Debate Positions

Position A: The Trump Administration has put forward an innovative set of policy strategies to rein in drug costs, including some proposals that are traditionally associated more with the left than with the right.

Position B: The Trump administration’s proposals are unlikely to have an impact because they are vague, limited in scope, lack coherence and are proving difficult to implement.

Discussion Questions

1. How concrete are the administration’s proposals on drug costs?
2. How feasible are these proposals?
3. In two recent setbacks, the administration killed its own rebate reform proposal and saw its rule requiring drug companies to disclose their pricing in television ads struck down. What is the significance of these developments?
4. The administration has floated tying some drug prices to those set by European governments. What are the implications of this type of de facto price-setting coming from a Republican administration?
5. The administration seems intent on moving forward with its plans to allow drug importation from Canada. What are the pros and cons of this and how might such a move play out?

At a Glance

Who?
- Patients
- Payers
- Employers
- Vendors
- Manufacturers
What are the proposals the Trump administration put forward?

**MEDICARE PART D & MEDICAID**

- **Two-sided Risk for Reinsurance Phase of Part D** (January 2019) (1)
  - The Centers for Medicare & Medicaid Services (CMS) released a model in January 2019 that aims to reduce spending. Medicare Part D payers will be able to keep a portion of what they are able to save the Medicare program if they can reduce spending compared to benchmarks.
    - The voluntary, 5-year model would introduce two-sided risk to a reinsurance phase of Part D, which pays for 80% of claims incurred during the “catastrophic” liability phase (2019 costs ≥ $8,140).
      - **2008-2017**: Federal spending on these liabilities increased 17% or $28 billion to $37.4 billion per year
  - When the model begins January 2020 Part D plans will be able to keep some of what they save Medicare by lowering costs, though they would also be liable for 10% of overspending compared to a benchmark.
    - This could put additional pressure on some drug prices. CMS has noted a “bifurcation” in spending, with increasing generic adoption driving it down, and specialty/branded drug prices driving it up.
      - Efforts to reduce spending in these categories could help Part D beneficiaries, who pay varying percentages of claims, and 5% of costs during the catastrophic coverage phase.
      - Branded and specialty drugs are typically the most resilient to pricing pressure since they are protected by patents, often face little or no competition, and Part D is required to cover all drugs in certain classes, including all cancer drugs.

- **Part D Negotiating Leverage and Part B Step Therapy** (November 2018 - Withdrawn May 2019) (1)
  - Medicare Part D plans would have had more tools to contain drug costs through increased flexibility around protected classes and use of step therapy in Part B.

- **Rebates in Medicare Part D & Medicaid** (February 2019 - Withdrawn July 2019) (1)
  - Under a proposed rule released by HHS in February 2019 rebates paid by drug manufacturers would no longer have been protected from anti-kickback laws.

- **Penalties for Misclassification** (April 2019) (1)
  - Life sciences companies will face new penalties under the ‘Medicaid Services Investment and Accountability Act’ law passed in April 2019, which aims to ensure companies don’t misclassify their drugs under the Medicaid Drug Rebate Program (MDRP).
  - Companies found to have intentionally misclassified their drug products to minimize the rebates they pay will be liable for twice the difference in improper payments. They are also liable to pay the difference back to CMS.
  - The MDRP requires a pharmaceutical company to offer the government the “best price” available for the drug, and then pay a rebate to the government. Depending on the category the rebate takes a percentage of the Average Manufacturer Price (AMP) for
    - **Innovative drugs**: 23.1% of AMP
    - **Line extensions**: 17.1% of AMP
    - **Generics**: 13% of AMP
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- **International Price Index** (October 2018)
  » The International Pricing Index (IPI) proposal, released on Oct. 30, 2018, was part of a broader attempt by the Trump administration to rein in drug pricing, in part by inducing greater competition in the US. The proposal would base reimbursement of drugs in the Medicare Part B program on prices paid for the same drugs in 14 countries including Canada, Japan and 12 European countries. (1)
  ▶ IPI countries vary in strategy. Many do not dictate what a pharmaceutical company charges for a drug, said Rachel Sachs, an associate professor of law at Washington University in St. Louis who studies drug pricing. Rather, she said, they are simply saying what the national insurance plan will pay. (2)
  ▶ Some of the countries in question also maintain private insurance systems beyond the government plan. For instance, in Canada, people have options, depending on the province where they live, of various forms of public and private prescription drug coverage, which differ in generosity. Therefore, what the government pays for a drug doesn’t necessarily dictate arrangements negotiated between drug companies and other insurers. (2)

  » CMS officials estimate using target prices based on foreign competition could reap substantial savings for Medicare Part B—and about 30% on a per-drug basis. Between 2020-2025, they expect to generate net savings of $17.9 billion for Part B, as well as $1.8 billion in reduced Medicaid spending due to impacts on the dual-eligible population. (1)

  » Because prices under the IPI model would be tied to countries that have pricing regulators, which limit price increases, the IPI model could limit pricing growth under Part B and reduce long-term spending.
  ▶ 27% of drugs covered by Medicare Part B saw greater than 10% annual average growth in the cost per dose between 2012 and 2016, according to an HRI analysis of CMS data.
  ▶ 40% saw another form of increase

  » The changes under the IPI model would subject 29 of the top 50 drugs under Medicare Part B to competition, according to an analysis of 2016 Medicare drug data and 2018 patent data by HRI. Those drugs accounted for $14.4 billion in spending in 2016, and the vast majority are biological medicines.

- **Generics**
  » **Citizen Petitions and Petitions for Stay of Action** (October 2018) (1)
    ▶ The FDA announced a draft guidance in October 2018 under which it would make public the names of pharmaceutical companies found to be unnecessarily delaying generic competition approvals. Companies also could be investigated by the Federal Trade Commission (FTC) under the proposal.
      ▶ It involves citizen petitions and petitions for stay of action, through which companies can ask the FDA not to approve a product—or to pull its approval—for reasons related to science, regulation or public health.
        ◦ The FDA has long said that many of these petitions are frivolous. The proposal would allow it to deny petitions that fail to raise valid scientific or regulatory issues.
        ◦ The issues that companies raise in citizen petitions often aren’t obviously frivolous and may therefore not be easy to dismiss. For example, a branded drug company may have reformulated its drug in response to public health concerns, so it may be reasonable to reject a generic that refers to the original formulation.
    ▶ From 2008 to 2016, the FDA received 182 petitions; it granted 8 in full. Of those
remaining, 127 were denied; 5 were withdrawn; and 42 were partially denied.

- If the new policy is enacted, its impact might be limited. The outcomes of citizen petition proceedings already are public through the federal docket. Many companies enlist third parties, such as law firms, to file petitions on their behalf.

» Speeding Generic Approvals (February 2019) (1)
- Generic pharmaceutical manufacturers may benefit from new FDA policies and funding designed to lower barriers to competition and hasten product reviews. The changes involve two new guidance documents and $269 million more in federal funding for the FDA, including $25.1 million in new funding for generic drug development.
- One draft guidance focuses on Competitive Generic Therapies (CGT)—generic drugs approved for conditions for which there is “inadequate generic competition.”
- A second new guidance document outlines requirements for companies to regularly submit to the FDA information about the marketing status of their products to show which are available to consumers.
- These changes could create modest new opportunities for companies to get their drugs to market more quickly. The FDA’s new priority review pathway for generic drugs is 8 months long, compared to the standard 10 months for nonpriority drugs.
  - An HRI analysis of data from Medicare Part D, which covers almost all pharmaceuticals, shows that 672 drugs (44%) have just one manufacturer. Industry consolidation—by generic manufacturers and retail channels—and low margins may reduce or eliminate the incentive to compete in some of these areas, leading to scarcity of competition.
    - A swelling number of new generics may affect drug prices less than regulators and policymakers hope because biological medicines have a growing influence on the market, and the number of patent expirations is decreasing. Generic competition won’t affect 46% of the estimated sales revenue of the top 100 drugs through 2023.
    - Generic competition would have no effect on 41% of the top 100 drugs by revenue, worth more than $600 billion. This trend is likely to accelerate in the years ahead as the FDA approves an increasing number of biologics each year.

» Canadian Drug Imports (July 2019)
- The Trump administration jumped into a fight with drug makers by promising to allow importation of cheaper drugs from Canada and other countries, advancing an idea the pharmaceutical industry and many Republicans have long opposed. (3)
- The health department said it would open up 2 pathways to let states and companies test drug importing programs, asserting it could assure products safety. (3) Imports would be Canadian versions of drugs rated by the FDA as safe and effective. U.S. states, wholesalers and pharmacists could submit plans for importing the drugs.
  - The plan wouldn’t apply to expensive drugs such as biologics. (4)
    - Current laws prevent importation of these drugs, including insulin. Under a second pathway outlined in the plan, U.S. drug companies could bring foreign versions of their own drugs, including biologics, to the U.S. with a cheaper price tag. But this would be up to the drug companies, who lack financial incentive to do so.

TRANSPARENCY
- Gag Clauses (October 2018) (1)
  - President Trump signed 2 bills into law in October 2018 to prohibit insurers and PBMs from restricting a pharmacy’s ability to inform patients about lower drug cost options.
Under some contracts between pharmacists and insurers or PBMs, a so-called “gag clause” restricts pharmacists from telling patients when the cash price of a medicine is less than what they would pay under their insurance plan.

This strategy is popular and represents low-hanging fruit. A USC study found that 23% of filled pharmacy prescriptions involved a patient overpayment of $7.69 on average. While each overpayment may be small, the total dollar amount could be significant.

**Drug Prices in Advertising** (October 2018 - Court Declared Illegal July 2019)
- The proposed rule required drug companies to include information in television ads about the Wholesale Acquisition Cost (WAC) of the drug, also known as the “list price,” for a typical 30-day supply of the product or a full course of treatment. (1)
- Under the rule, if a medicine’s list price was more than $35 a month, it would have to be stated during the commercial. (5, 6)
- HHS could have enforced the rule by listing violators online at least once a year. (1)
- The final regulation was struck down by the US District Court of the District of Columbia, with a district court judge ruling that the regulation lacked a proper legal basis. (1)
- HHS filed a notice of appeal on August 21st to challenge the July federal court ruling. (6)

**Why?**

**Why is this a priority for the Trump administration?**
- President Donald Trump has long identified drug pricing as a priority for his administration. After first releasing a drug pricing “blueprint” for action in 2018, the Trump administration has released new policies, proposals and regulations to lower list prices, decrease what consumers pay at the pharmacy and allow insurers to negotiate more aggressively. (1)
- Unlike many other nations, the U.S. government doesn’t directly regulate the price of medicine. Drug companies in the U.S have the power to set prices at whatever the market will bear. In Canada, a federal body sets a price ceiling for patented drugs based on a comparison of prices in seven industrialized countries. Prices for generic drugs aren’t capped and are often higher than in the U.S. (4)
- Drug prices are still increasing. While growth in spending on drugs has slowed in recent years, total national spending continues to grow. Americans spend more than anyone else in the world. The average person spends $1,025 per year on medication—an inflation-adjusted increase of elevenfold since 1960. (8)
- An annual supply of insulin in the U.S. costs more than in any other country, around $6,000. From 2012 to 2016, the price roughly doubled.

**When?**

**When can we expect changes?**
- It’s difficult to predict. While the Trump Administration has floated some of the most innovative proposals in recent decades to control drug costs, little has been implemented. Many observers question the seriousness of the Administration in making change. (8)

**Where?**

**Where could we see some of these impacts?**
- The cost of drugs at retail accounts for only about 10% of the country’s health expenditures, and this trend has been steady for almost two decades. Exorbitant as drug prices are, a relatively small 24% of people say they have any “difficulty affording medications.” (8) However, the fastest-growing portion of drug spend is the non-retail drugs (mostly biologics) that are administered in medical offices or hospitals, and though these account for only about 4% of healthcare expenditures, their high costs fall on a small fraction of patients.
- Overall, it is medical bills that cause much more angst and financial hardship, and are now the leading cause of bankruptcy in the United States. Slowing the growth of pharmaceutical
The Trump administration is relying on the consumer price index (CPI) for prescription drugs, a measure of drug price inflation that aims to capture what consumers, along with their insurance companies or other payers, are paying for a basket of retail prescriptions. The Bureau of Labor Statistics’ most recent figures show the CPI for prescriptions dropped by 2% from June 2018 to June 2019. Interestingly, this is rarely highlighted in the media.

The CPI has its shortcomings. Experts point out that it doesn’t include specialty drugs, which tend to be expensive, and its ability to accurately measure what insurers pay is hindered by what pharmacies can report. Barry Bosworth, a senior fellow at the Brookings Institution, told us the CPI for prescription drugs is “the best that is available.”

How can Trump decrease U.S. drug costs?

- Discourage Healthcare Lobbyists (8)
  » PBMs spent $1.5 million in lobbying Q1 of 2019, an all-time high
  » The pharmaceutical industry spent $9.9 million lobbying Q1 of 2019.

- Allow Medicare to Negotiate Prices with Manufacturers (8)
  » It has bipartisan support of 92 percent among Americans. It was also endorsed in a recent report from the National Academies of Sciences, Engineering, and Medicine. The Trump administration made a partial gesture in this direction last year, announcing that it would allow Medicare Advantage plans (those paid for by the government but administered by private insurance companies) to negotiate prices with drug companies. But the administration has not pursued negotiations on behalf of the larger Medicare pool.

- Use “March-In-Rights” for Tax-Funded Drug Discoveries Unavailable to the Public (8)
  » If Trump wanted to rally populist support around the problem of drug prices, he could call attention to the fact that tax dollars are used to develop drugs. Federal law gives the government “march-in rights” when a company using a taxpayer-funded discovery is not made available to the public “on reasonable terms.” In such cases—which have never actually happened—the government could override a patent and license someone else to market a drug.

Background

Out of Pocket Drug Costs Over Time (10)
Drug Spending Growth Drivers Over Time (10)

Stakeholders & Impacts

**LOWERING DRUG COSTS**

**International Pricing Index (8)**
- The public perception that many or most U.S. drugs are maliciously overpriced comes largely from the minority of cases of brand-name drugs for which companies have consistently raised prices far beyond inflation. <Instead, can we say something about differences in OOP spending on drugs in the US vs. other countries?>

**Canadian Drug Importation (4)**
- Patients could get cheaper drugs from Canada but many economists and industry observers don’t believe that this strategy will work broadly. Canadian officials likely would restrict exportation due to concerns that supplies would run short in their country, and pharma companies probably wouldn’t allow lower prices in the smaller market to affect those in the larger one.

**TRANSPARENCY**

**Gag Clauses (1)**
- “All our citizens deserve to know the lowest price available at our pharmacies, and now that’s what they’ll be getting.” -President Donald Trump

**Drug Prices in Advertising (5)**
- “While holding drug makers accountable for prices is welcome, we remain skeptical that drug companies could be shamed, as the administration intended, into lowering their prices.” - Patient Advocate Groups
- "Judge Amit Mehta’s ruling is a step backward in the battle against skyrocketing drug prices and providing more information to consumers. Americans should be trusted to evaluate drug price information and discuss any concerns with their health care providers." -AARP, group representing older Americans
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Government

- **International Price Indexing**
  - “The IPI proposal, is a top priority.” - Seema Verma, CMS Administrator (13)
  - Shifts in White House policy point to a potential rift between President Trump and Secretary of HHS Alex Azar. On several occasions, Azar has warned legislators and policymakers that tying U.S. drug prices to international benchmarks would not be effective as companies may raise prices in international markets to gain latitude in setting prices in the U.S. (14)

- **Two-sided Risk for Reinsurance Phase of Part D** (17)
  - 70% of practices in Medicare’s Oncology Care Model (OCM) would owe payments to CMS if they transition to the program’s two-sided financial risk tracks, a new Avalere analysis finds.
  - “Many practices that could be required to switch to two-sided risk will likely face recoupment payments to CMS in future performance periods. The decision to drop out of the OCM or switch to the new track will be decided on a practice-by-practice basis and will depend on many factors.” - Biruk Bekele, Avalere Consultant

Payers

- **Two-sided Risk for Reinsurance Phase of Part D** (17)
  - Section 128 of the draft Prescription Drug Pricing Reduction Act (PDPRA) proposes inflation-based Medicare Part D rebates. According to CBO scoring of the draft bill, this provision accounts for $57 billion of the $92 billion of projected savings over 10 years. Further, the CBO anticipates a downstream reduction in costs for commercial insurance plans if this provision successfully limits drug price increases.

Private

Lowering Drug Costs

- **Rebates in Medicare Part D & Medicaid** (10)
  - The Large Employers’ 2019 Health Care Strategy and Plan Design Survey found employers project the total cost of providing medical and pharmacy benefits will rise 5% for the sixth consecutive year in 2019. Including premiums and out-of-pocket costs for employees and dependents, the total cost of health care is estimated to be $14,099 per employee this year, and projected to rise to an average of $14,800 in 2019. Employers will cover roughly 70% of those costs. Employers cited high cost claims, specialty pharmacy, and specific diseases as key drivers of cost increases.
  - “Health care cost increases continue to outpace workers’ earnings and increases in inflation, making this trend unaffordable and unsustainable over the long term.” - Brian Marcotte, President and CEO of the National Business Group on Health

Employers

- In 2017, prescription drugs at retail accounted for 10% of U.S. health
spending but 21% of employer insurance benefits. That is not much less than the 23% employers spent on inpatient hospital care.

**TRANSPARENCY**

- **Drug Prices in Advertising (8)**
  - Several layers of middlemen and reimbursement schemes keep costs hidden from both patients and doctors, and fully apart from most decision making. While the advertising-disclosure requirement is a move toward cultural consciousness of cost, it has traditionally been market competition that has led to real price decreases.

**LOWERING DRUG COSTS**

- **International Price Indexing**
  - According to an HRI analysis of data from HHS’s Office of the Assistant Secretary for Planning and Evaluation (ASPE), if the US adopted volume-weighted international pricing, 5 companies would be expected to lose revenue of $500 million per year or more – the difference between their international and domestic prices. Another 6 companies have between $100 and $500 million in annual revenue at stake. (1)
  - The proposal has drawn fierce opposition from the pharmaceutical industry, a powerful force in Washington, as well as from many congressional Republicans, who warn that the move amounts to “price controls” and is a departure from free-market GOP orthodoxy. (13)

- **Generics**
  - **Canadian Drug Imports (3)**
    - The pharmaceutical industry swiftly attacked the plan. Because the U.S. would ultimately be relying on Canada’s regulatory process rather than FDA scrutiny, some U.S. pharmaceutical executives argue that the proposal could put American patients at risk.
      ▶ "Rather than surrender the safety of Americans by importing failed policies from single-payer countries, we should work on solutions here at home that would lower patient out-of-pocket costs at the pharmacy counter." -Stephen Ubl, CEO PhRMA
      ▶ "There is simply no way to adopt an importation scheme that doesn't jeopardize the health and well-being of America's patients. This is a misguided attempt to keep an ill-informed campaign promise." -Jim Greenwood, President BIO

**TRANSPARENCY**

- **Drug Prices in Advertising (5)**
  - Merck, Eli Lilly and Amgen sued the Trump administration over the rule, arguing that it would violate the companies’ free speech rights.
References