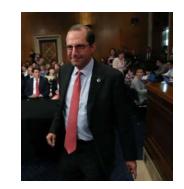
- Examining the Drug Supply Chain (December 2017)
- Examining How Covered Entities Utilize the 340B Drug Pricing Program (October 2017)
- Examining HRSA's Oversight of the 340B Drug Pricing Program (July 2017)



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

- 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."

"HHS Secretary Azar Defends Trump Drug Pricing Plan, Faces Doubts from Senate" (TheStreet)



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