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The Debate Over High Prescription Drug Prices: Prospects for Reform

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AHLA Annual Meeting

June 27, 2017

Setting the stage: Basic Principles

- In general, the United States does not regulate prescription drug prices
- With respect to private insurance (the individual market or employer-based insurance in the group market), insurers typically rely on pharmacy benefit managers (PBMs) to negotiate drug prices, price concessions, rebates, etc., in exchange for favorable formulary placement
- With respect to government health insurance programs (Medicare, Medicaid, VA, DoD, federal public health programs), the federal government and state governments have market power and they use that market power to drive price concessions
- In neither case (private plans or government programs) does the federal government set drug prices

A Changing Paradigm?

- In December, 2013, the US FDA approved the first direct-acting antiviral (Sovaldi®) to treat Hepatitis C. Some additional Hepatitis C therapies followed.
- Because Sovaldi® and the other direct-acting antivirals were a cure for a life-altering disease, the manufacturers of these therapies used a different paradigm to set prices
- The high prices for these therapies and the manufacturers were widely criticized. A Congressional investigation of Sovaldi's price followed.
- This new paradigm (pricing based on a cure rather than on a lifetime maintenance supply of a drug) is here to stay. It is likely that calls for greater regulation of drug prices will follow.

Medicaid, health care system confronting high cost of specialty drugs

DAVID WAHLBERG dwahlberg@madison.com Apr 27, 2017



The Post and Courier

Winner of the Pulitzer Prize

Rising rates of hepatitis C in sound alarm bells

By Mary Katherine Wildeman mkwildeman@postandcourier.com May 6, 2017

business breaking news

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MAY 11, 2017 8:00AM

Ben Hirschler, Reuters



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THE HILL

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BY JESSIE HELLMANN - 02/28/17 09:43 PM EST

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POLICY-ISH

Trump, Democrats Look For Common Ground On Drug Prices

March 8, 2017 - 8:25 PM ET

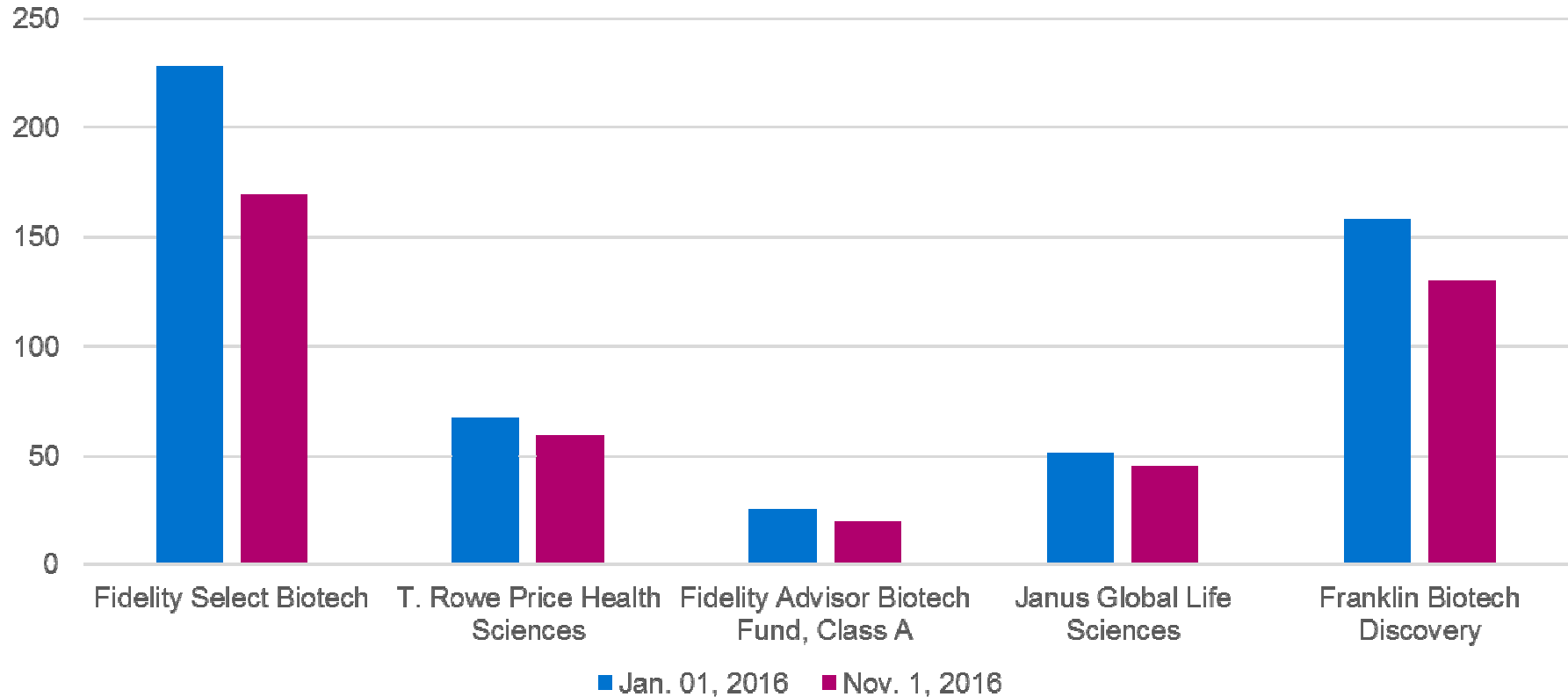
SARAH JANE TRIBBLE

FROM KHN KAREN HEALTH NEWS



Drug Funds Experience Decline

Select Mutual Fund NAV



- All of these funds were showing robust growth up until late September of last year as both Trump and Clinton were criticizing drug prices

Federal Government Market Power Over Drug Pricing

- As previously indicated, both the Medicare and Medicaid programs have significant market power over prescription drug purchasing decisions
- Depending upon the program, the government exercises its market power in different ways
- Medicare
 - Health insurance program for elderly (65+), disabled, end-stage renal disease
 - Drugs covered under two pathways
 - Part B drugs: typically physician-administered drugs as a medical benefit
 - Part D drugs: designed as a pharmacy benefit for self-administered drugs typically dispensed by a pharmacy
- Medicaid
 - Largest health insurance program in the United States that covers low-income individuals. Administered by the states and jointly financed by states/federal government.
 - Outpatient prescription drugs are not a mandatory benefit but all states cover them

Federal Government Market Power Over Drug Pricing

Medicare Part B

- Drugs are reimbursed based on the average sales price of the drug, plus 6%
- Manufacturers set price and must report net sales, prices, price concessions, rebates, etc.
- CMS then reimburses the user of the drug (physician office, hospital outpatient department, pharmacy) at ASP+6%
- CMS attempted to alter this reimbursement model via a demonstration program in 2016, but after significant Congressional opposition, dropped the proposal

Medicare Part D

- Benefit delivered entirely through private insurance plans
- Part D plans use contract PBMs or their own PBMs to negotiate pricing, price concessions, rebates, formulary placement and pharmacy access
- Notably, there is a statutory preclusion on federal government interference in these negotiations between Part D plans, manufacturers, and pharmacies
- Manufacturers must grant a 50% discount off of their negotiated price for Part D enrollees with a high drug spend

Federal Government Market Power Over Drug Pricing

■ Medicaid

- A statutory provision in the Medicaid program allows states to use many of the same prescription drug management tools available to insurers in the private sector.
- States may impose prior authorization programs for prescription drugs and may establish formularies.
- Manufacturers must pay rebates (23.1% of AMP or AMP minus best price) as a condition of having their drugs covered under Medicaid.
- However, once a manufacturer agrees to pay rebates, states have very limited tools to exclude a drug from its formulary.

- The Obama Administration made several proposals to more aggressively regulate drug pricing in government markets, but these were never adopted by Congress.
 - The Obama Administration proposed:
 - Mandatory Medicaid-like rebates for the Medicare Part D program (at least for dual-eligible enrollees)
 - Greater manufacturer rebates in Part D
 - Repeal of Part D non-interference clause and requirements for direct negotiation of drug prices by HHS/CMS
 - Part B drug two-phase demonstration project
 - Prohibiting “pay to play” deals to delay generic entrants
- Other proposals
 - “Reimportation” of brand name drugs
 - Greater flexibility for states to manage formularies in Medicaid
 - Greater PBM transparency (“C-THRU” Legislation)

The Year Ahead — What are the Chances?

None

- Congress will attempt to regulate drug prices in private sector plans

Infinitesimal (but not zero)

- HHS will permit re-importation of brand name drugs

Small

- Congress will require rebates in Part D or repeal non-interference clause; slightly higher chance that HHS will resurrect Part B drug demonstration project

Much higher likelihood

- States will impose additional regulation in individual insurance market
- Rewrite Medicaid prescription drug rebate statute to permit greater state flexibility to manage formularies
- Enhance PBM transparency and potentially require that all rebates be passed through to consumers at point of sale
- Authorize alternative reimbursement models for drugs dispensed to patients of gov't programs (Medicare, Medicaid)