PhRMA Update: A View from Washington

Julie Wagner | Senior Assistant General Counsel

November 6, 2019

We Are In a New Era of Medicine

Then

- Medicines made of chemical compounds
- Medicines treat broad diseases
- Radiation and chemotherapy to treat cancer

Now

- Medicines made from living cells
- Medicines targeted to specific patient based on genetic makeup
- Immunotherapy that harnesses a body's own immune system to fight disease
- CAR T-cell therapy
- CRISPR

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

Exciting Advancements in Biopharmaceutical Labs Across the U.S.

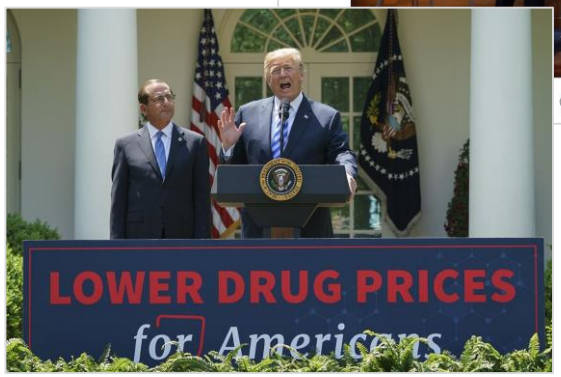
The New York Times

New York says end of AIDS epidemic is near

CBS

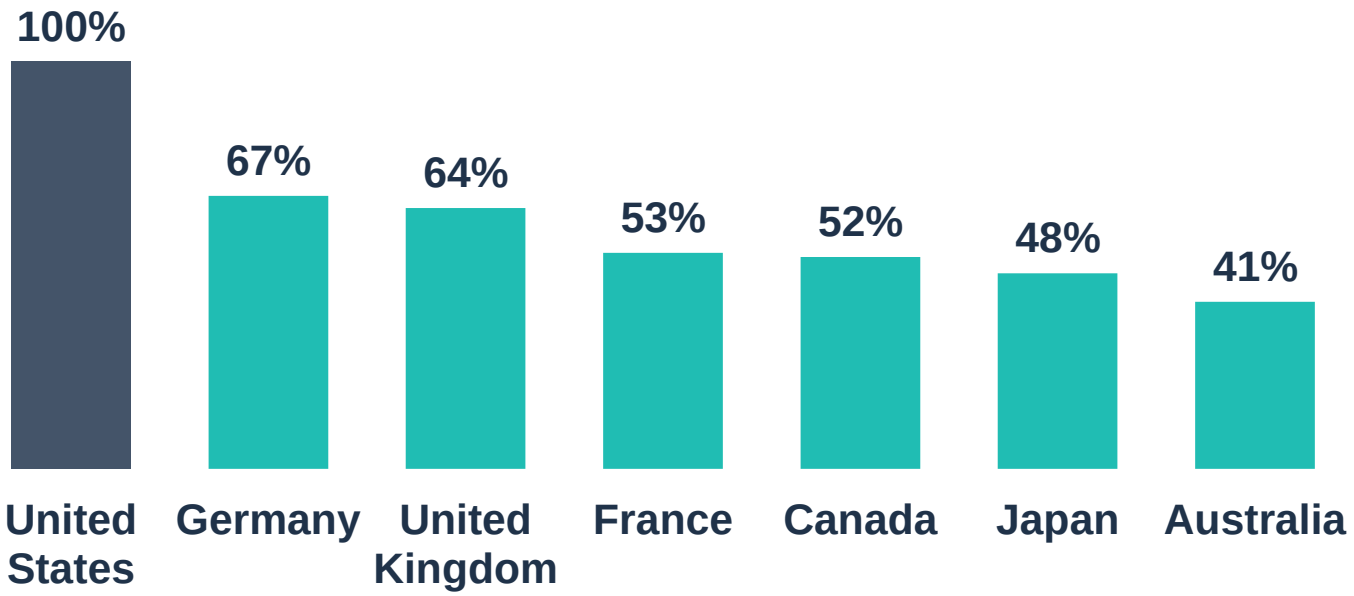
Newly approved drug being called 'game changer' for people who suffer from hemophilia

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

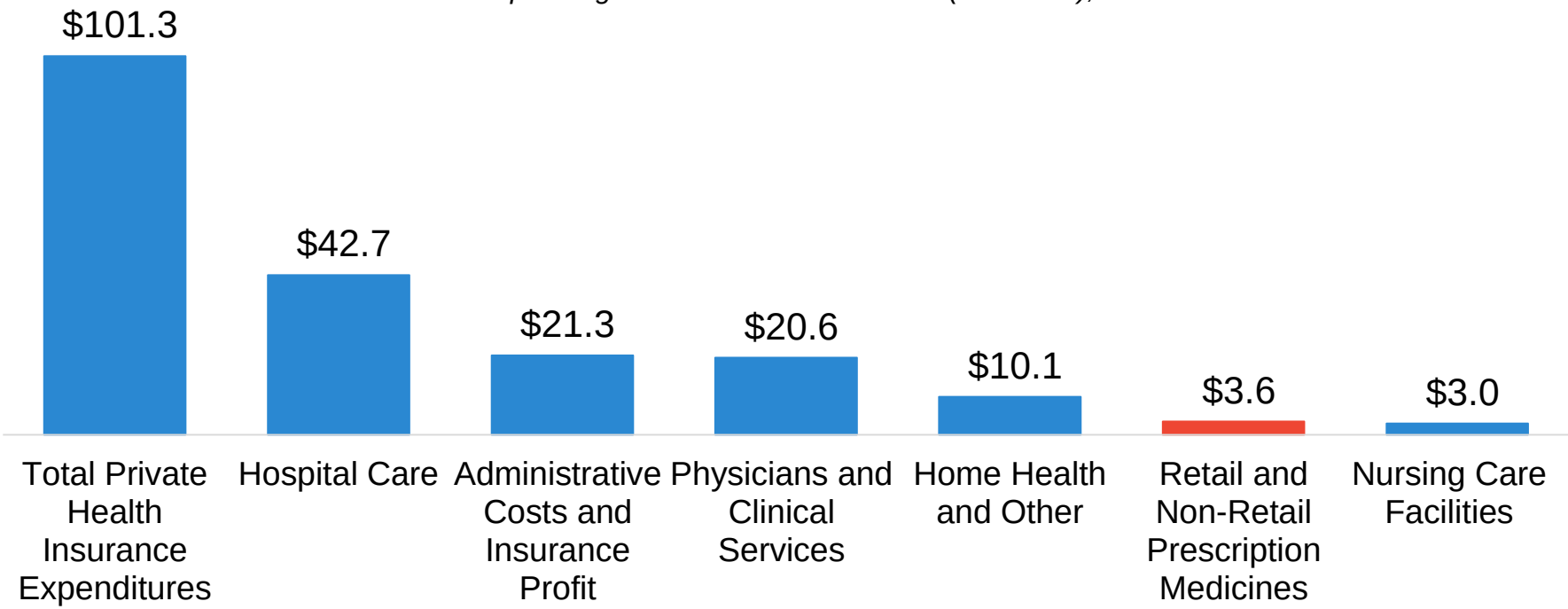
Number of New Medicines Available by Country
(of 270 global new medicines launched in the United States from 2011-2018)



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 Over Three Years (in Billions), 2016-2019



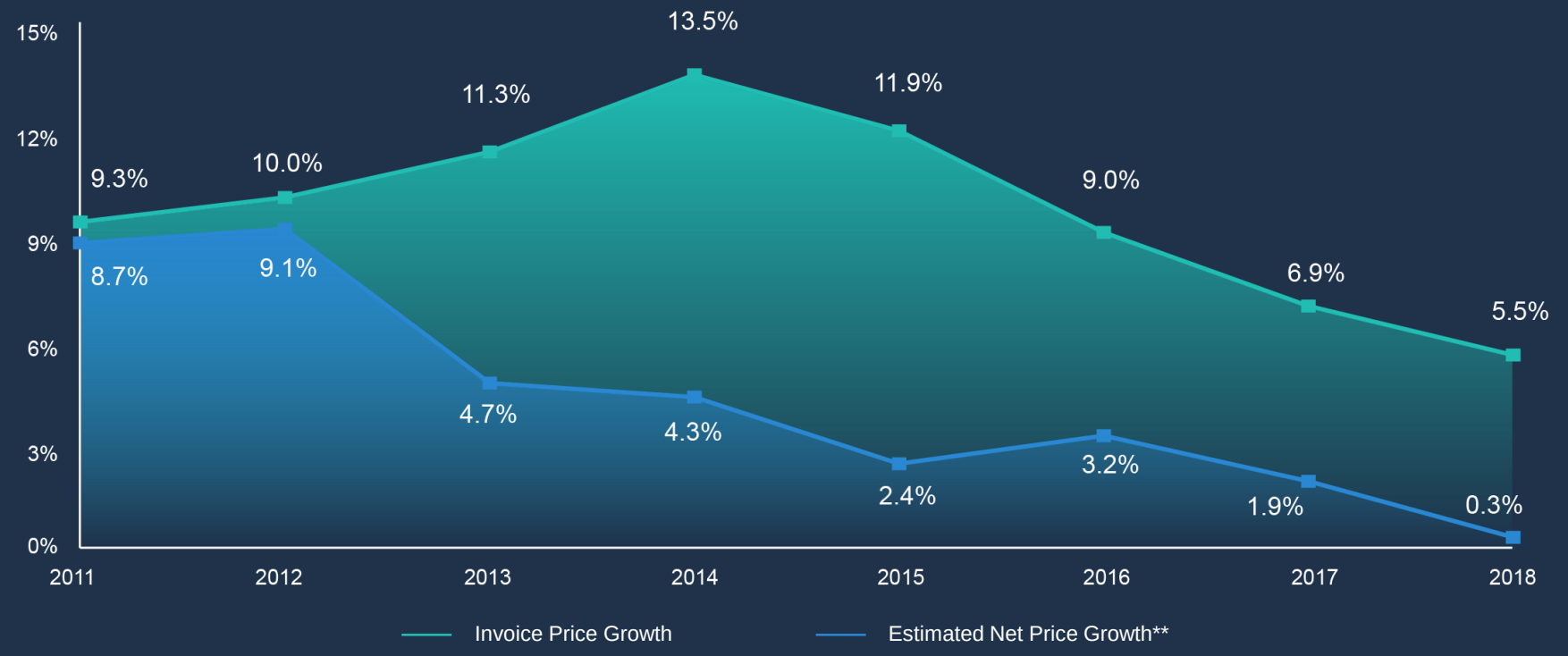
Notes: PhRMA analysis of Centers for Medicare & Medicaid Services (CMS) National health expenditure data adjusted for non-retail drug allocation based on Roehrig, C "Projections of the Prescription Drug Share of National Health Expenditures including Non-Retail." Altarum, May 2018.

Medicine Cost Growth is Declining

EXPRESS SCRIPTS®	CVS Health®	IMS Health & Quintiles are now IQVIA™
5.3% 2015	**5.0%** 2015	**8.5%** 2015
0.4% 2018	**3.3%** 2018	**4.5%** 2018

Note: IQVIA data is reflective of retail and physician-administered medicine spending.

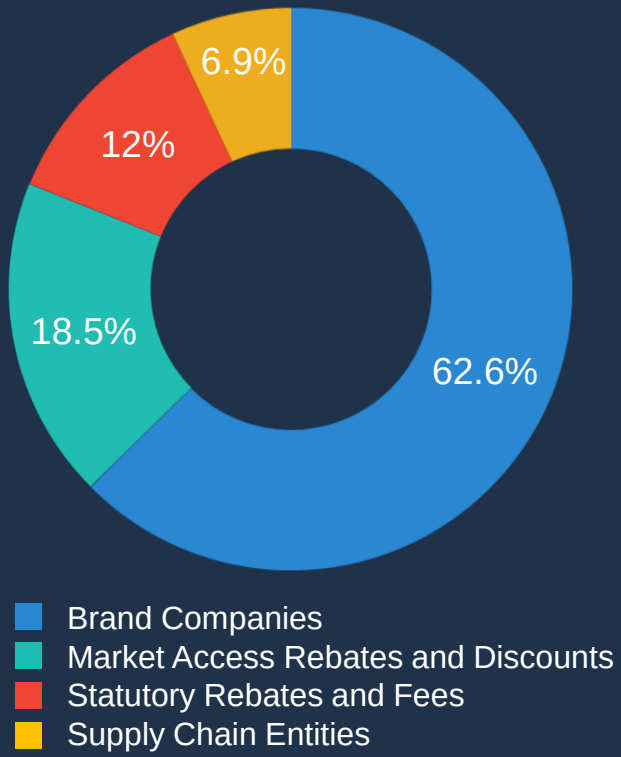
In Fact, After Discounts and Rebates, Brand Medicine Prices Grew Just 0.3% in 2018



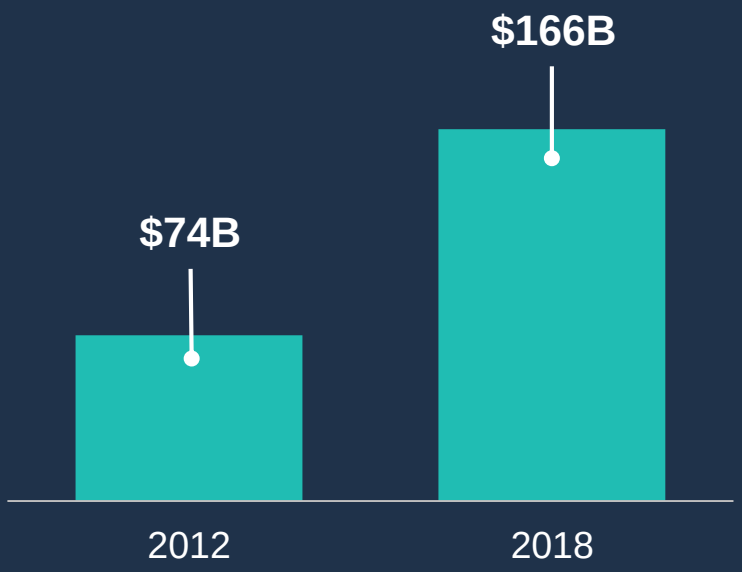
Source: IQVIA, January 2019.
*Includes protected brand medicines only (ie, brand medicines without generic versions available in the year indicated).
**Net price growth reflects impact of off-invoice rebates and discounts provided by manufacturers.

More than 1/3 of the List Price is Rebated Back to Payers, the Government and Other Stakeholders in the Supply Chain

Brand companies retain just 63% of list price spending on medicines



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



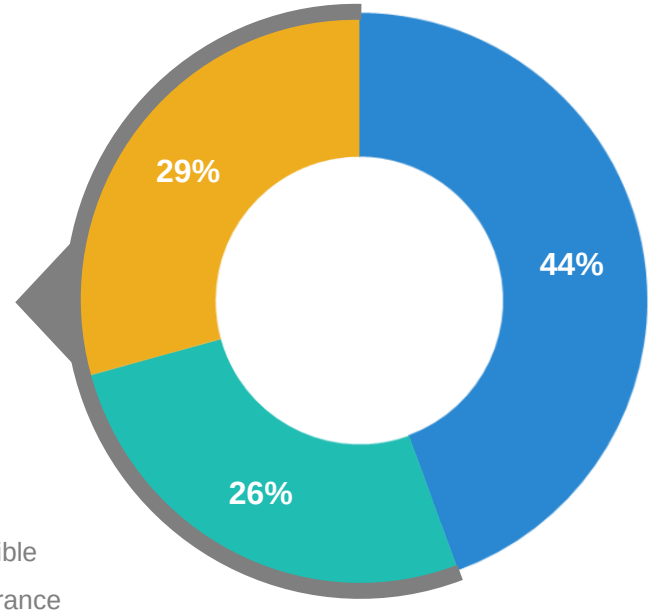
Source: Berkeley Research Group. Fein AJ; Drug Channels Institute

But it Doesn’t Feel that Way for Patients Because Too Often, Negotiated Savings do not Make their Way Directly to Patients

More than half of commercially insured patients’ out-of-pocket spending for brand medicines is based on the full list price

Cost sharing for nearly 1 in 5 brand prescriptions is based on list price

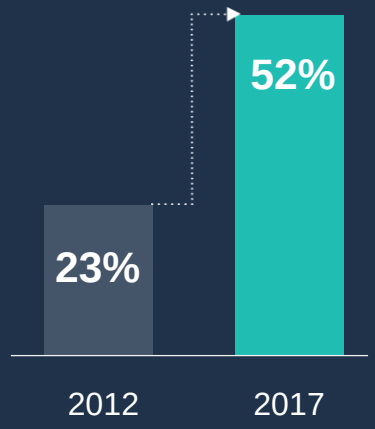
55%



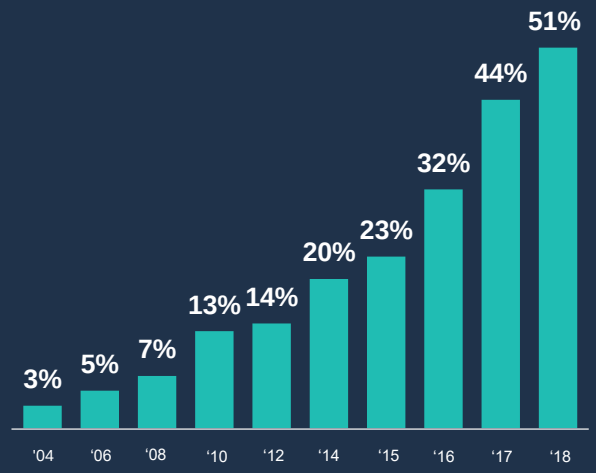
Source: IQVIA. May 2018.

Patients in the United States are Facing Rising Out-of-pocket Costs and Other Barriers to Care

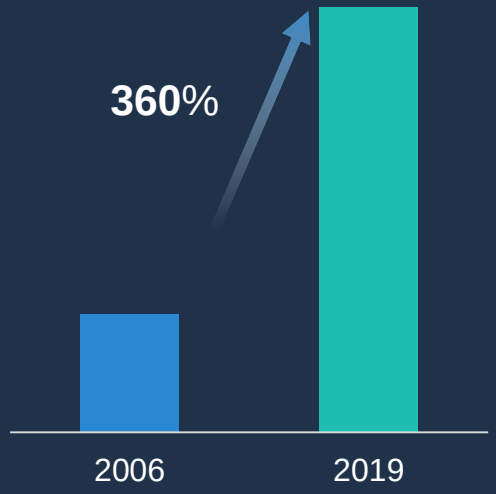
Percent of plans with deductibles on prescription drugs



The use of four or more cost-sharing tiers is becoming more common on employer plans



Patient deductibles have tripled since 2006

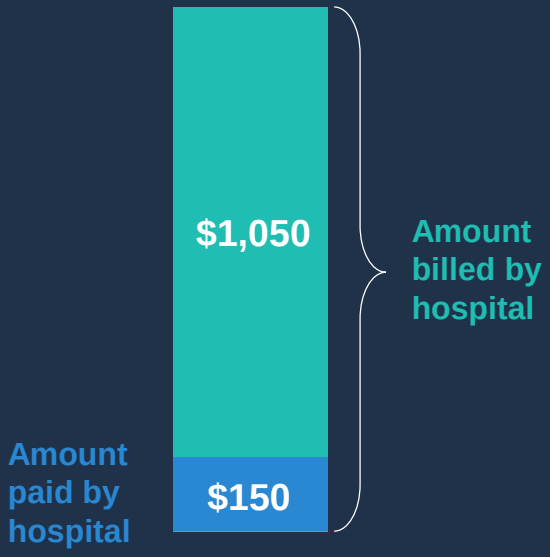


Source: PWC, KFF

Hospitals also Take Advantage of Misaligned Incentives In The Supply Chain

Nearly one in five hospitals marks up medicine prices to 700% or more of their acquisition cost

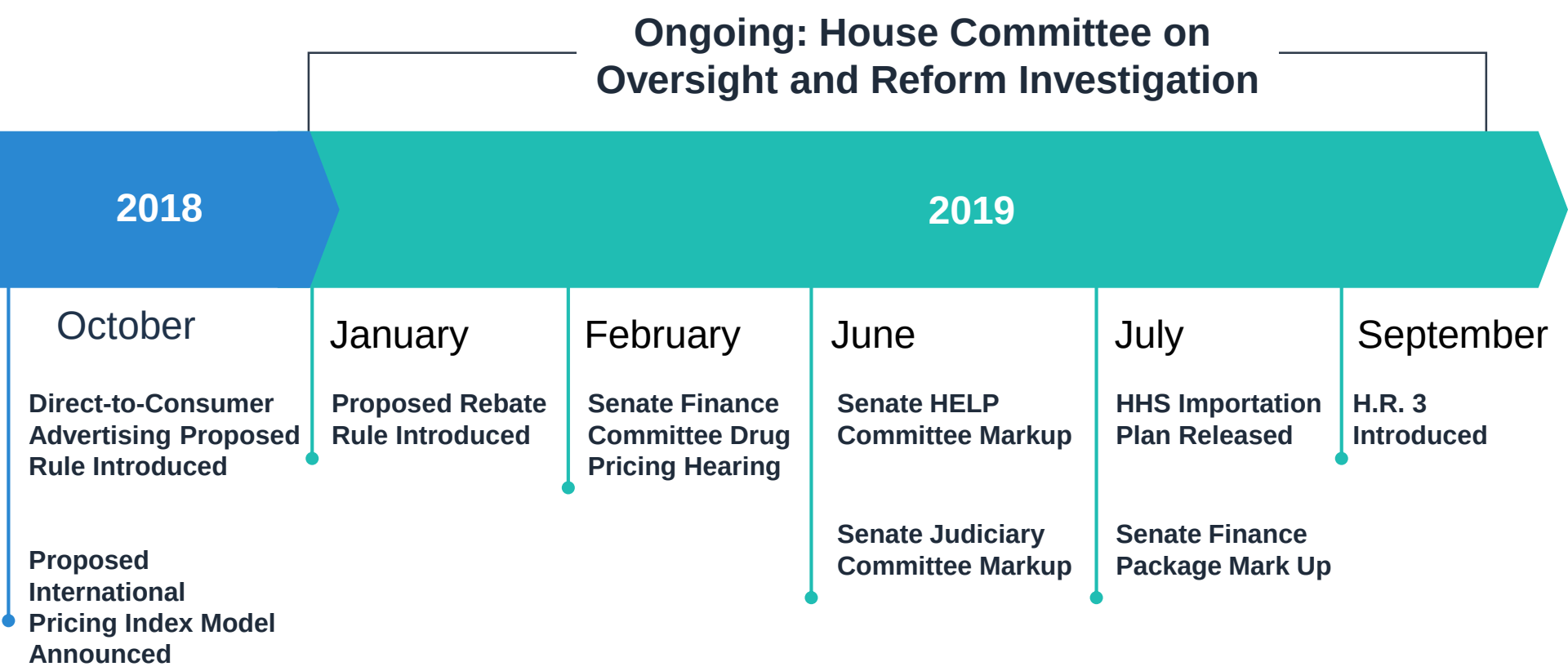
If a hospital purchased a medicine for $150, a 700% markup could result in patients being billed $1,050 for that medicine



An analysis found that 320 hospitals mark up some medicine prices at least 1000%

Source: The Moran Company. *Hospital Charges and Reimbursement for Medicines: Analysis of Cost-to Charge Ratios*. September 2018.

Increased Action on Drug Pricing in the Past Year



Rebate Reform Could Have Saved Seniors Money at the Pharmacy Counter

The HHS OIG rebate rule would have helped make sure Medicare Part D works the way insurance is supposed to work.

Outline of Proposal

- HHS proposed changes to the AKS safe harbors aimed at ensuring biopharmaceutical company discounts are used to reduce patients' out-of-pocket costs
- Today, many patient cost-sharing amounts are tied to the list price of medicines, even if insurers are charged far less
- The proposal aimed to ensure patients benefit from medicine discounts

Effects of Proposal

- **For a Part D enrollee who takes a $300 medicine where the price discount to the plan / PBM is about 30%**
  - Patient could save $100 monthly
  - Patient could see $5 monthly premium increase, although it would likely be less under the proposed CMS demo

The Dangers of Importation

To permit commercial importation of drugs from Canada, the HHS Secretary must first certify that such importation would pose no additional risk to public health/safety and would generate significant savings for American consumers.

No secretary has done so.

Foreign governments will not and cannot ensure the prescription drugs entering the United States from abroad are safe and effective.

Counterfeiters are sophisticated in large-scale illegal manufacturing of fake products that look like the real drug, posing significant health and safety risk to patients.

Importation is not an effective approach to reducing drug costs.

Senate Finance Package Puts Government Ahead of Patients

Redesigns Medicare Part D

- 20% manufacturer liability on medicines in catastrophic targets new innovative and critically needed medicines
- According to Avalere, nearly a 70% increase in industry liability following 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 industry ($30B 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

Avalere, "SFC Drug Pricing Proposal Would Significantly Increase Medicare Part D Manufacturer Discount Liability for Some Therapeutic Areas," October 7, 2019

Speaker Pelosi's Proposal Is Unprecedented

Price Setting

- Sets prices each year for 25 to 250 medicines, plus insulins
- Applies government price setting to Medicare, and requires resulting price be offered in commercial 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 in Medicare Part B and Part D
- 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% liability on medicines in catastrophic phase
- 10% liability on medicines before catastrophic phase
- Targets innovative therapies for new mandatory discounts

H.R. 3 Raises Serious Constitutional Concerns

H.R. 3 Would Amount to an Unconstitutional Taking of Patent

- It would categorically take for the government an essential patent right – the right to set prices consistent with the grant of the patent.
- The bill gives HHS unbridled discretion to force companies to agree to prices even lower than the price cap (AIM), with the threat of a steep penalty.
- It forces companies to provide these prices to most payors, not just Medicare.
- Biopharmaceutical companies have invested billions of dollars in developing medicines in reliance on the strength of existing patent laws, which give manufacturers the lawful right to set prices through negotiation at levels necessary to recoup their investment.

H.R. 3 Would Violate the Eighth Amendment's Protection Against "Excessive Fines"

- Taxing companies on up to 95% of a medicine's sales is significantly disproportionate to the offense of failing to reach agreement on a steeply discounted price that will apply to nearly all payors nationwide.
- While the Excessive Fines Clause usually applies to criminal fines, it also reaches civil fines designed at least in part to punish, and any fine must be proportional to the offense that it is designed to punish.

There Are Ways to Mend 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%

Correcting 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

Thank You

Resource Slides

Administrative Action on Direct-to-Consumer Advertising

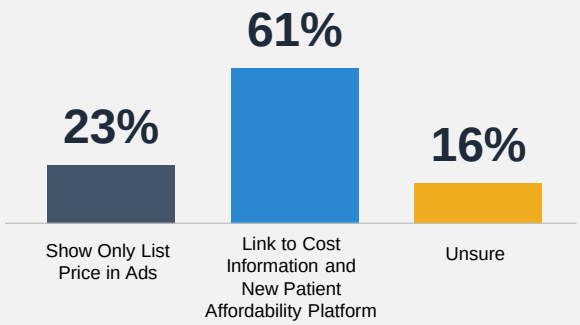
Administration Rule

- Required TV advertisements for medicines to include current list price for medicines
- HHS would have included companies that failed to comply on a list and companies would have been exposed to liability for false and misleading advertising under the Lanham Act

PhRMA Approach

- PhRMA member companies voluntarily direct patients to information about their medicine costs – including list price and average out-of-pocket costs – in DTC advertisements
- PhRMA created MAT.org, a patient affordability platform that provides cost and financial assistance information

By **3:1** Margin, Voters Prefer Our Approach to Only Including List Prices in DTC TV Ads



IPI Model Would Replace Market Competition With Government-Set Prices

Proposal Aims to Cut Part B Payments an Average of 30% Over Five Years, Starting in 2020

Outline of Proposal

- Mandatory demo for half of all Part B drug spending plus impact on ASP
- Providers must purchase medicines from a vendor
- Government pays vendors based on international reference price index
- Pays providers a flat fee

Effects of Proposal

- Imports foreign price controls that may ultimately restrict patient access
- Disincentivizes lifesaving research and development
  - $50 billion over eight years – much greater if expanded
- Savings primarily flow to plans

The IPI Model Would Exceed CMMI's Authority

The Goal of CMMI:

- Established by the Affordable Care Act to test new models for paying for and delivering health care in the Medicare, Medicaid and CHIP programs
- If model improves quality of care without increasing Medicare spending, CMMI has authority to expand model
- To expand models, statute requires rulemaking, but to continue using waiver authority, Congressional action required

The IPI Model Goes Too Far:

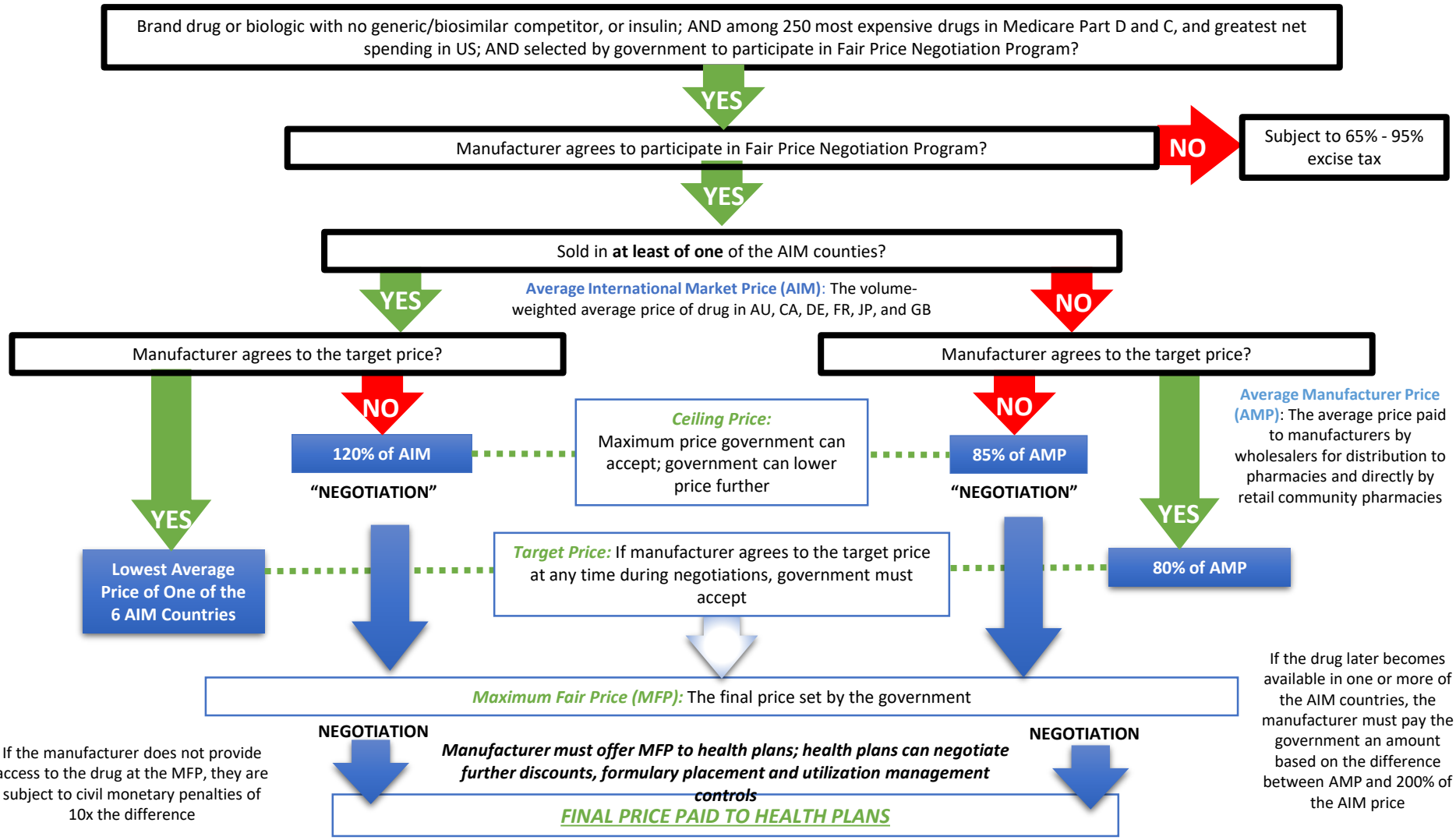
- Not a True "Test": National-scale overhaul of Medicare policy
- Violates Separation of Powers: Executive branch would be effectively canceling the effect of existing legislation via broad use of waivers
- Conflicts with U.S. Patent Law: Effectively imports foreign regimes for patent protection into the U.S. and would result in the unauthorized, de facto weakening of U.S. patent protection

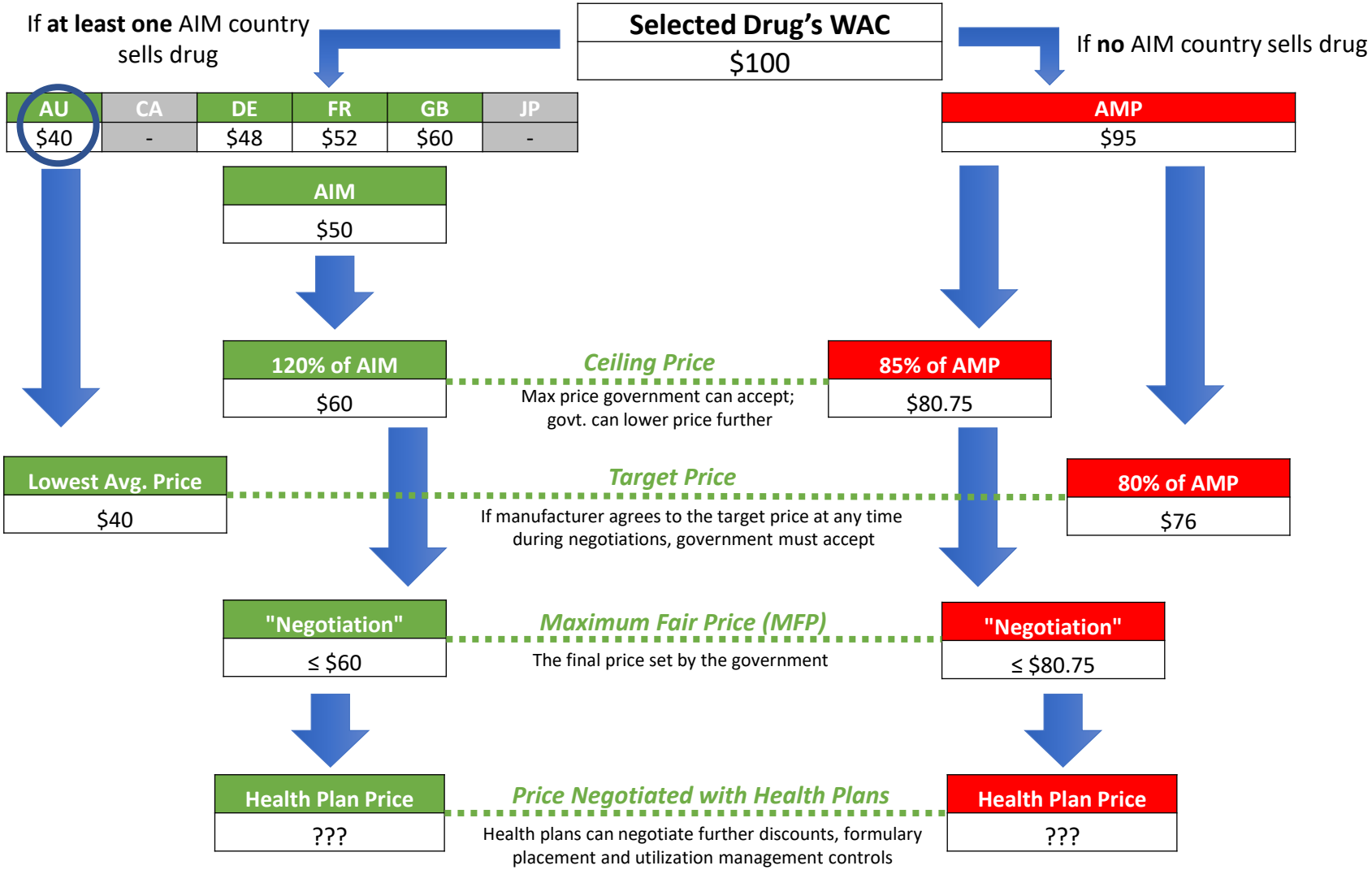
HHS "Safe Importation Action Plan" Pathway 1

- HHS will issue a Notice of Proposed Rulemaking (i.e. a "Proposed Rule") under section 804 of the FDCA to authorize "demonstration projects" to allow importation of drugs from Canada.
- The NPRM would contain the following proposals, among others:
  - Condition certification of section 804 on the ability to limit the program to demonstration projects
  - Allow States, wholesalers, or pharmacists to submit applications to HHS demonstrating how they will comply with statutory safety and cost conditions
  - Condition the demonstration on "additional safety requirements"
- The NPRM would make clear that the provisions of Pathway 1 are not severable. If any provision of Pathway 1 in final rulemaking is invalidated, the entirety of Pathway 1 should be invalidated.

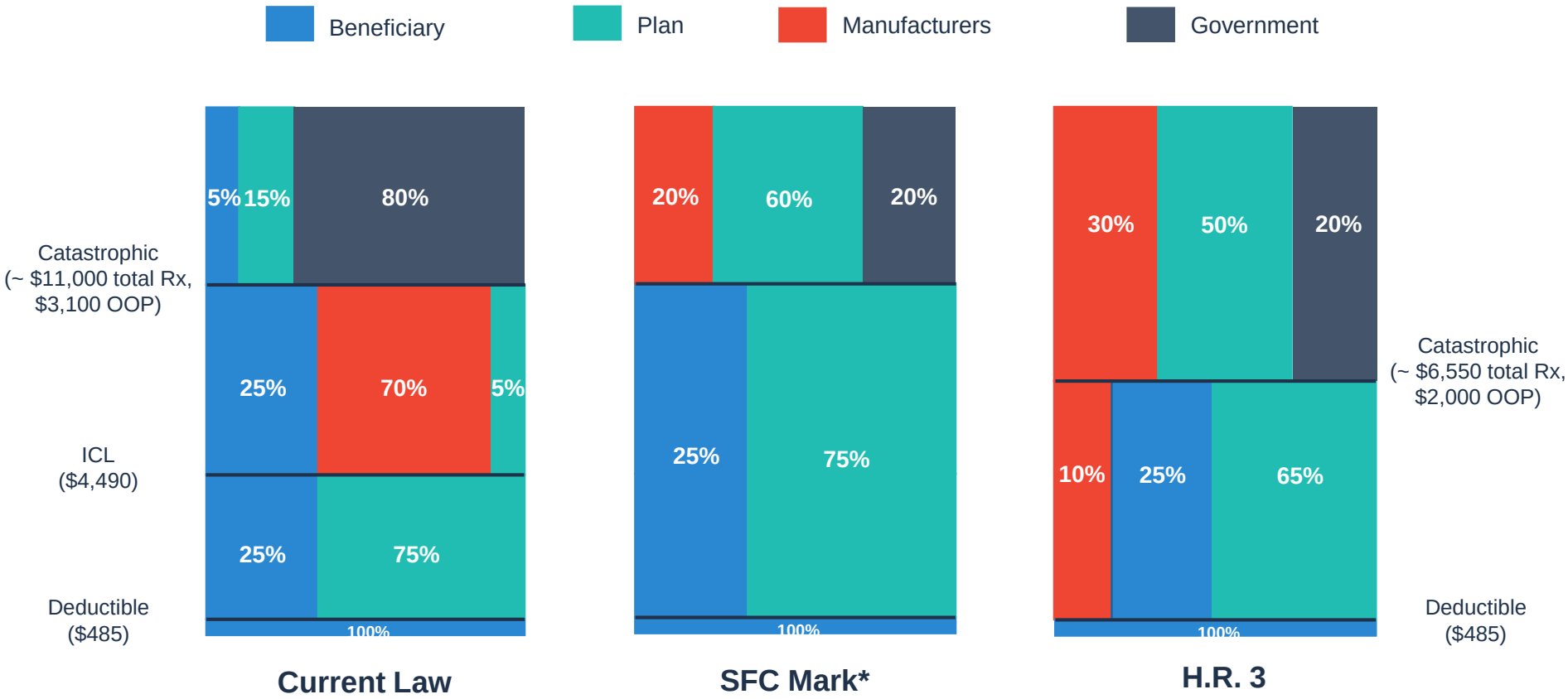
HHS “Safe Importation Action Plan” Pathway 2

- FDA would authorize manufacturers to assign a different NDC code to “foreign versions” of an FDA-approved drug.
  - FDA hopes that manufacturers would use this pathway to import lower cost, foreign versions of their FDA-approved drugs.
- FDA may seek comments on whether the pathway could be more effectively implemented under section 804.
- FDA intends to issue guidance to implement Pathway 2.


Brand drug or biologic with no generic/biosimilar competitor, or insulin; AND among 250 most expensive drugs in Medicare Part D and C, and greatest net spending in US; AND selected by government to participate in Fair Price Negotiation Program?
YES
Manufacturer agrees to participate in Fair Price Negotiation Program?
NO
Subject to 65% - 95% excise tax
YES
Sold in at least of one of the AIM counties?
YES
NO
Average International Market Price (AIM): The volume-weighted average price of drug in AU, CA, DE, FR, JP, and GB
Manufacturer agrees to the target price?
Manufacturer agrees to the target price?
NO
NO
120% of AIM
"NEGOTIATION"
Ceiling Price: Maximum price government can accept; government can lower price further
85% of AMP
"NEGOTIATION"
Average Manufacturer Price (AMP): The average price paid to manufacturers by wholesalers for distribution to pharmacies and directly by retail community pharmacies
YES
YES
Lowest Average Price of One of the 6 AIM Countries
Target Price: If manufacturer agrees to the target price at any time during negotiations, government must accept
80% of AMP
Maximum Fair Price (MFP): The final price set by the government
NEGOTIATION
NEGOTIATION
If the manufacturer does not provide access to the drug at the MFP, they are subject to civil monetary penalties of 10x the difference
Manufacturer must offer MFP to health plans; health plans can negotiate further discounts, formulary placement and utilization management controls
FINAL PRICE PAID TO HEALTH PLANS
If the drug later becomes available in one or more of the AIM countries, the manufacturer must pay the government an amount based on the difference between AMP and 200% of the AIM price


If at least one AIM country sells drug
Selected Drug's WAC
$100
If no AIM country sells drug
AU
CA
DE
FR
GB
JP
$40
-
$48
$52
$60
-
AMP
$95
AIM
$50
120% of AIM
$60
Ceiling Price
Max price government can accept; govt. can lower price further
85% of AMP
$80.75
Lowest Avg. Price
$40
Target Price
If manufacturer agrees to the target price at any time during negotiations, government must accept
80% of AMP
$76
"Negotiation"
≤ $60
Maximum Fair Price (MFP)
The final price set by the government
"Negotiation"
≤ $80.75
Health Plan Price
???
Price Negotiated with Health Plans
Health plans can negotiate further discounts, formulary placement and utilization management controls
Health Plan Price
???

Significant Redesign of Medicare Part D Program



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

* Reflects full phase-in of plan liability in catastrophic phase

TennCare 1115 Waiver Amendment Key Components

"Block Grant" Funding

- Creates new federal allotment funding structure
- **"Outpatient drugs" are excluded – could be included later**
- Would adjust based on growth projections and enrollment

Closed Formulary and Other Flexibilities

- **"Commercial-style closed formulary" with at least one drug per class**
- **Flexibility to exclude accelerated approval drugs until they meet price or cost-effectiveness thresholds**
  - Thresholds/cost effectiveness method unstated in the proposal
- Exceptions from federal oversight requirements

Shared Savings

- TN can "share" in 50% of unused federal allotment dollars
- No state match required to keep the funds
- No defined restrictions on use