



Implications of Speaker Pelosi's Drug Pricing Plan

PhARMA
RESEARCH • PROGRESS • HOPE

October 10, 2019

We See Amazing Science, But It's Overlooked in Washington

Exciting Advancements in Biopharmaceutical Labs Across the U.S.

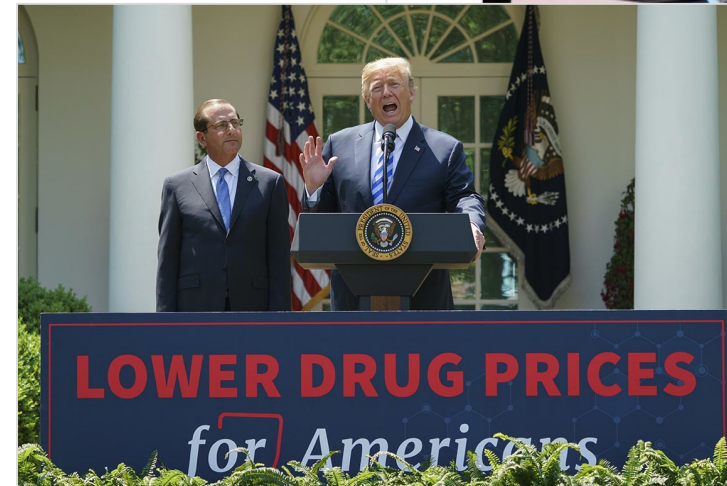
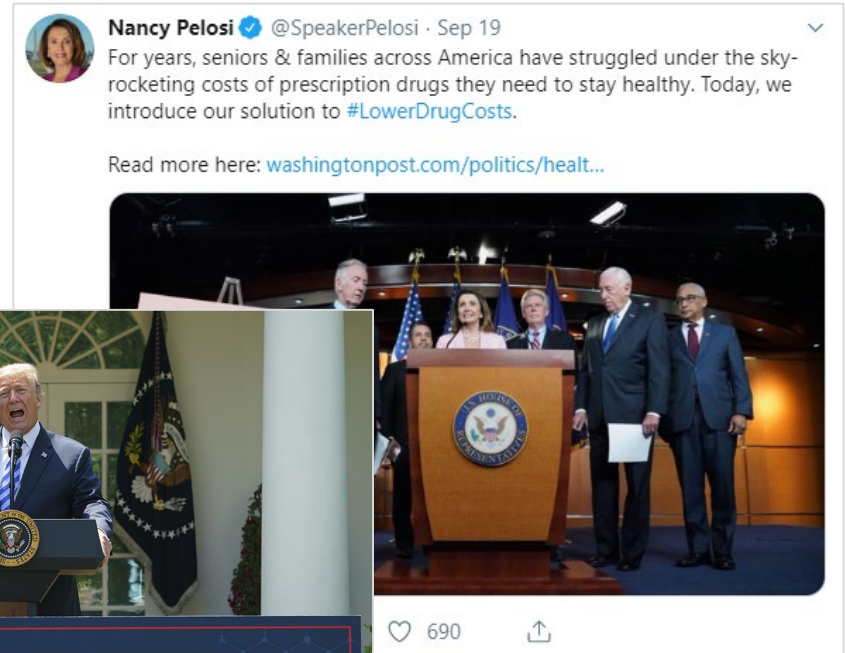
The New York Times

New York Says End of AIDS Epidemic Is Near

CBS

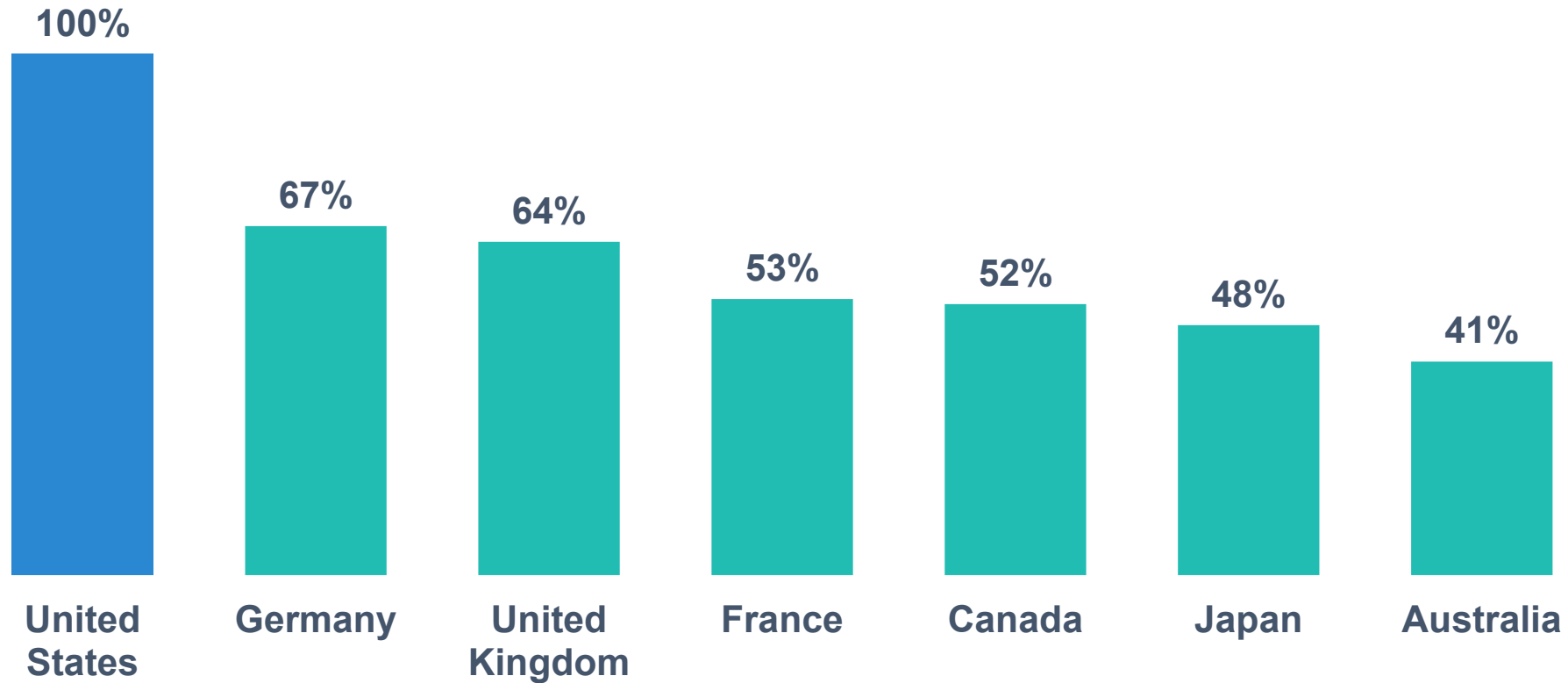
Newly Approved Drug Being Called 'Game Changer' For People Who Suffer From Hemophilia

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



Today, Americans Have Access to More New Medicines Than Anywhere Else in the World

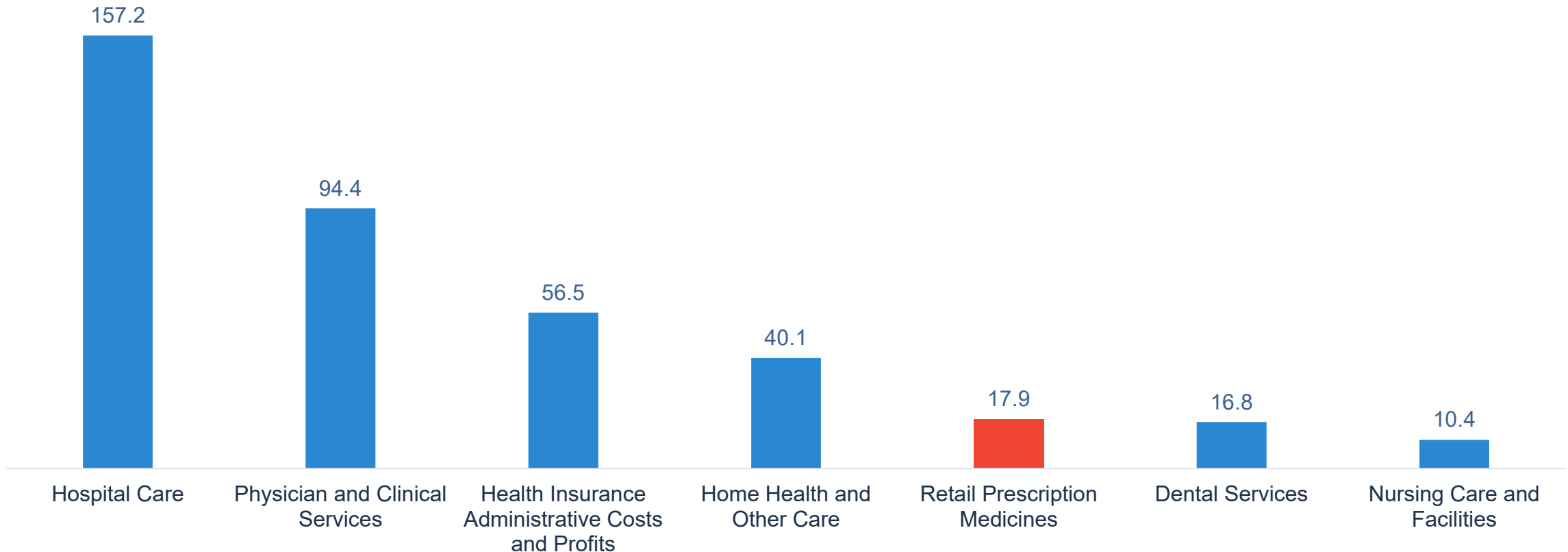
Number of New Medicines Available by Country
(of 270 global new medicines launched in the United States from 2011-2018)



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)



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

Price Growth for Brand Medicines Virtually Flat

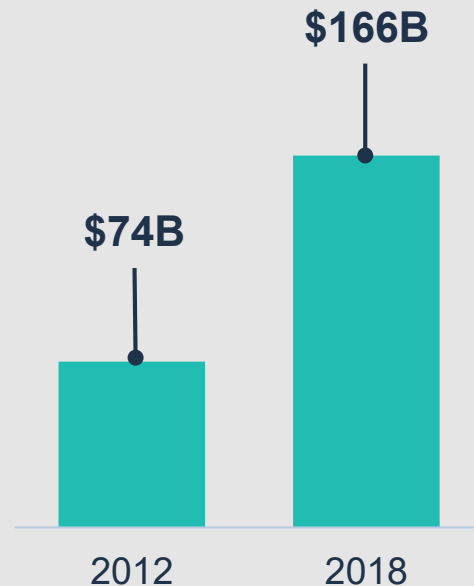


0.3%

2018

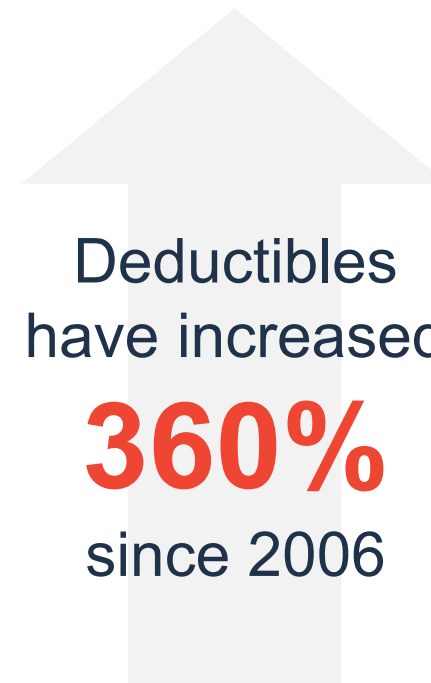
Discounts and Rebates Growing

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



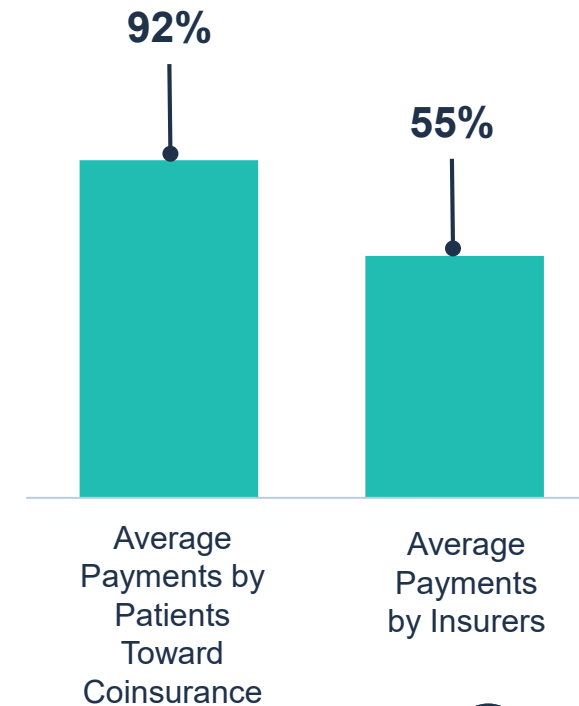
Patient Out-of-Pocket Costs Increasing

2006-2018



Patient Costs Rising Faster Than Insurer Costs

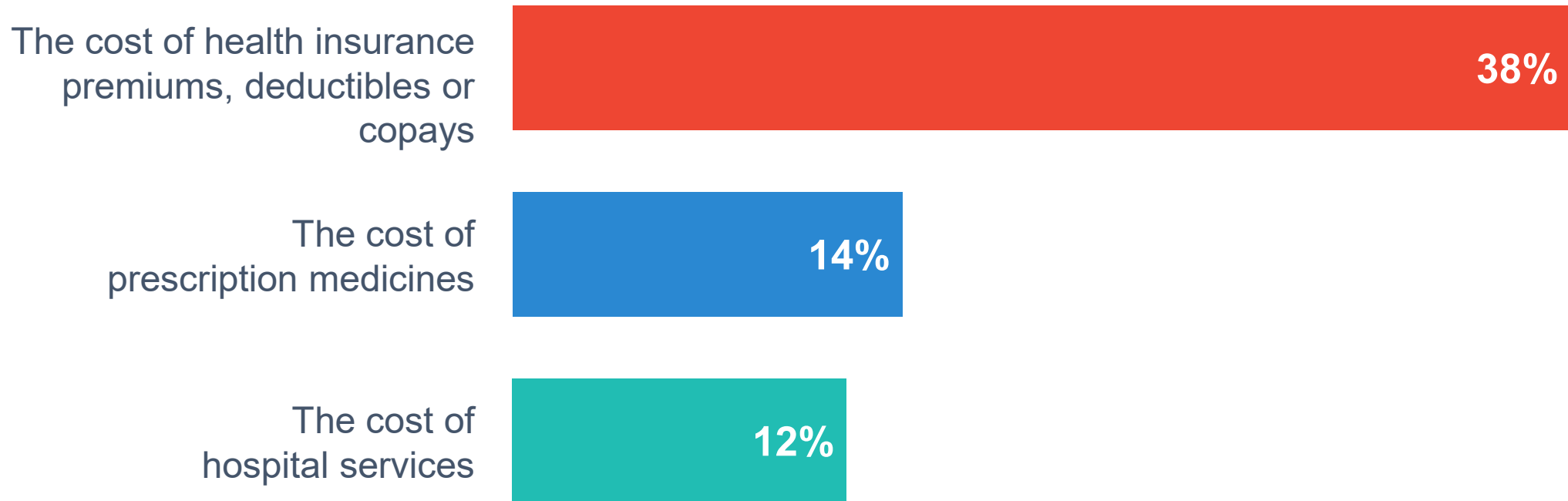
2006-2017



Source: IQVIA. "2018 Medicine Use and Spending." 2019.; Fein, Adam J., "The 2019 Economic Report on U.S. Pharmacies and Pharmacy Benefit Managers," Drug Channels Institute, 2019.; Kaiser Family Foundation, "2019 Employer Health Benefits Survey," 2019.; Kaiser Family Foundation. "Tracking the rise in premium contributions and cost-sharing for families with large employer coverage," 2019.

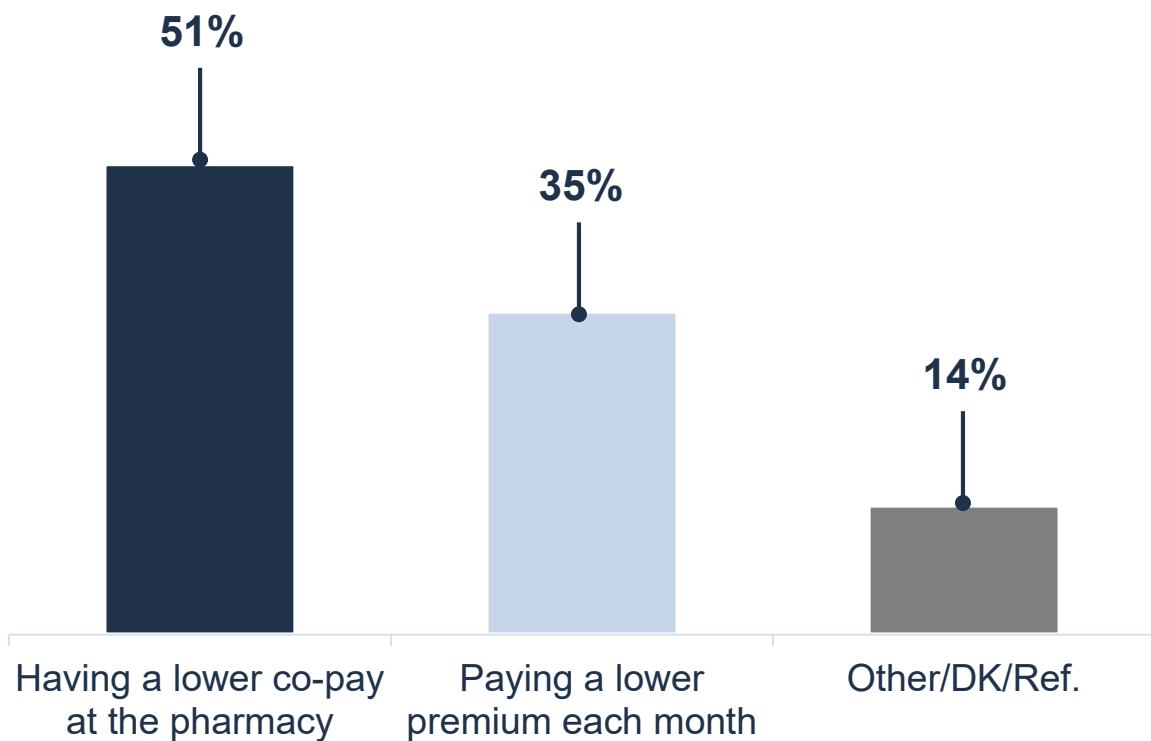
It's No Wonder, Health Insurance Costs Top Americans' Concerns About Health Care

Which health care issue is most important to you?

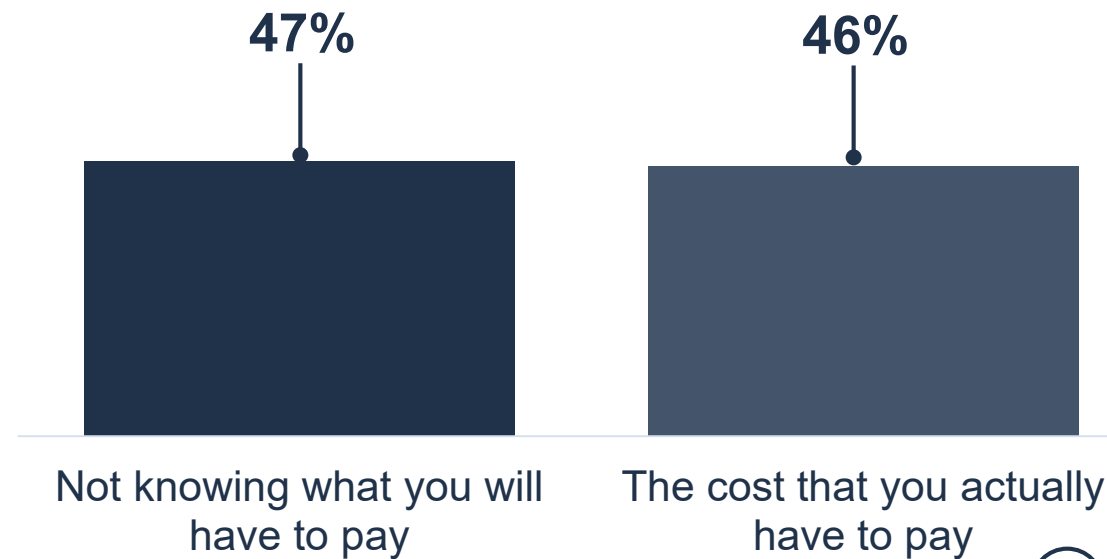


Voters Want Lower Out-of-Pocket Costs and Predictability

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



Which is more of a concern for you?



Senate Finance Package Puts Government Ahead of Patients

Redesigns Medicare Part D

- 20% tax on medicines in catastrophic targets new innovative and critically needed medicines
- According to Avalere, nearly a 70% increase in industry liability on top of BBA changes last year

Adopts Price Control in Parts B and D

- Imposes inflation penalty
- Savings would primarily go to government, not beneficiaries
- Duplicative of inflation penalty already used by many commercial plans and Part D plans

Does Little to Help Patients

- Siphons more than \$150B from R&D
- Part D out-of-pocket cap only benefits 2% of patients in 2022
- Affordability improvements should be added to help those who don't reach catastrophic threshold

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

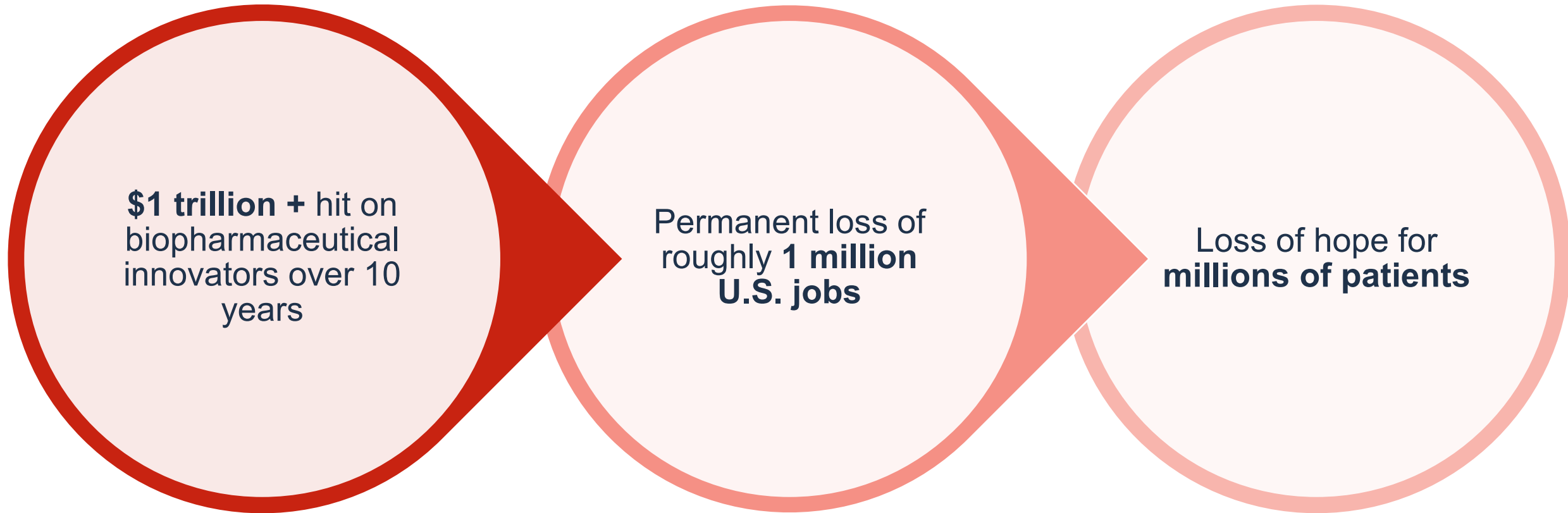
- Upends market-based system with government price control
- Retroactive 3 years to 2016
- Paid to the Medicare Trust Fund
- Duplicative of inflation penalty already used by many commercial and Part D plans



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



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

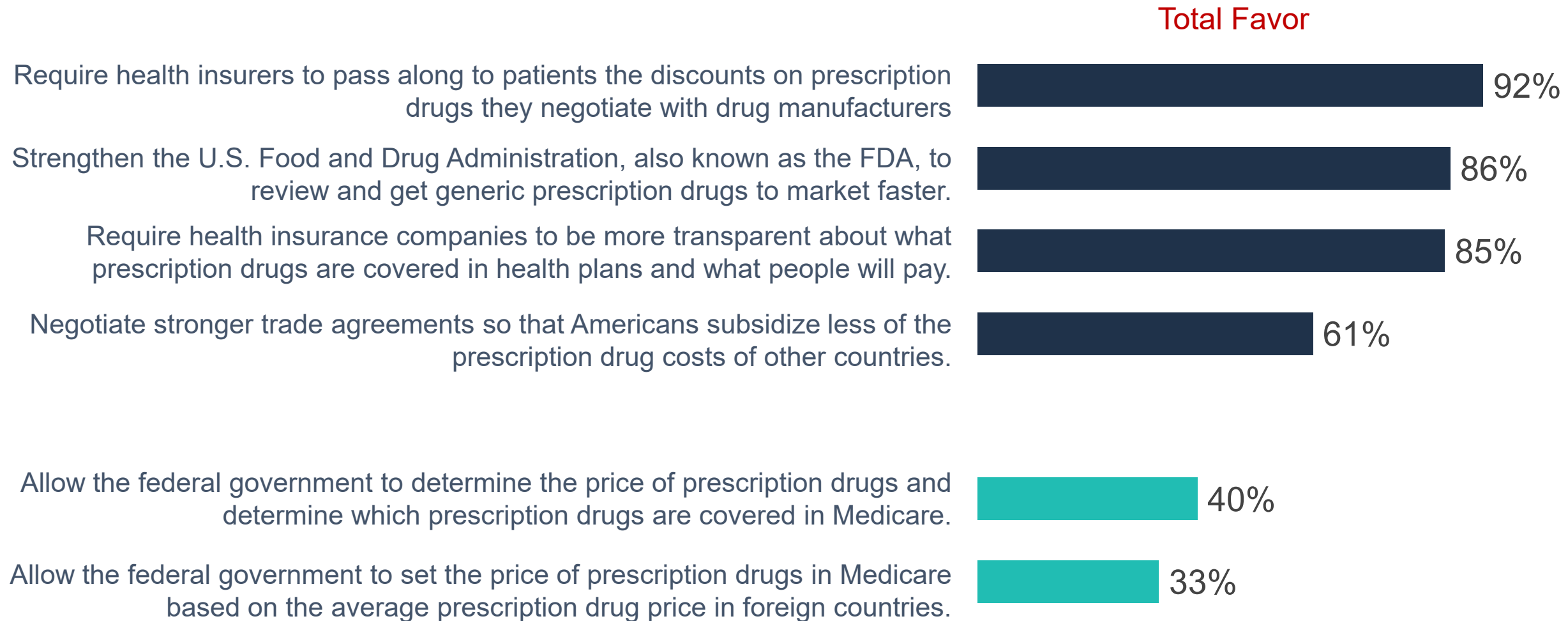
- Remove barriers to innovative payment arrangements
- Better tools for value assessment



Increasing Competition

- CREATES Act
- Citizen Petitions
- Patent settlements
- Patent Transparency

Market-Based Solutions Are More Popular with Voters



“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



UK



FRANCE



CANADA



JAPAN



AUSTRALIA

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

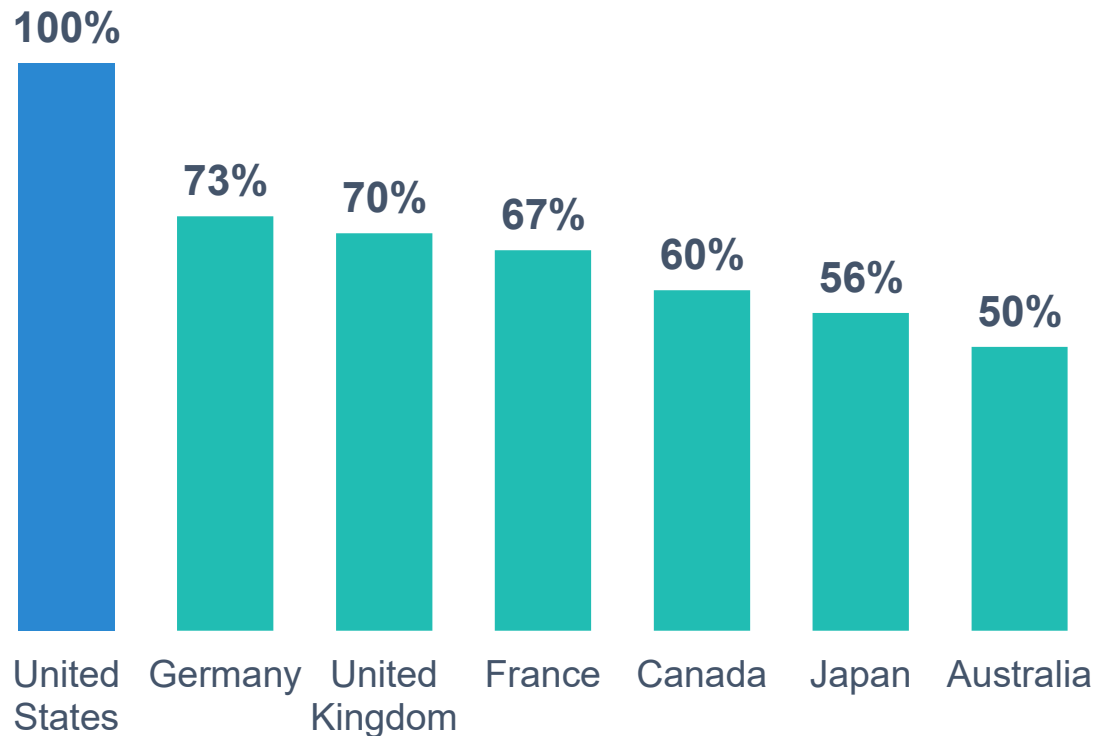
Manufacturers must offer commercial
plans government-set price or pay

**civil monetary
penalties of 10X**

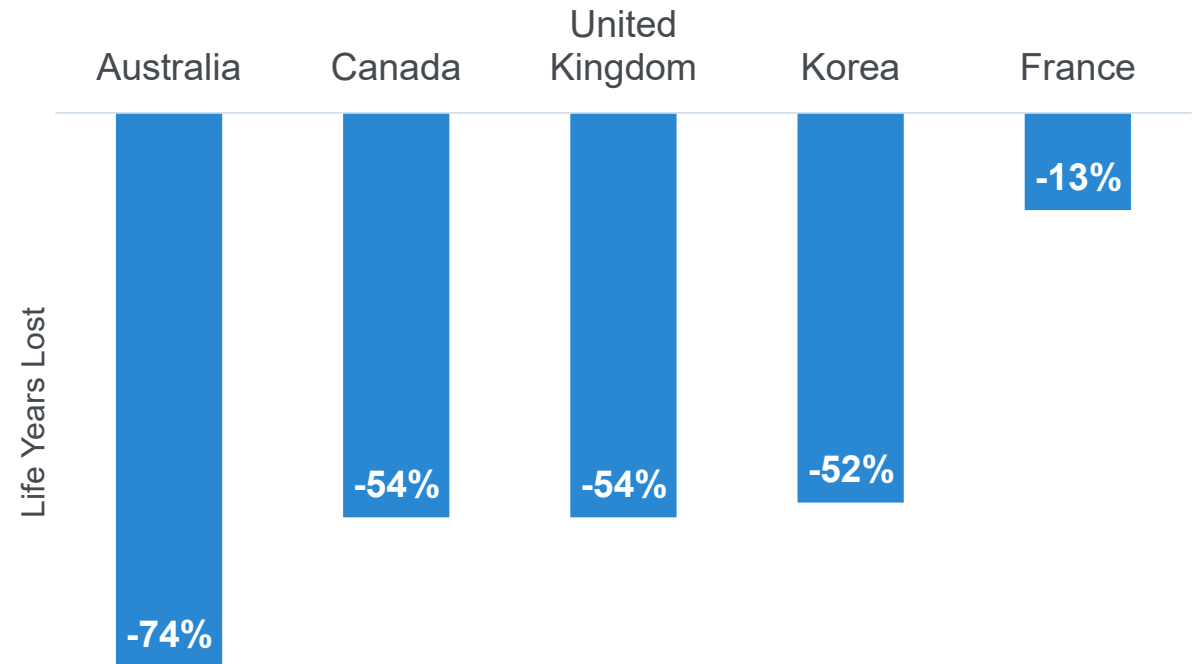
the difference in the prices

Exposes Americans to Access Restrictions and Delays

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



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



Retrospective Inflation Penalty Imposes Anti-Competitive Price Controls

Pelosi's Inflation Penalty Is Extreme

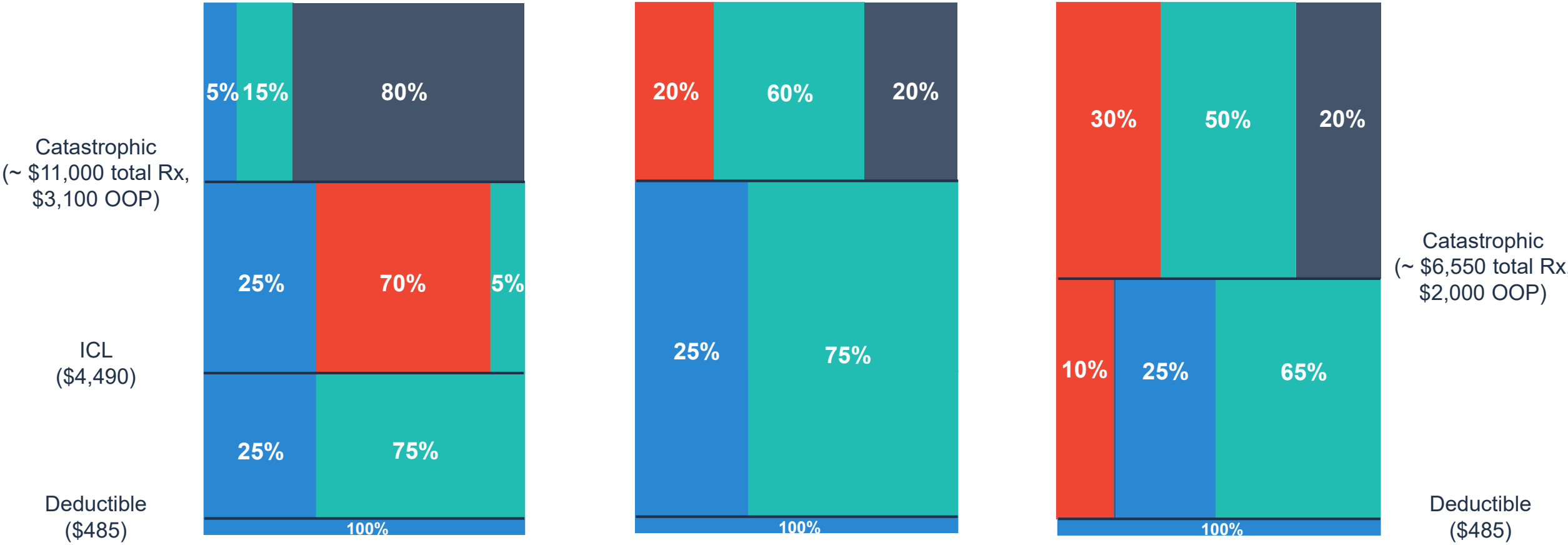
- Retroactive to 2016
- Penalty paid to the Medicare Trust Fund
- Funds would not go toward helping patients afford their medicines under Part D
- Does not address misaligned incentives in the supply chain

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

■ Beneficiary
 ■ Plan
 ■ Manufacturers
 ■ Government



Current Law

SFC Mark*

H.R. 3

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 + =

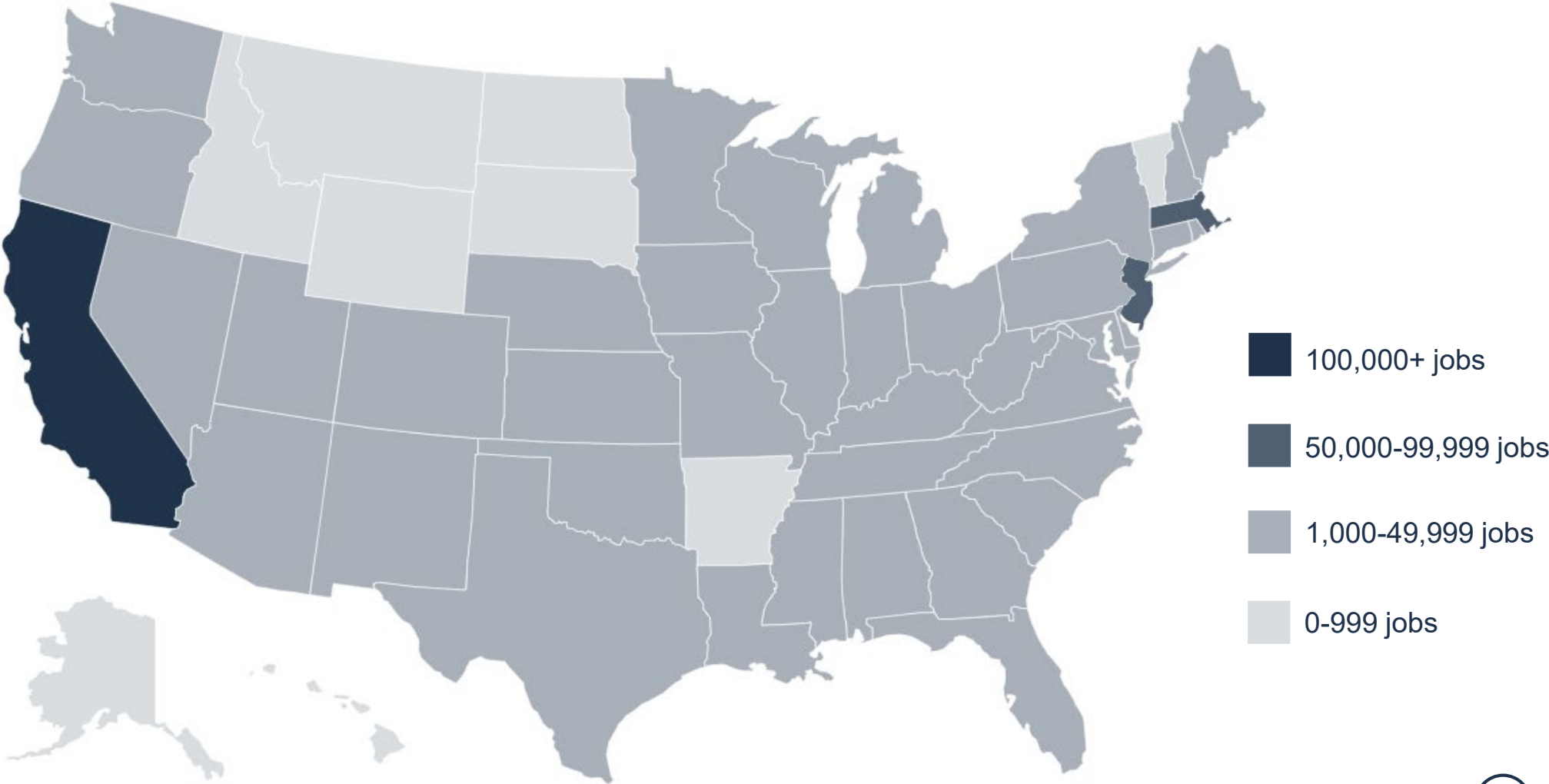
from biopharmaceutical
innovators

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

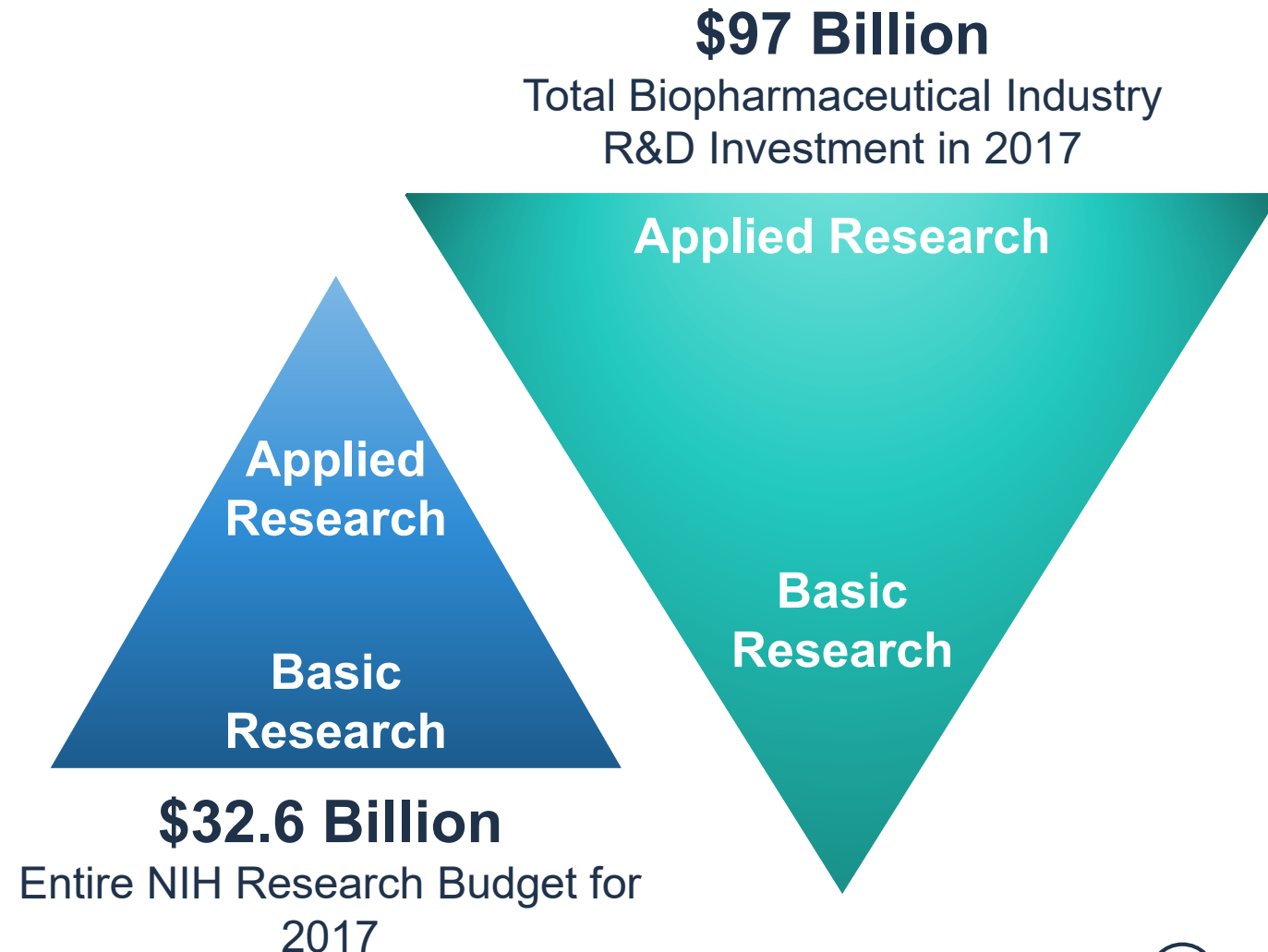
NIH Not Equipped to Fill in Gaps in Lost R&D

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



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**