Implications of Speaker Pelosi’s Drug Pricing Plan

October 10, 2019
We See Amazing Science, But It’s Overlooked in Washington

Exciting Advancements in Biopharmaceutical Labs Across the U.S.

New York Says End of AIDS Epidemic Is Near

Newly Approved Drug Being Called ‘Game Changer’ For People Who Suffer From Hemophilia

But Washington Is Considering Policies That Would Disincentivize Continued R&D

Nancy Pelosi @SpeakerPelosi • Sep 19
For years, seniors & families across America have struggled under the sky-rocketing costs of prescription drugs they need to stay healthy. Today, we introduce our solution to #LowerDrugCosts.

Read more here: washingtonpost.com/politics/health...
Today, Americans Have Access to More New Medicines Than Anywhere Else in the World

Number of New Medicines Available by Country
(of 270 global new medicines launched in the United States from 2011-2018)

Source: PhRMA analysis of IQVIA Analytics Link and U.S. Food and Drug Administration, European Medicines Agency, Japan Pharmaceuticals and Medical Devices Agency, Health Canada and Australia Therapeutic Goods Administration data.

Note: New active substances approved by the above regulatory agencies and launched in the United States and other countries from January 1, 2011 to December 31, 2018.
Medicine Spending Is Not the Biggest Driver of Health Cost Growth

Cumulative Spending Growth from 2015 to 2018 (in Billions)

- Hospital Care: 157.2
- Physician and Clinical Services: 94.4
- Health Insurance Administrative Costs and Profits: 56.5
- Home Health and Other Care: 40.1
- Retail Prescription Medicines: 17.9
- Dental Services: 16.8
- Nursing Care and Facilities: 10.4

There Are Ways Our System Works Well, But It Doesn’t Always Work for Patients

Price Growth for Brand Medicines Virtually Flat

Discounts and Rebates Growing

Patient Out-of-Pocket Costs Increasing

Patient Costs Rising Faster Than Insurer Costs

Rebates, discounts, fees and other price concessions have more than doubled since 2012

2006-2018

2006-2017

Deductibles have increased

360% since 2006

It’s No Wonder, Health Insurance Costs Top Americans’ Concerns About Health Care

Which health care issue is most important to you?

- The cost of health insurance premiums, deductibles or copays: 38%
- The cost of prescription medicines: 14%
- The cost of hospital services: 12%
Voters Want Lower Out-of-Pocket Costs and Predictability

Thinking about your prescription drug coverage, which is more important to you?

- Having a lower co-pay at the pharmacy: 51%
- Paying a lower premium each month: 35%
- Other/DK/Ref.: 14%

Which is more of a concern for you?

- Not knowing what you will have to pay: 47%
- The cost that you actually have to pay: 46%

Note: Among adults, 65 and over with prescription drug coverage.
Source: KFF Health Tracking Poll (Conducted February 14-24, 2019); Public Opinion Strategies, 1,100 Registered Voters, June 2019
### Senate Finance Package Puts Government Ahead of Patients

<table>
<thead>
<tr>
<th>Redesigns Medicare Part D</th>
<th>Adopts Price Control in Parts B and D</th>
<th>Does Little to Help Patients</th>
</tr>
</thead>
<tbody>
<tr>
<td>• 20% tax on medicines in catastrophic targets new innovative and critically needed medicines</td>
<td>• Imposes inflation penalty</td>
<td>• Siphons more than $150B from R&amp;D</td>
</tr>
<tr>
<td>• According to Avalere, nearly a 70% increase in industry liability on top of BBA changes last year</td>
<td>• Savings would primarily go to government, not beneficiaries</td>
<td>• Part D out-of-pocket cap only benefits 2% of patients in 2022</td>
</tr>
<tr>
<td></td>
<td>• Duplicative of inflation penalty already used by many commercial plans and Part D plans</td>
<td>• Affordability improvements should be added to help those who don’t reach catastrophic threshold</td>
</tr>
</tbody>
</table>

Speaker Pelosi’s Proposal Is Unprecedented

**Price Setting**
- Sets prices each year for 25-250 medicines
- Applies government set price to public and private market

**Tax**
- Implements massive tax of as much as 95% of the gross sales for a medicine

**Inflation Penalty**
- Upends market-based system with government price control
- Retroactive 3 years to 2016
- Paid to the Medicare Trust Fund
- Duplicative of inflation penalty already used by many commercial and Part D plans

**Part D Changes**
- 30% tax on medicines in catastrophic phase
- 10% tax on medicines before catastrophic phase
- Targets innovative therapies for new mandatory discounts
Speaker Pelosi’s Plan Puts the Pipeline for Future Treatments and Cures at Risk

- $1 trillion+ hit on biopharmaceutical innovators over 10 years
- Permanent loss of roughly 1 million U.S. jobs
- Loss of hope for millions of patients
There Are Ways to Fix the System and Help Patients

**Improving Patient Affordability**
- Pass-through rebates
- Establish out-of-pocket cap
- Predictable monthly out-of-pocket costs
- Lowering coinsurance from 25% to 20%

**Fixing Market Incentives**
- Supply chain payments not tied to list prices
- Reduce 340B distortions

**Shifting Toward Value**
- Remove barriers to innovative payment arrangements
- Better tools for value assessment

**Increasing Competition**
- CREATES Act
- Citizen Petitions
- Patent settlements
- Patent Transparency
Market-Based Solutions Are More Popular with Voters

- Require health insurers to pass along to patients the discounts on prescription drugs they negotiate with drug manufacturers: 92%
- Strengthen the U.S. Food and Drug Administration, also known as the FDA, to review and get generic prescription drugs to market faster: 86%
- Require health insurance companies to be more transparent about what prescription drugs are covered in health plans and what people will pay: 85%
- Negotiate stronger trade agreements so that Americans subsidize less of the prescription drug costs of other countries: 61%
- Allow the federal government to determine the price of prescription drugs and determine which prescription drugs are covered in Medicare: 40%
- Allow the federal government to set the price of prescription drugs in Medicare based on the average prescription drug price in foreign countries: 33%
“Which candidate do you prefer?”

Candidate A: H.R. 3 Proposals
- Government-set price
- Importing prices
- 95% tax on industry
- Redesign Medicare Part D

All Voters: 26%
Republicans: 20%
Democrats: 32%

Candidate B: Moderate Approach
- Pass along discounts
- More generics to market
- Increase competition

All Voters: 55%
Republicans: 64%
Democrats: 50%
Deep Dive on Speaker Pelosi’s Plan
Speaker Pelosi’s Plan Is Far-Reaching in Size and Scope

- Quickly encompasses the entire market, including up to 250 medicines each year.
- Could include roughly 97% of spending on Part B eligible medicines.
- Stretches far beyond Medicare, impacting the private market, including employer-sponsored plans.
Imports Lowest Prices From Other Countries

References prices in 6 countries to create Average International Market (AIM) Price:

- Germany
- Australia
- France
- Canada
- Japan
- UK

Manufacturer must:

1. Accept the **lowest average price** of any one of the AIM countries, called the target price

Or:

2. Attempt to “negotiate” with a ceiling price of **120% of the AIM price**

Or:

3. Pay a **tax of 65%-95%**

On top of all of this, manufacturers must offer the government-set price to commercial plans who can negotiate **more discounts, formulary placement and UM**
Speaker Pelosi’s Plan Is Anything BUT Negotiation

Manufacturers either comply or pay a massive tax of 65%-95% of gross sales for the medicine.

Manufacturers must offer commercial plans government-set price or pay civil monetary penalties of 10X the difference in the prices.
Exposes Americans to Access Restrictions and Delays

Of the 84 new cancer medicines available in the United States, what percentage are available abroad?

<table>
<thead>
<tr>
<th>Country</th>
<th>Percentage Available Abroad</th>
</tr>
</thead>
<tbody>
<tr>
<td>United States</td>
<td>100%</td>
</tr>
<tr>
<td>Germany</td>
<td>73%</td>
</tr>
<tr>
<td>United Kingdom</td>
<td>70%</td>
</tr>
<tr>
<td>France</td>
<td>67%</td>
</tr>
<tr>
<td>Canada</td>
<td>60%</td>
</tr>
<tr>
<td>Japan</td>
<td>56%</td>
</tr>
<tr>
<td>Australia</td>
<td>50%</td>
</tr>
</tbody>
</table>

U.S. Patients with Non-Small Cell Lung Cancer Would Lose Life Years If U.S. Government Replicated Flawed Policies of Foreign Governments

<table>
<thead>
<tr>
<th>Country</th>
<th>Life Years Lost</th>
</tr>
</thead>
<tbody>
<tr>
<td>Australia</td>
<td>-74%</td>
</tr>
<tr>
<td>Canada</td>
<td>-54%</td>
</tr>
<tr>
<td>United Kingdom</td>
<td>-54%</td>
</tr>
<tr>
<td>Korea</td>
<td>-52%</td>
</tr>
<tr>
<td>France</td>
<td>-13%</td>
</tr>
</tbody>
</table>

### Retrospective Inflation Penalty Imposes Anti-Competitive Price Controls

#### Pelosi’s Inflation Penalty Is Extreme
- Retroactive to 2016
- Penalty paid to the Medicare Trust Fund
- Funds would not go toward helping patients afford their medicines under Part D
- Does not address misaligned incentives in the supply chain

#### Market-Based System Controls Costs
- Today, market competition in Medicare Part B and Part D successfully controls medicine costs
  - Over the past 10 years, Part D benefit payments have increased by an annual rate of just 3.8% on a per enrollee basis
  - Often commercial plans and Part D plans already use an inflation penalty
  - Average price growth in Part B is below medical inflation with Part B medicines accounting for just 3% of total Medicare spending in 2016

---

Significant Redesign of Medicare Part D Program

**Current Law**
- Catastrophic (~ $11,000 total Rx, $3,100 OOP)
  - Beneficiary: 5%, 15%
  - Plan: 80%
  - Manufacturers: 20%
  - Government: 5%
- ICL ($4,490)
  - Beneficiary: 25%
  - Plan: 70%
  - Manufacturers: 5%
  - Government: 25%
- Deductible ($485)
  - Beneficiary: 75%
  - Plan: 25%

**SFC Mark***
- Catastrophic (~ $6,550 total Rx, $2,000 OOP)
  - Beneficiary: 20%
  - Plan: 60%
  - Manufacturers: 20%
  - Government: 10%
- ICL ($4,490)
  - Beneficiary: 25%
  - Plan: 75%
  - Manufacturers: 25%
  - Government: 25%
- Deductible ($485)
  - Beneficiary: 100%

**H.R. 3**
- Catastrophic (~ $6,550 total Rx, $2,000 OOP)
  - Beneficiary: 30%
  - Plan: 50%
  - Manufacturers: 20%
  - Government: 10%
- ICL ($4,490)
  - Beneficiary: 10%
  - Plan: 25%
  - Manufacturers: 65%
  - Government: 5%
- Deductible ($485)
  - Beneficiary: 100%

Note: Reflects coverage for brand medicines starting in 2022 for non-LIS beneficiaries

* Reflects full phase-in of plan liability in catastrophic phase
Sweeping Changes Without Protections for Patients

- No guarantee that medicine is covered
- Insurers still get to use utilization management and other tools to restrict access
- Money from inflation penalties goes to the Medicare Trust Fund, not patients
Threatens to Shift Biopharmaceutical R&D, Investments and Jobs Abroad

Over next 10 years, siphons

$1 trillion +

from biopharmaceutical innovators

= Over $100 billion a year, which is more than annual R&D spending

40% of all projected revenue for the industry over the next 10 years

Permanent loss of roughly 1 million U.S. jobs
Job Losses Would Be Seen Across the Country

Note: Estimates of potential biopharmaceutical job losses over 10 years under Pelosi Plan
NIH Not Equipped to Fill in Gaps in Lost R&D

NIH focuses on “basic” research

• Only a portion of NIH’s budget goes to drug development
• Looks at ways to expand understanding of body and root causes of disease

Biopharmaceutical companies conduct basic research, but prioritize “applied” research

• Develop a medicine that can go into the human body and treat a disease
• Most costly and difficult part of drug development
• Takes an average of 10 years and more than $2B to develop a new medicine

$97 Billion
Total Biopharmaceutical Industry R&D Investment in 2017

$32.6 Billion
Entire NIH Research Budget for 2017

Source: DeMasi JA et al.; Research!America.
Chills Investment in Future Treatments for Unmet Medical Needs

Search for a Cure for ALS

• **ALS affects 14,000-15,000 Americans**, 5,000-6,000 of whom are newly diagnosed each year

• Only **4 medicines** have been approved to treat symptoms of ALS, but there is **no cure**

• Between 1995 and 2019, **28 medicines in clinical trials failed** to make it to market

Search for a Cure for Alzheimer’s

• Alzheimer’s **affects 5.8 million Americans**

• If no new treatments are found by 2050, the total cost of care for Alzheimer’s is projected to increase to **more than $1.1 trillion**

• Only **4 medicines** have been approved to treat symptoms of Alzheimer’s, but there is **no cure**

• Between 1998 and 2017, **146 treatments in development failed**