American Patients First

Policy Overview of Trump Administration's Drug Cost Policy Plan

Alex Jung

September 11, 2018

Agenda

- **Executive Summary**
- Details of American Patients First
- Reception

Executive Summary

The Trump Administration's American Patients First plan is designed to lower drug prices for consumers but was poorly received as weak handed

1. On Friday, May 11th, 2018, President Trump released his American Patients First plan, detailing **>50 regulatory and legislative measures** to reduce drug costs for American consumers

2. The proposals are organized in **four categories**: increasing competition, bettering negotiations, lowering list prices, and lowering out of pocket costs

3. The document received **poor reception** by the public, largely due to the Administration's choice to exclude two major populist proposals: letting Medicare negotiate directly for lower drug prices and promoting the import of low cost medicines

Source: The New York Times; American Patients First; Drug Channels; EY-Parthenon Analysis

Executive Summary

The proposal contains 4 main solution themes along various levels of development – from "accomplishments" to requests for public comment

American Patients First, Plan Outline
2018

Solution Theme
Administration categorization of initiatives

Description
General goal of initiatives

Mechanisms of Action
Summary of policy approaches to bring about change

	Solution Theme	Description
1	Increasing Competition	Increasing generic / biosimilar market share
2	Bettering Negotiations	Improving Medicare Part D
3	Lowering List Prices	Ensuring discounts and rebates are passed along to the intended patients
4	Lowering Out-of-Pocket Costs	Helping patients understand drug prices, rebates, and treatment alternatives

Claimed "Accomplishments"
Current and pending administration achievements, especially FY2019 Budget Proposals

HHS Directives
The Department of Health and Human Services can take these actions "to the extent permissible by law"

Policies and Issues Open for Public Comment
The Department of Health and Human Services are requesting public comments on these broad issue and policy concepts

Source: American Patients First; EY-Parthenon Analysis

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Details of American Patients First

Policies to increase competition are broadly designed to increase generics and biosimilar share of US pharma spending

	1 Increasing Competition	2 Bettering Negotiations	3 Lowering List Prices	4 Lowering Out-of-Pocket Costs
Description	• Increasing generic / biosimilar market share			
Mechanisms of Action	• Accelerating FDA approval of generics and biosimilar • Increasing price and science transparency across payers, clinicians, patients, and other stakeholders • Addressing anticompetitive practices like using REMS to limit generic distribution or withholding of reference samples			
Claimed "Accomplishments"	• FDA approved >1000 generic drugs in 2017, more than in any previous year • FDA established a Drug Competition Action Plan to improve generic review process and close "loopholes" for branded drugs • FDA announced it will facilitate more information sharing across stakeholders • FY2019 budget proposes to end "indefinite"180 day exclusivity extensions for first to file generics • Finalizing a policy to identify each biosimilar with its own Medicare billing code increase price competition			
HHS Directives	• Provide guidance regarding how manufactures uses REMS to delay or block generic competition • Support biosimilar development • Educate clinicians, patients, and payers about biosimilar and other interchangeable products			

Policies and Issues Open for Public Comment	• Changing HHS pricing incentives – ex. Best Price reporting requirement of the Medicaid Drug Rebate Program
	• Affordable Care Act taxes and rebates
	• Access to reference product samples
	  ◦ Distribution restrictions, particularly related to REMS
	  ◦ Difficulty of obtaining samples for biosimilar and generic development
	• Biosimilar Development, approval, education, and access
	  ◦ Resources and tools for the FDA – which new tool and resources need to be developed?
	  ◦ Improving the Purple book
	  ◦ Educating providers and patients			

Source: American Patients First; EY-Parthenon Analysis

Details of American Patients First

Improving negotiations mostly involves revisiting categorizations related to rebate programs, formularies and treatment guild lines within Medicare Part D

1 Increasing Competition | 2 **Bettering Negotiations** | 3 Lowering List Prices | 4 Lowering Out-of-Pocket Costs

Description	• Improving Medicare Part D
Mechanisms of Action	• Scrutiny of drug categorizations across rebate programs, formularies, and treatment guidelines • Demonstration projects • Capping prices increases
Claimed "Accomplishments"	• FY2019 Budget Proposes updating formulary standards to allow for better negotiating leverage with drug manufacturers (ex. Allowing for a min of 1 drug per category or class rather than 2) and leveraging Medicare Part D plans to negotiate lower prices for Part B drugs • FY2019 Budget proposes establishing an inflation limit for Medicare Part B Drugs and increasing pricing scrutiny • FY2019 Budget proposes more carefully redefining branded drugs so they can't be incorrectly categorized as "generics" • FY2019 Budget proposes a 5 state experiment of drug covering and financing reforms, especially related formularies • HHS has already increased scrutiny around the Medicaid Drug Rebate Program – including manual drug-by-drug reviews
HHS Directives	• CMS directed to develop value-based care demonstration projects • Allow Medicare Part D to update formulary / benefit design mid-year to address price changes • Provide plans "full flexibility" to negotiate • Update Drug Plan Consumer Service star rating methodology to improve utilization of high-cost drugs • Allow for high-cost drugs to be reimbursed at different levels based on the target indication • Send president a report of drugs in Part B that would benefit from moving to Part D • Bolster the Competitive Acquisition Program (CAP) for Part B drugs • Develop knowledge base about price disparities across borders
Policies and Issues Open for Public Comment	• Value-based arrangements and price reporting • Indication-based reimbursement schemes • Long-term financing models (spreading high cost payments over multiple years) • Part B Competitive Acquisition Program (CAP) • Moving drugs from Part B to Part D • Policies to fix global "freeloading" (proposed policies unspecified) • Site neutral payment policies for physician administered drugs and inpatient vs outpatient settings (Part A vs Part B) • Price data set review

Source: American Patients First; EY-Parthenon Analysis

Details of American Patients First

Policies to lower list prices are focused on increasing transparency, especially for discount and rebate programs for 340b patients and Medicare Part D

1 Increasing Competition | 2 Bettering Negotiations | 3 **Lowering List Prices** | 4 Lowering Out-of-Pocket Costs

Description	• Ensuring discounts and rebates are passed along to the intended patients
Mechanisms of Action	• Increasing discount and rebate transparency so discounts and rebates get passed on to patients • Re-examining eligibility and macro impact of 340b • Increasing price transparency through Medicare and Medicaid
Claimed "Accomplishments"	• FY2019 Budget proposes excluding manufacturer discount from calculation of beneficiary out of pocket costs in the Part D coverage gap • FY2019 Budget proposes reforming 340b program to ensure it benefits low income patients and others are not free riding
HHS Directives	• Evaluate inclusion of list prices in direct-to-consumer advertising • Create Medicare and Medicaid drug price dashboard tool so consumers can predict costs • Re-evaluate the ACA Maximum Rebate Amount (100% of average manufacturer price) provision

Policies and Issues Open for Public Comment	• Establishing fiduciary duty for PBMs
	• Restricting federal rebate programs that inflate drug prices for the public
	• Incentives to discourage large price increases
	  ◦ Protected classification
	  ◦ Healthcare Common Procedure Coding System – earlier assignment if manufacturers commit to certain price for period of time
	• Inflationary rebate limits
	• Exclusion of certain payments, rebates, or discounts from Average Manufacturer Price or Best Price calculation
	• Copay Discount Cards
	• 340 B Drug discount program
	  ◦ Program growth – has it effected list prices and cross-subsidized
	  ◦ Program eligibility – might currently be too broad
	  ◦ Duplicate Discounts – 340b + Medicaid drug rebate

Source: American Patients First; EY-Parthenon Analysis

Details of American Patients First

Much like policies to lower list prices, policies to lower out of pocket costs are generally directed at increasing patient knowledge around treatments and costs

	1 Increasing Competition	2 Bettering Negotiations	3 Lowering List Prices	4 Lowering Out-of-Pocket Costs
Description				• Helping patients understand drug prices, rebates, and treatment alternatives
Mechanisms of Action				• Increasing price and rebate transparency pre-pharmacy visit • Increasing rebates and subsidies at point of sale, especially for low income and 340b beneficiaries • Forcing payers and pharmacies to be more forthright about low cost alternatives for patients
Claimed "Accomplishments"				• Finalizing Medicare Outpatient Prospective Payment System (OPPS) to reduce 340b beneficiary out of pocket spending • Requesting information and comment on increasing price transparency for Medicare and rebates • Updating Part C and D regulation that allows low income patients to receive subsidies for biosimilar purchases • FY2019 Budget 5 proposes eliminating cost sharing on generic drugs for low income beneficiaries • FY2019 Budget 5 proposes requiring Part D plans to apply a substantial portion of rebates at the point of sale
HHS Directives				• Prohibit Part D plans from using gag clauses to prevent pharmacists from disclosing cheaper alternatives • Require Part D sponsors to provide more information about drug price increases and alternatives to members
Policies and Issues Open for Public Comment				• Part D end of year statement on drug price changes and rebates collected • Federal preemption of contracted pharmacy gag clauses • Increasing information to Medicare beneficiaries about cost sharing and lower cost alternatives

Source: American Patients First; EY-Parthenon Analysis

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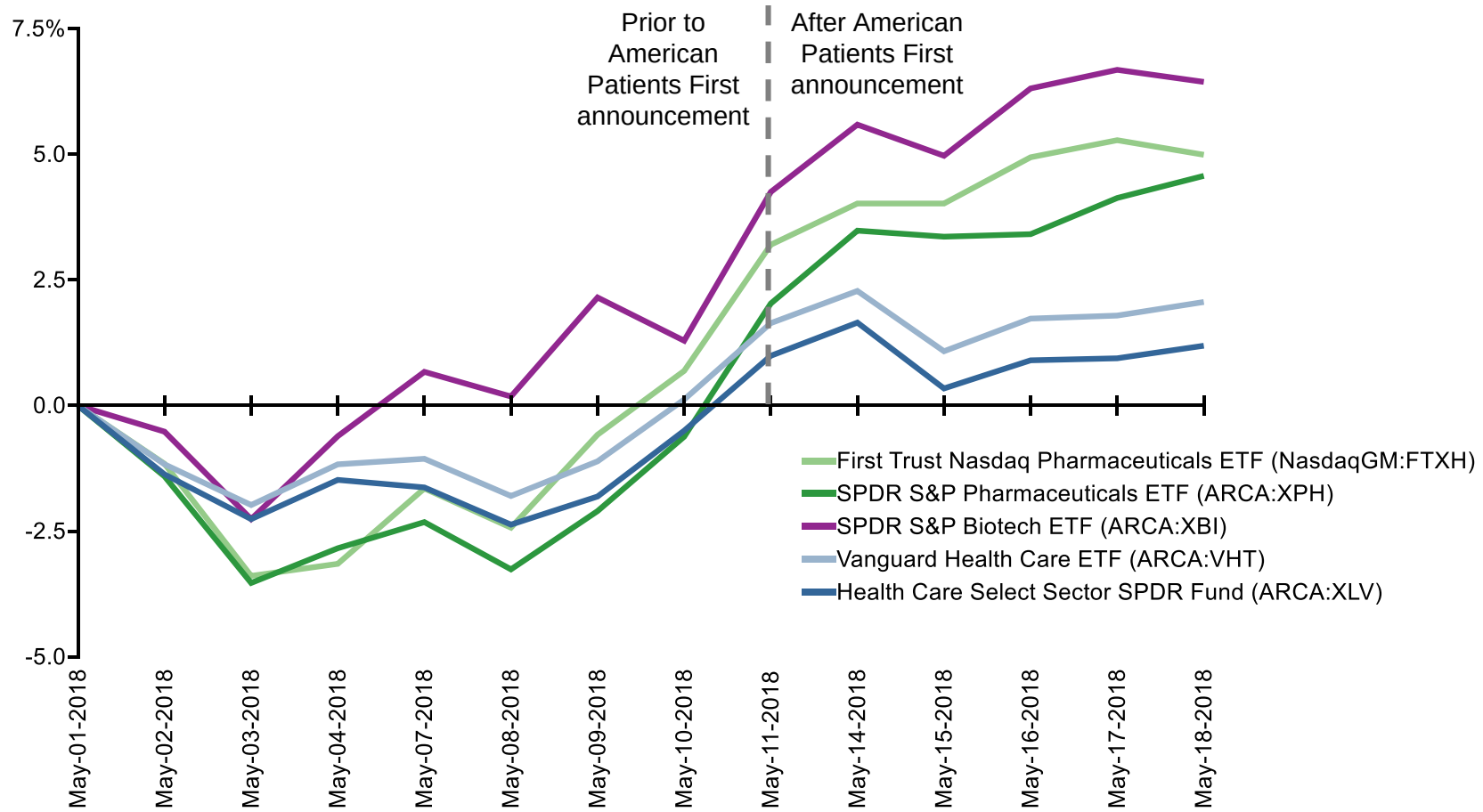
Reception

Biotech and pharma stocks reacted positively while healthcare stocks have remained flat since American Patients First was announced

Popular Pharma, Biotech, and Healthcare ETF Price Changes

May 2018

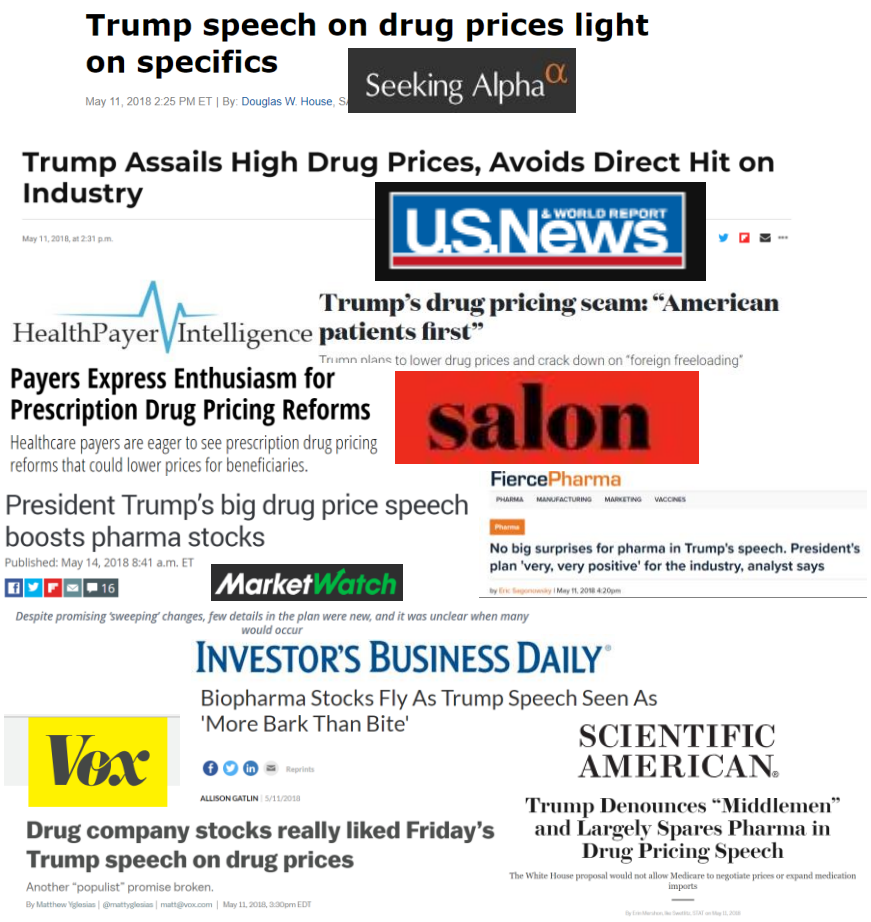


Source: CapIQ

Reception

The policy is seen as a neutered compromise between the pharma industry and an Administration walking back on aggressive anti-pharma campaign promises

Headlines related to American Patients First
2018



Commentary

Many feel that American Patient's First does not have the teeth to dramatically effect pharma companies

- *"President Trump delivered a measured and speedy address and unveiled a menu of potential policy changes that hardly touch the (pharma) industry he once denounced"*
  – Scientific American (2018)
- *"Trump has abandoned ideas to lower drug costs he supported during the campaign, including allowing the government's Medicare plan for older Americans to negotiate prices directly with drugmakers, and enabling U.S. consumers to import lower-cost medicines from other countries. On Friday, Trump's senior health officials outlined more modest policy proposals"*
  – U.S. News (2018)

The plan was viewed as vague on policy or implementation specifics, and therefore favoring industry over consumers

- *"The "American Patients First" solution is the vague and limited result of compromise between special interests and Trump's campaign promises"* – TownHall (2018)
- *"The proposed reforms were somewhat vague and didn't describe any truly impactful near-term changes"*
  – GBS Benefits (2018)

Though, some outlets acknowledge the proposal could have dramatic long term effects

- *"This administration's blueprint offers a thoughtful diagnosis of U.S. drug pricing along with the unintended consequences and warped incentives of our drug channel system. Many people are discounting the plan as no big deal and therefore underestimating how radically the system could change"* – Drug Channels (2018)

Sources: Seeking Alpha; U.S. News; Salon; HealthPayer Intelligence; MarketWatch; FiercePharma; Investor's Business Daily; Vox; Scientific American; TownHall; GBS Benefits; Drug Channels

Nevada

Sec. 19. A pharmacy benefit manager has a fiduciary duty to a third party with which the pharmacy benefit manager has entered into a contract to manage the pharmacy benefits plan of the third party and shall notify the third party in writing of any activity, policy or practice of the pharmacy benefit manager that presents a conflict of interest that interferes with the ability of the pharmacy benefit manager to discharge that fiduciary duty.

https://www.leg.state.nv.us/App/NELIS/REL/79th2017/Bill/5822/Text

South Dakota

Manager to perform duties in good faith. Each pharmacy benefits manager shall perform its duties exercising good faith and fair dealing toward the covered entity.

http://sdlegislature.gov/Statutes/Codified_Laws/DisplayStatute.aspx?Type=Statute&Statute=58-29E-3

Source: CapIQ

Employers as Plan Sponsors & Fiduciary - Update

Forbes / Pharma & Healthcare / #PublicHealth

CFOs And HR Execs Facing Millions In Personal Liability Due To Unmanaged Health Benefits Plans

Dave Chase, SUBSCRIBER

May 26, 2016 7:12 AM 14,042

Dereliction of Fiduciary Duties Triggering Department of Labor Investigations

The most recent case against the GAP and United Health is even more worrying for companies and their executives. Beyond the civil suits, the Department of Labor is now involved. Further, since ERISA requires IRS reporting (IRS Form 5500), the fact that the details of this case show that what the GAP reported (unknowingly) on their IRS forms was incorrect. For example, Form 5500 requires reporting on administrative expenses and whether a service provider received indirect compensation. The case details would imply that GAP's Form 5500 is technically false even though the GAP was unaware of this:

> On May 10, 2016, in the southern district of Texas Federal Court, United HealthCare administered self-insured ERISA plan, GAP Inc. and its Plan Administrators, Cynthia Radovich and Lesley Dale, were sued for alleged ERISA plan assets "self-dealing and embezzlement," deceptively concealed through an "illegitimate recoupment scheme that financially rewards United for wrongfully recouping valid benefits."

Source: CapIQ

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