



IHEA Pre-Congress Workshop. 9<sup>TH</sup> JULY 2023

Anticipating the Potential Impacts of the Inflation Reduction Act

*What can be Learnt from Global Experience on the Impact of Price Regulation on Patient Access and Equity of Access?*



This material was produced with financial support from PhRMA. The views expressed in these presentations are those of the speakers and do not necessarily reflect PhRMA's views or positions. This material does not constitute legal advice – it represents the speakers' best read of the **Inflation Reduction Act of 2022, Public Law 117-169**, and the subsequent CMS memos (Solicitation of Comments & Final Guidance) as of July 2023.





***PROF GRAHAM COOKSON***

Chief Executive  
OHE



***DR AMANDA COLE***

Associate Director  
OHE

A black and white photograph of various medical supplies scattered on a dark, textured surface. In the foreground, there are several blister packs containing white and dark pills, a white plastic pill bottle, a thermometer, a stethoscope, and a measuring tape. The background is dark and out of focus.

OHE

# Welcome

Prof Graham Cookson, Chief Executive, OHE

## AGENDA

14.00 - 14.05	<b>Welcome</b>	Prof Graham Cookson
14.05 - 14.15	<b>Introduction</b> to the US healthcare system and IRA policy context	Prof Graham Cookson
14.15 - 14.35	<b>Explaining the IRA:</b> Overview of the three key provisions of the IRA relating to prescription drug pricing and access	Dr Amanda Cole
14.35 - 14.55	<b>Roundtable Discussion:</b>  <b>1. What are some implications of introducing price-setting into the otherwise market-based insurance system that underpins the Medicare drug benefit?</b>	
14.55 - 15.00	<i>Comfort Break</i>	
15.00 - 15.15	<b>Roundtable Discussion:</b>  <b>2. What can the US learn from global experience with price regulation?</b>	
15.15 - 15.35	<b>Insights on Impact:</b> How will the innovation landscape be impacted, and what are the implications for equity?	Dr Amanda Cole
15.35 - 15.55	<b>Roundtable Discussion:</b>  <b>3. If the US adopted price controls at launch for all drugs, what might the impact be on global innovation?</b>	
15.55 - 16.00	Closing Remarks	Prof Graham Cookson





The IRA brings about substantial changes to the way some medicines are reimbursed

# What are the aims of this workshop?



To provide an accessible explanation of the IRA



To consider the changing incentives for innovation.



To discuss and debate patient access and equity impact, both within the US and internationally.

**OHE**

MODULE 0

## Introduction to the US Healthcare System

**PRMA**

**OHE**

MODULE 1

## Drug selection and price setting process

**PRMA**

**OHE**

**OHE**

MODULE 2

## Inflation Rebate Provisions

**PRMA**

**OHE**

MODULE 3

## Medicare Part D Benefit Redesign and Other Provisions

**PRMA**



You can find out more on OHE's dedicated platform

<https://www.ohcourseinflationreductionact.com/>

For interactive questions please use  
your phones to scan the QR code

Or you can access via [www.slido.com](https://www.slido.com) with event [#3358934](#)

Or at this link: [IHEA pre-congress IRA workshop \(sli.do\)](#)



Who's in the room?



**Where do you live / work?**

Multiple choice: US; other North America; South America; Africa; Asia; Europe; Australia

OHE

Polling  
question

# Current understanding of the IRA and its provisions



How confident are you that you could describe all  
three key parts of the IRA that impact pharmaceutical  
prices and spending?

very confident / somewhat confident / not confident

OHE

Polling  
question



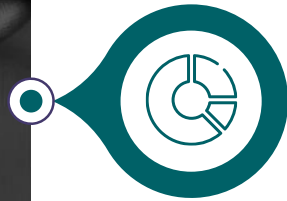
# Introduction to US Healthcare

Prof Graham Cookson, Chief Executive, OHE

# The US has a predominantly private, market-based health care system.

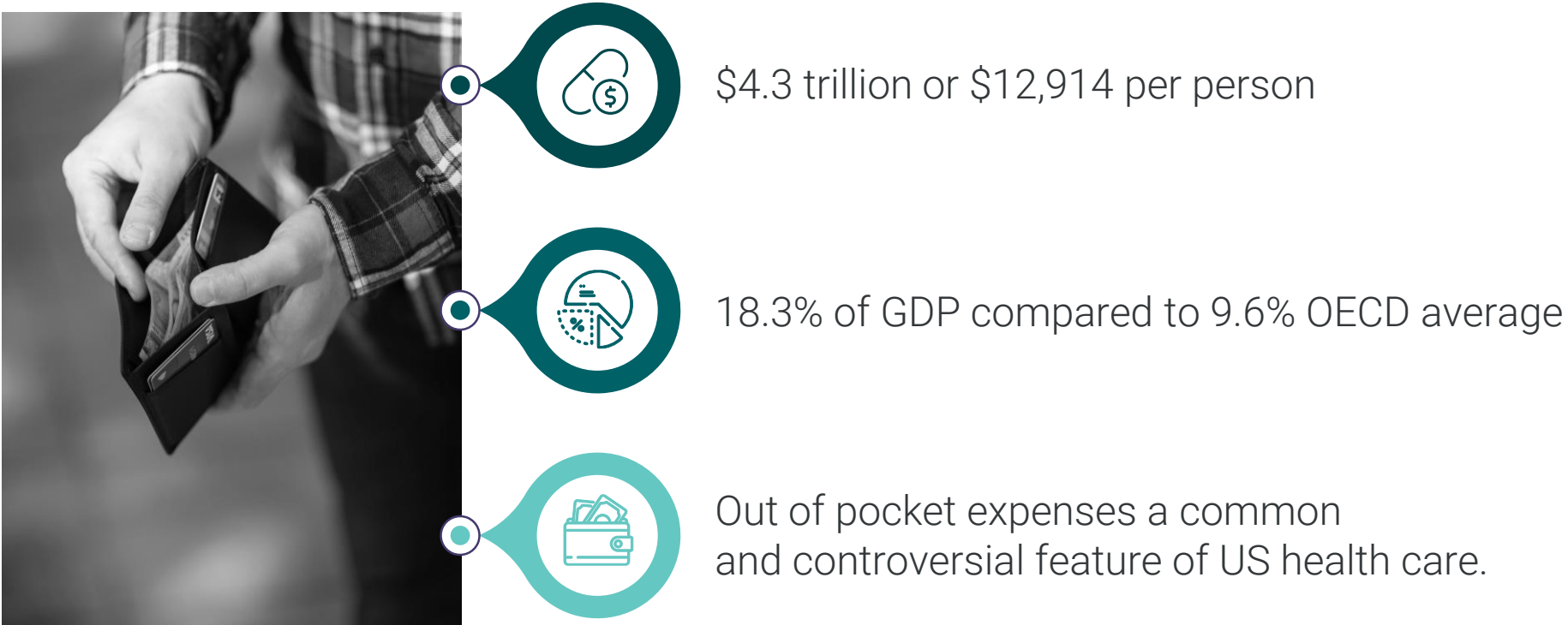


Largely a market-based system through private plans

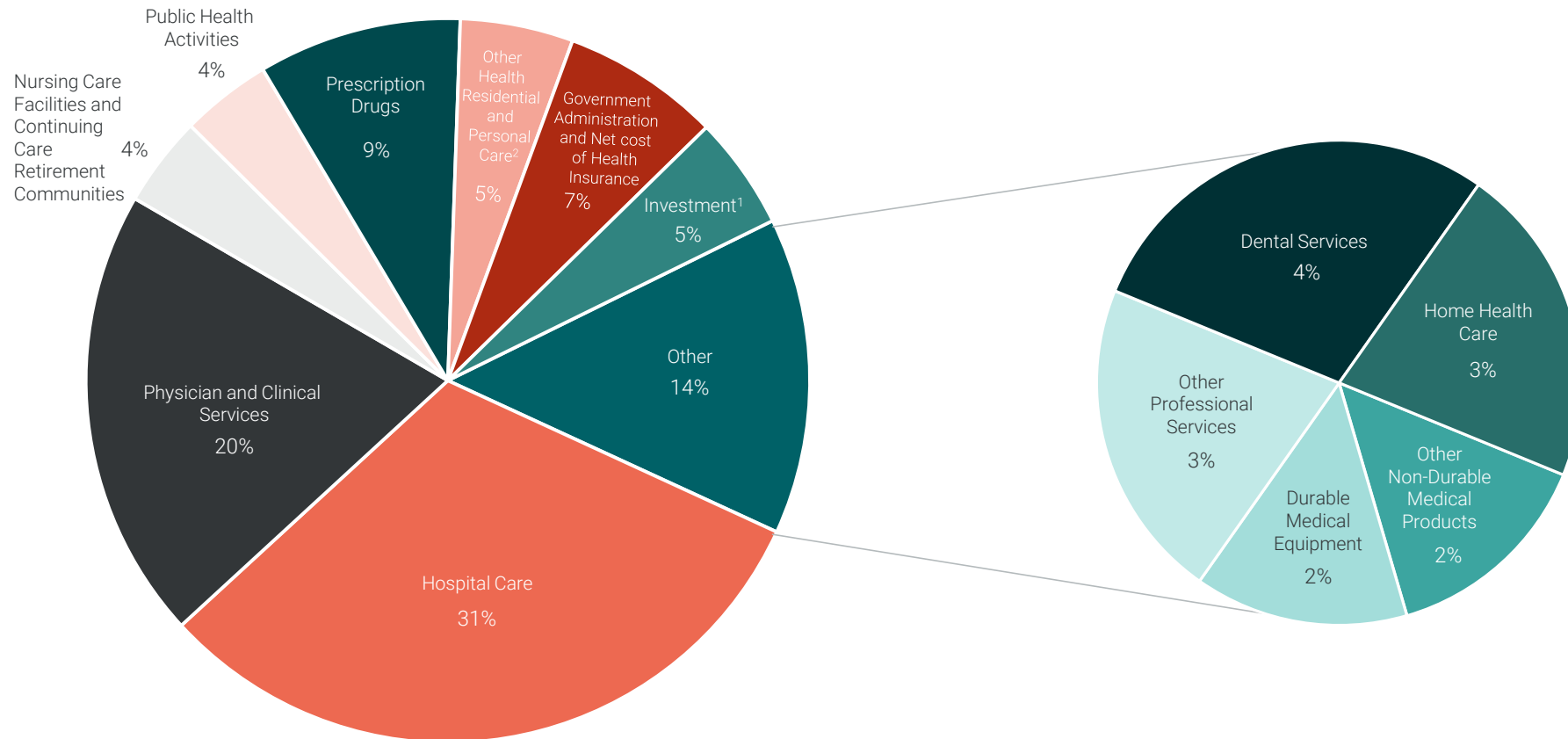


Complex mix of public and private, for-profit, and non-profit **insurers** and health care **providers**

# Health care spending in the US is high.



# But pharmaceuticals aren't the driving factor.

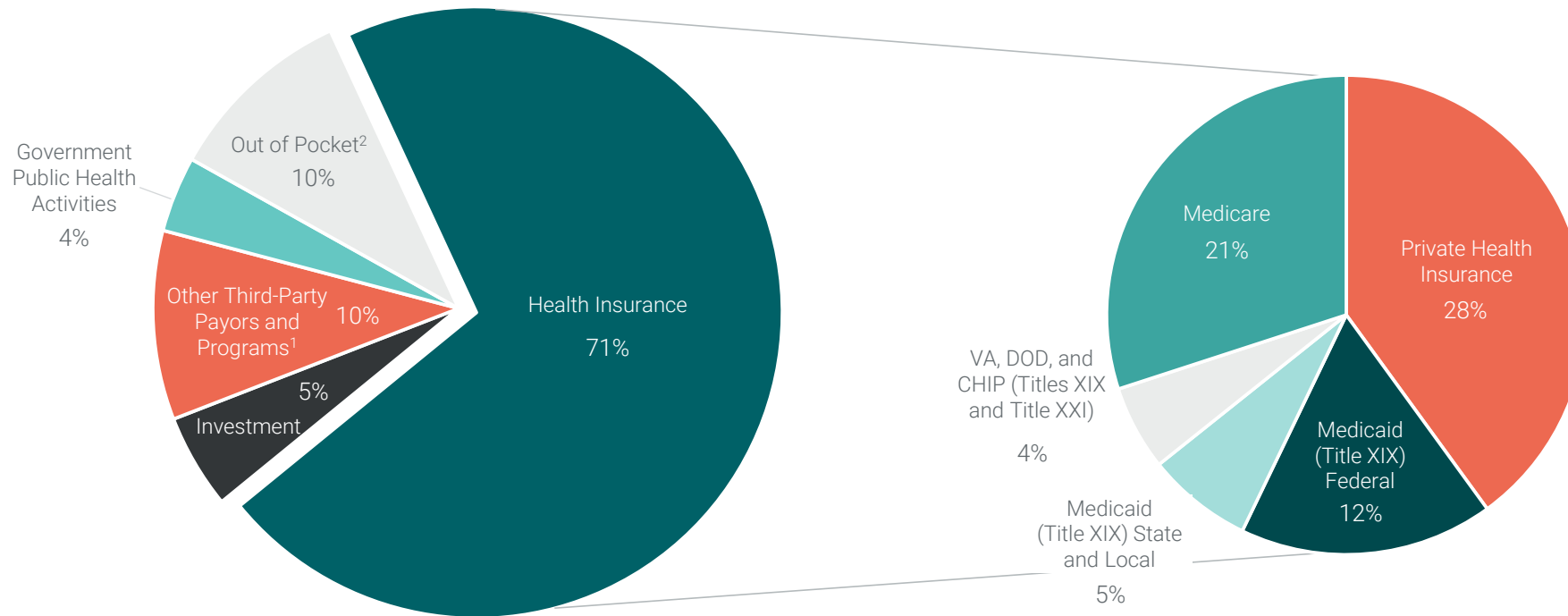


<sup>1</sup> Includes Noncommercial Research and Structures and Equipment.

<sup>2</sup> Includes expenditures for residential care facilities, ambulance providers, medical care delivered in non-traditional settings (such as community centers, senior citizens centers, schools, and military field stations), and expenditures for Home and Community Waiver programs under Medicaid. Note: Sum of pieces may not equal 100% due to rounding.

SOURCE: Centers for Medicare & Medicaid Services, Office of the Actuary, National Health Statistics Group.

# Most expenditure is covered by health insurance, and 42% is government funded



<sup>1</sup> Includes worksite health care, other private revenues, Indian Health Service, workers' compensation, general assistance, maternal and child health, vocational rehabilitation, Substance Abuse and Mental Health Services Administration, school health, and other federal and state and local programs.

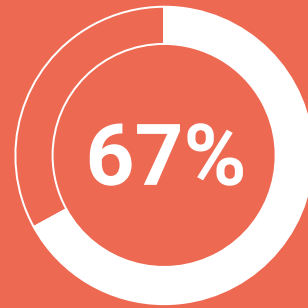
<sup>2</sup> Includes co-payments, deductibles, and any amounts not covered by health insurance. Note: Sum of pieces may not equal 100% due to rounding.

SOURCE: Centers for Medicare & Medicaid Services, Office of the Actuary, National Health Statistics Group.

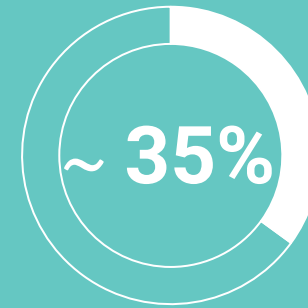
# The US health care market is a mix of public and private sources of coverage



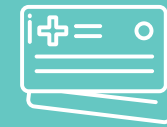
92%  
of the population  
has coverage



67%  
of population with  
insurance is covered  
through private insurance



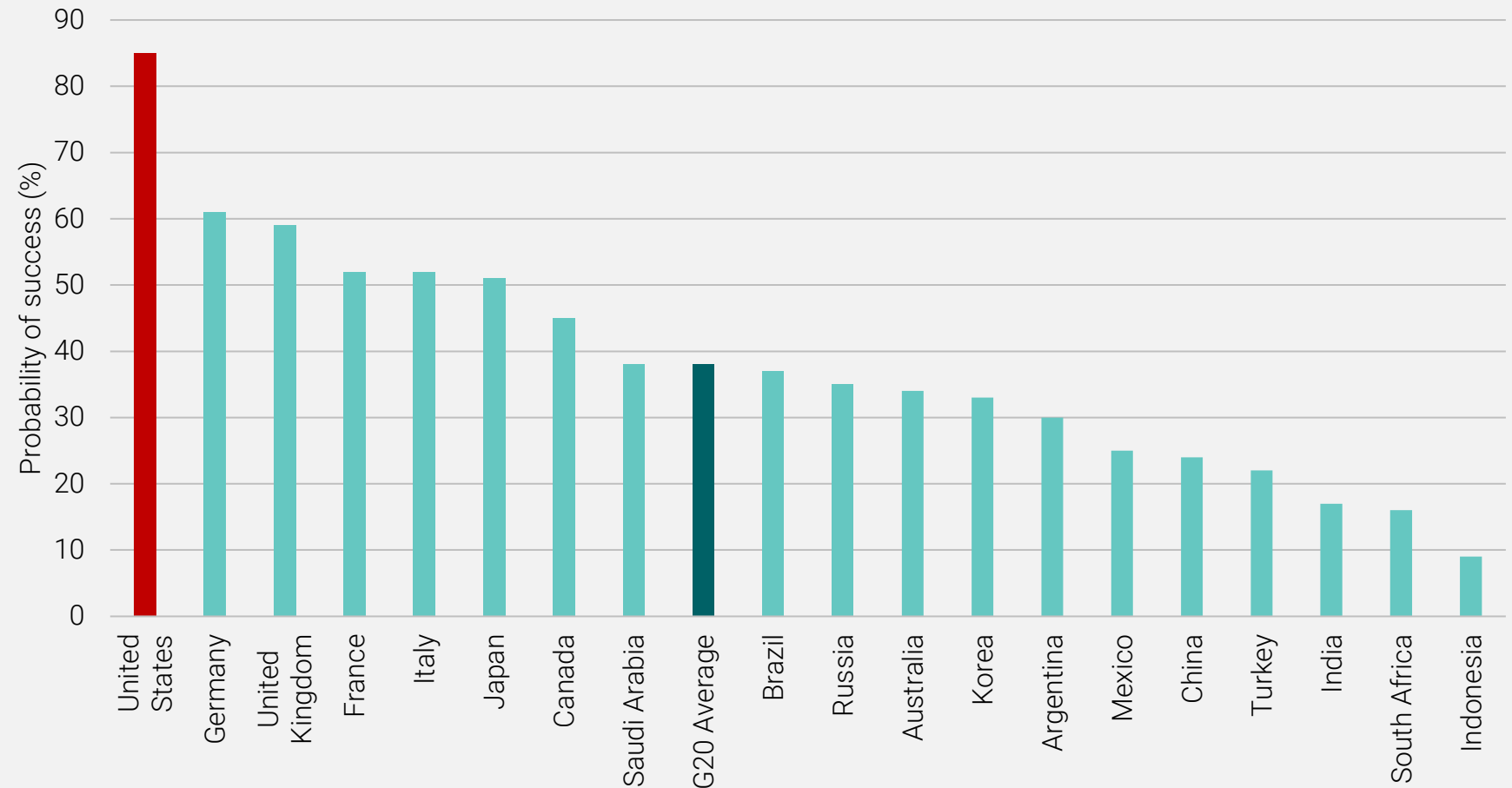
~ 35%  
covered through  
government programs  
(e.g., Medicare, Medicaid,  
and Veterans Health Affairs)



# The US currently has **broader** and **faster** access to medicines



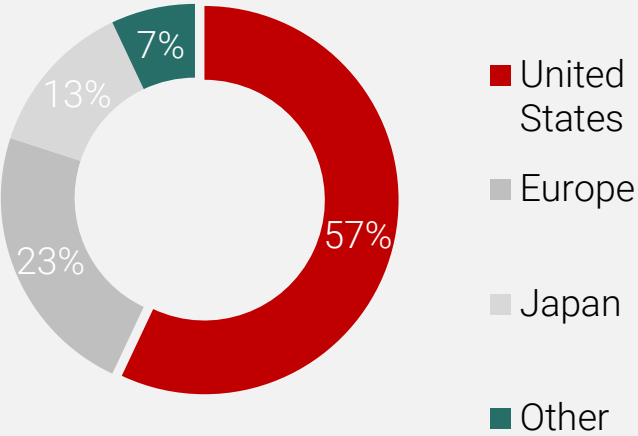
Percentage of new medicines launched by G20 country (of all 460 new medicines launched from 2012 to end of 2021)



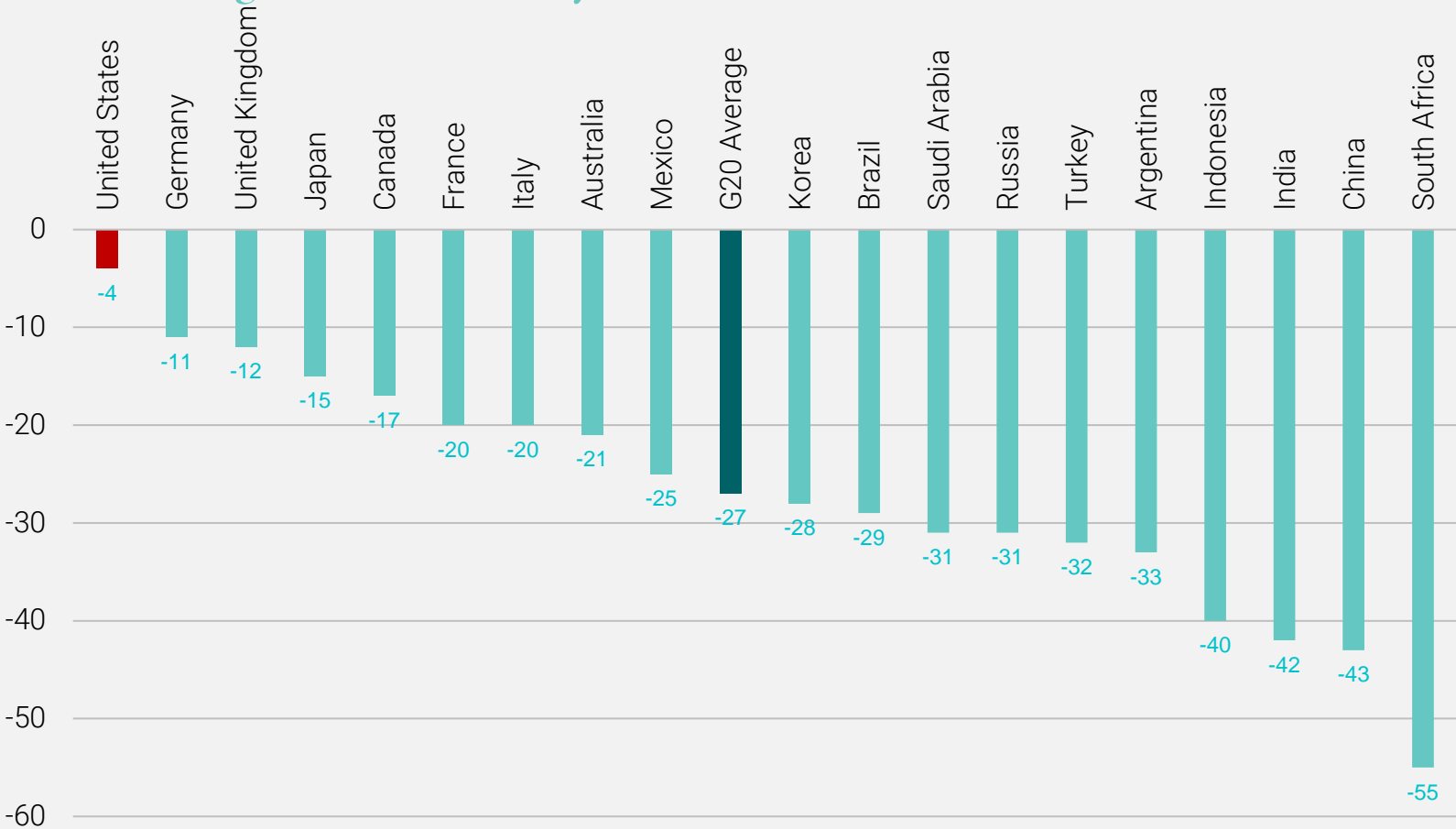
# The US currently has broader and faster access to medicines



Global first launch of new medicines by country (2012 to 2021)



Average months of delay in launch of new medicines (2012-2021)



# Government's role in health care is more limited in the US vs. other countries



- Federal spending is less than a third of total spending
- Largest funding allocated to Medicare and Medicaid
- Negligible role in directly owning and supplying providers
- Largest role is in administration and regulation of federal health care programs
- Facilitated access to and covered the cost of COVID-19 testing, vaccines, and therapeutics during Public Health Emergency

# Medicare covers mainly older people



## ***Part A***

Inpatient/hospital coverage,  
including inpatient medicines

## ***Part B***

Outpatient/medical coverage;  
prescription medicines  
administered by a provider  
(20% patient co-insurance)

## ***Part C***

(Medicare Advantage)

## ***Part D***

Retail prescription medicines  
(patient cost sharing varies)

# The Inflation Reduction Act (IRA) introduces drug price setting into Medicare for the first time



Companies generally are free to set list prices, and negotiate net prices with plans, which can vary.



In Part D, Pharmacy Benefit Managers control formularies and negotiate discounts/rebates.



Before the IRA, Medicare didn't directly set prices for medicines covered by Part B or Part D.

# Overview of drug pricing provisions in the Inflation Reduction Act



## ***Price setting***

Beginning in 2026, HHS will set Medicare prices for eligible prescription medicines in Part D. In 2028, this will be expanded to include medicines in Part B.



## ***Inflation Rebates***

IRA introduces an inflation rebate to quarterly (Part B) and annual (Part D) price increases above inflation.



## ***Part D Redesign***

Changes stakeholder liability for drug costs, caps out-of-pocket spending, smooths cost sharing, and other changes to benefits.



## ***Insulin policies***

Beginning in 2023, requires pre-deductible coverage and limits cost sharing to \$35 for covered insulin.



# Key provisions in the IRA

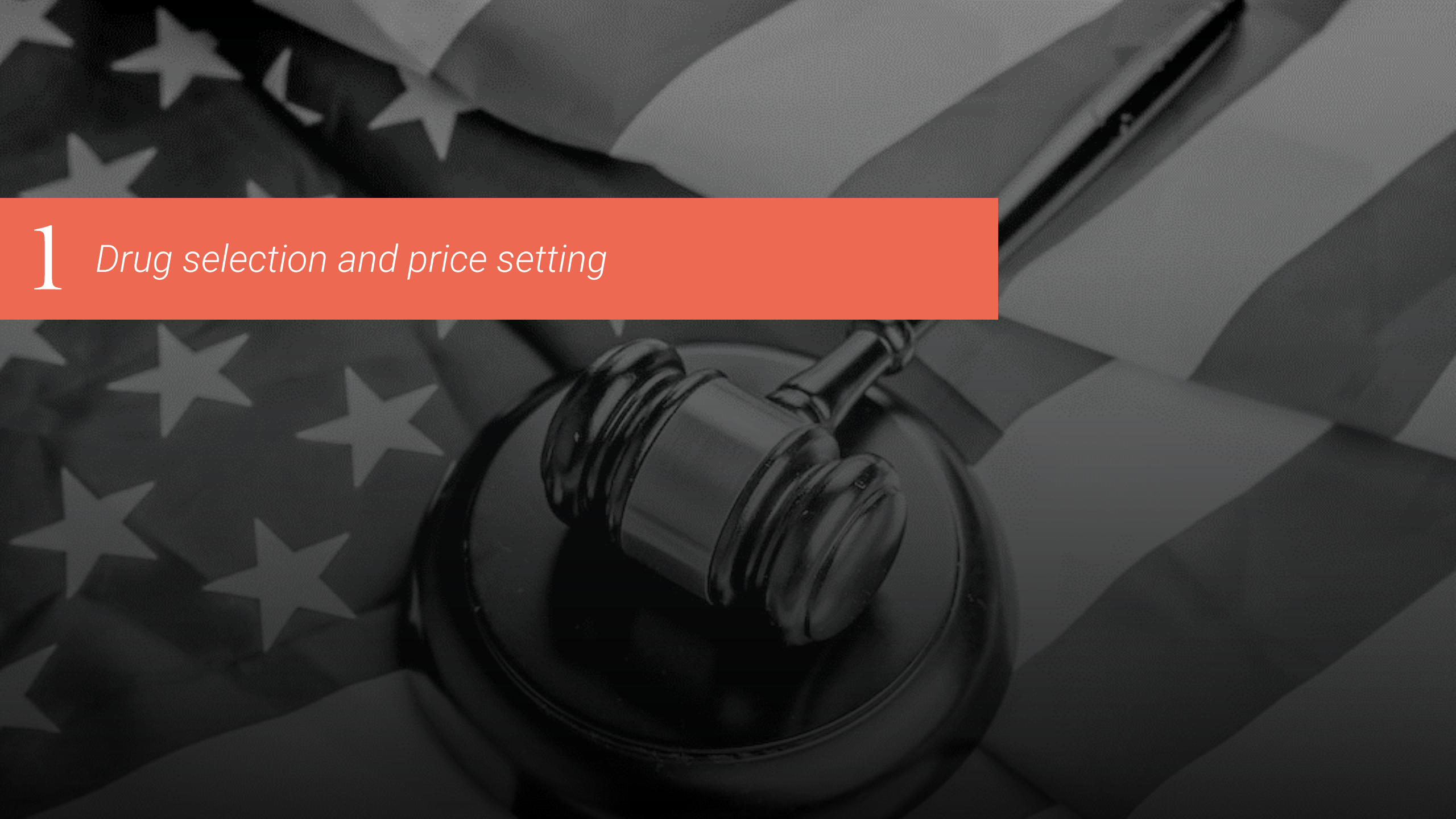
Dr Amanda Cole, Associate Director, OHE

# What we'll be covering

1 *Drug selection and price setting*

2 *Inflation rebate provision*

3 *Medicare Part D benefit redesign and other provisions*



# 1 *Drug selection and price setting*

# *Under the IRA, federal government will set prices for selected drugs covered under Medicare*



## *Before the Inflation Reduction Act (IRA)*

- Part D was a market-based system with drug prices privately negotiated
- Direct government involvement in pricing prohibited by the **non-interference clause** in Medicare Part D.
- Payment for physician-administered drugs covered by Medicare Part B generally based on Average Sales Price (ASP) + 6%

## *Now*

- IRA introduces provisions for the Secretary of the Department of Health and Human Services (HHS) to set Medicare prices for certain eligible medicines
- The Centers for Medicare & Medicaid Services (CMS) is an operating division of HHS and will implement the Medicare Drug Price Negotiation Program.



CENTERS FOR MEDICARE & MEDICAID SERVICES

# What drugs are eligible for selection?



## *Eligible for selection*

Drugs with the highest total Medicare Part B & D expenditures\*

Top 50 eligible drugs in **Part B**, ranked by program expenditures



Top 50 eligible drugs in **Part D**, ranked by program expenditures

- ✓ Single-source drugs, 7 or more years after FDA approval
- ✓ Single-source biologics, 11 or more years after FDA approval

\* For years 2026 and 2027, only the top 50 Part D list is used

## *Ineligible for selection*

- ⊗ Drugs with a single orphan designation that are only approved for that indication(s)\*
- ⊗ Plasma-derived products
- ⊗ “Low spend Medicare drugs” (total Part B & Part D expend <\$200 mill annually)
- ⊗ Certain “small biotech drugs” up until 2028

\*Under CMS' guidance, risk that as soon as the sponsor has an additional designation or any additional indication (whether under a subsequent orphan designation or not) they are no longer ineligible

Note: CMS released updated guidance on June 30 that offers more details on implementation of the MFP setting process

# Manufacturer is subject to penalties for refusing to participate or not accepting MFP.

## Other penalties could apply



Excise tax is nominally between 65% and 95% of manufacturer's total sales for the drug, over the term in which manufacturer fails to accept MFP.



Alternatively, manufacturer can exit program but must remove all of its drugs from Medicare and Medicaid.

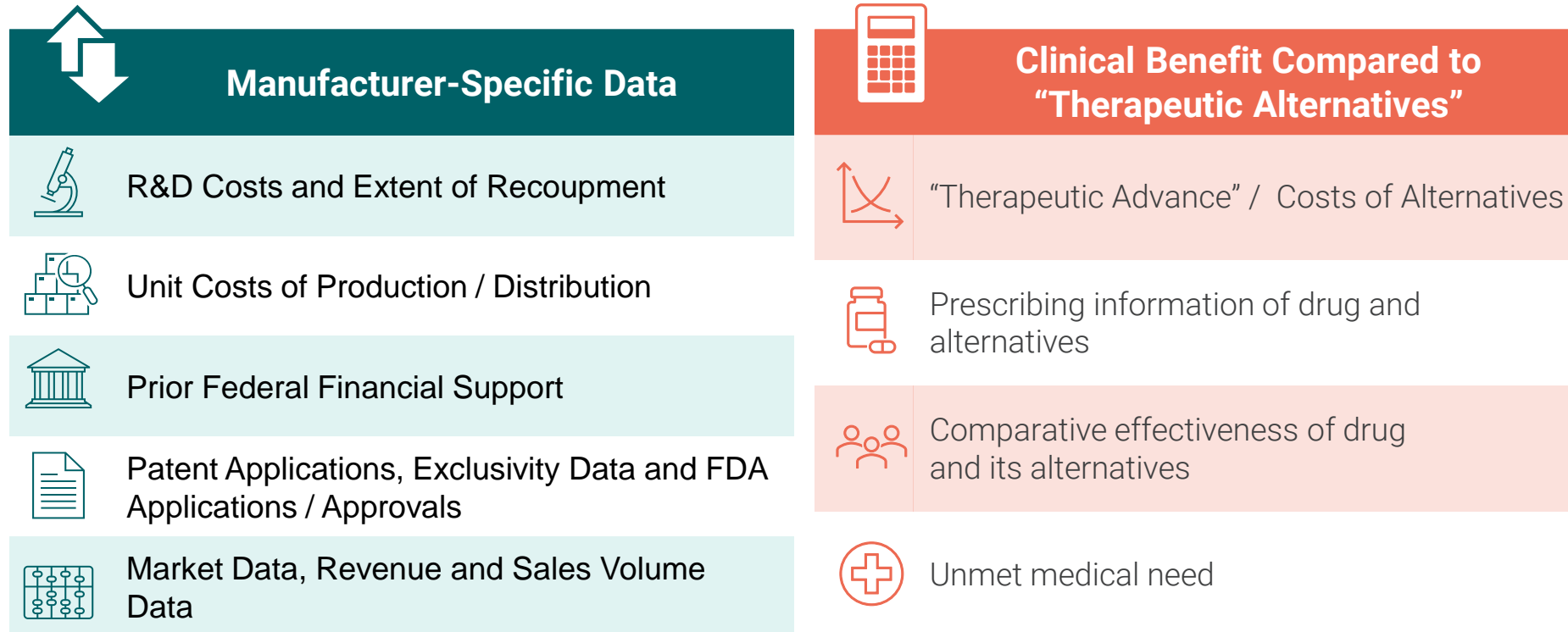


Significant civil monetary penalties for failing to comply with certain requirements or knowingly submitting false information

# Process for determining the maximum fair price



IRA specifies 2 sets of factors that HHS should consider in determining the *maximum fair price*, but does not indicate how the factors will be considered.



# Methodology for developing an initial offer



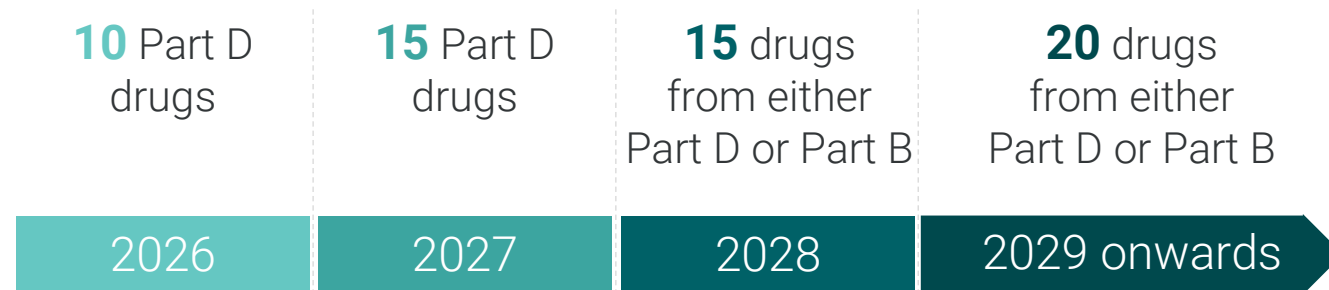
- To assess clinical benefit, CMS will consider submitted data from manufacturers and interested third parties as well as review of existing literature and internal analytics. Clinical trial evidence, real world evidence, and expert opinion will be considered.
- CMS intends to consider study rigor, relevance to selected drug, risk of bias, and other factors in assessing data but does not specify methodological standards it may apply.
- QALYs will not be relied on in developing price offers, but studies that use QALYs may be considered in assessment of clinical benefit if clearly separated from other evidence submitted.

*There is a 30-day window for manufacturers and interested parties to submit data to CMS.*

# More drugs will be selected for price setting each and every year

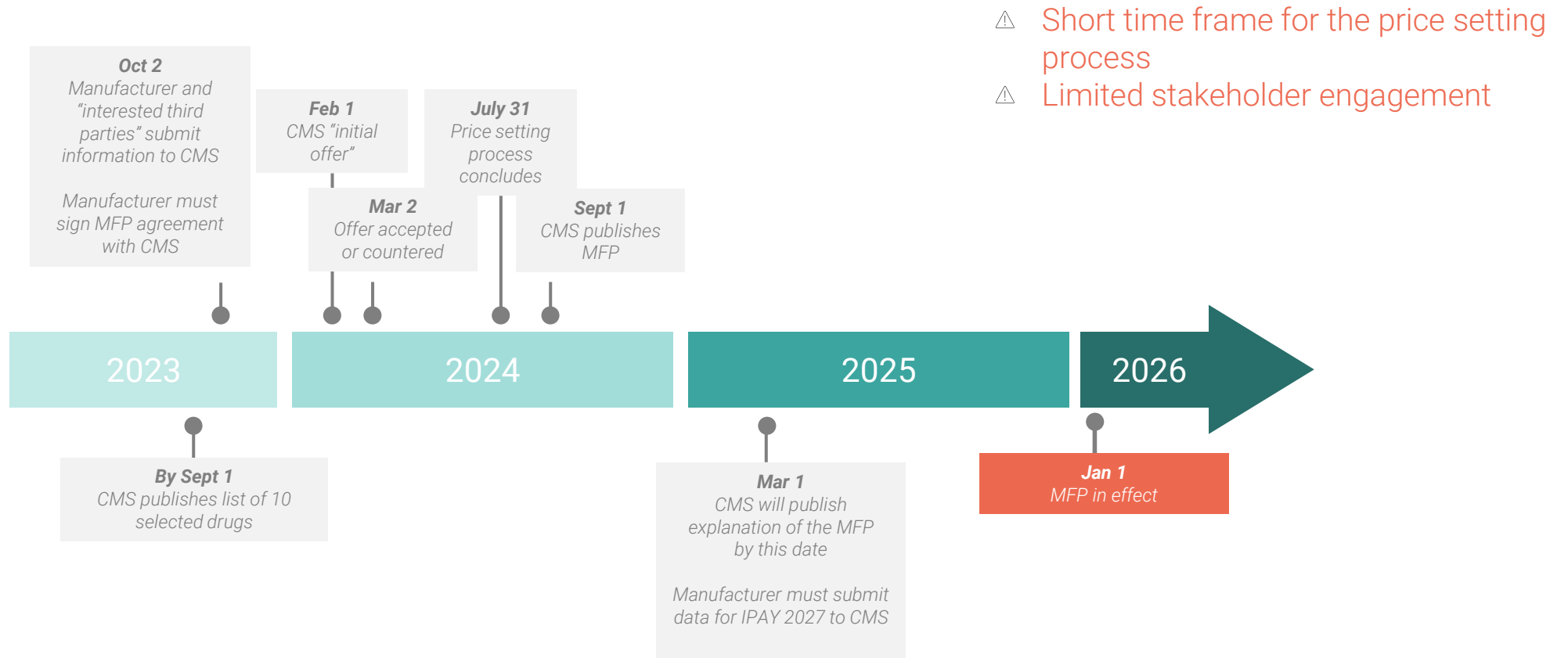


- Beginning in 2026, CMS will set Medicare prices for eligible prescription drugs

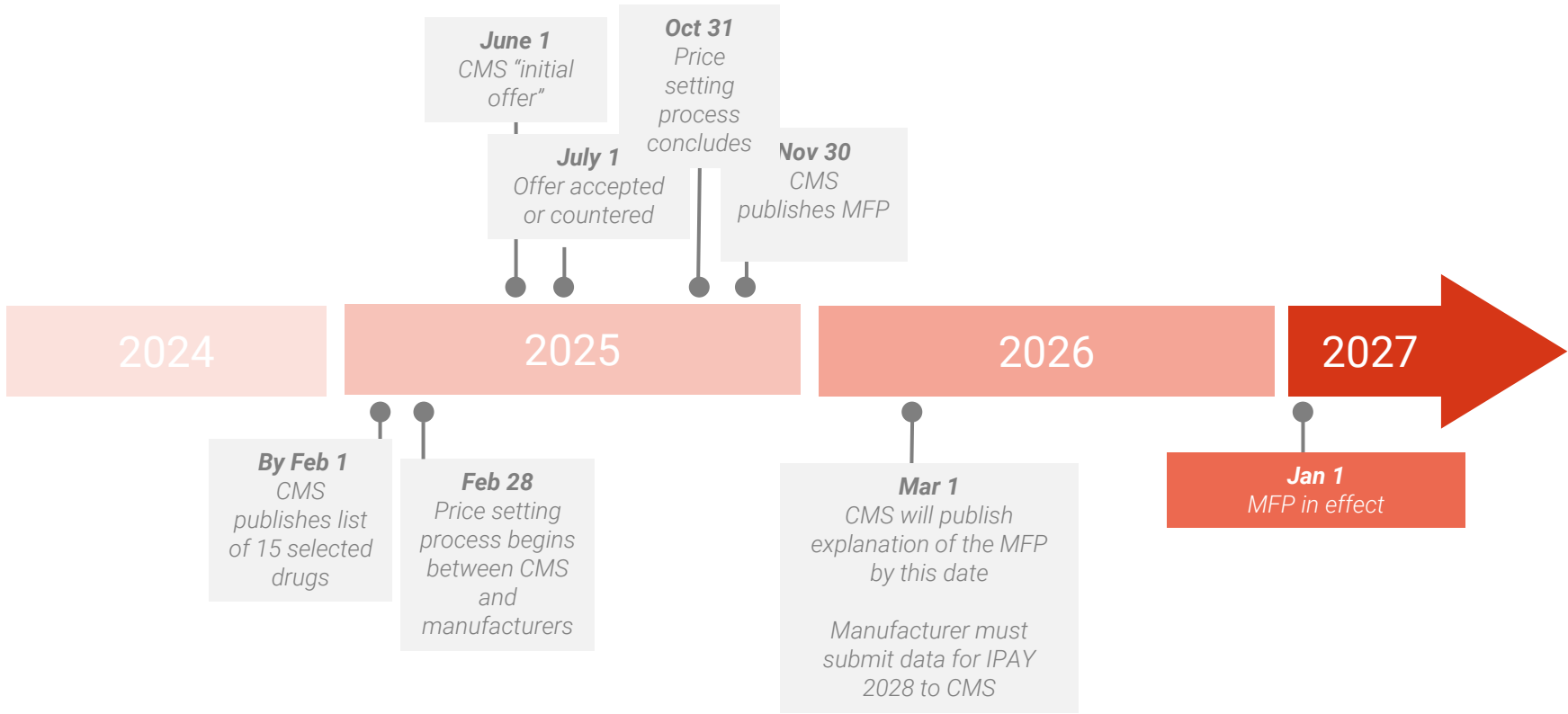


- Selection of drugs each year is cumulative, adding to the number of previously selected drugs.

# Price setting for the first group of Part D drugs will take effect in 2026



# Timeline for 2027 and beyond: a two-year process





## *2 Inflation rebate provision*

# Manufacturers must already rebate Medicaid if their prices rise faster than inflation. **OHE**

*Price changes are measured cumulatively against a fixed benchmark*



# IRA brings inflationary rebates to Medicare but with a different reference date.



$$\text{Rebate} = \text{Quantity sold} \times \text{Price Growth in Excess of Inflation}$$

- The benchmark price is **Q3 2021 for Part B** medicines, and **January through September 2021 for Part D** medicines.
- The benchmark CPI-U for both rebates is **January 2021**.
- Price is measured based on the payment amount (e.g., average sales price (ASP) + 6%) in Part B and average manufacturer price (AMP) in Part D
- Most branded drugs are included in the provision but there are some *exclusions*:
  - For **Medicare Part B**, medicines with an annual cost of <\$100 in 2023 and preventative vaccines.
  - For **Medicare Part D**, drugs with annual cost of <\$100 in 2023.



### *3 Medicare Part D benefit redesign and other provisions*

# The IRA reallocates prescription drug costs between patients, manufacturers, plans, & gov't



The Medicare Part D redesign is intended to:

Lower cost sharing for patients, including a limit on annual out-of-pocket spending (\$2,000 beginning in 2025)



Decrease direct federal government liability and increase Part D plan liability above the catastrophic threshold



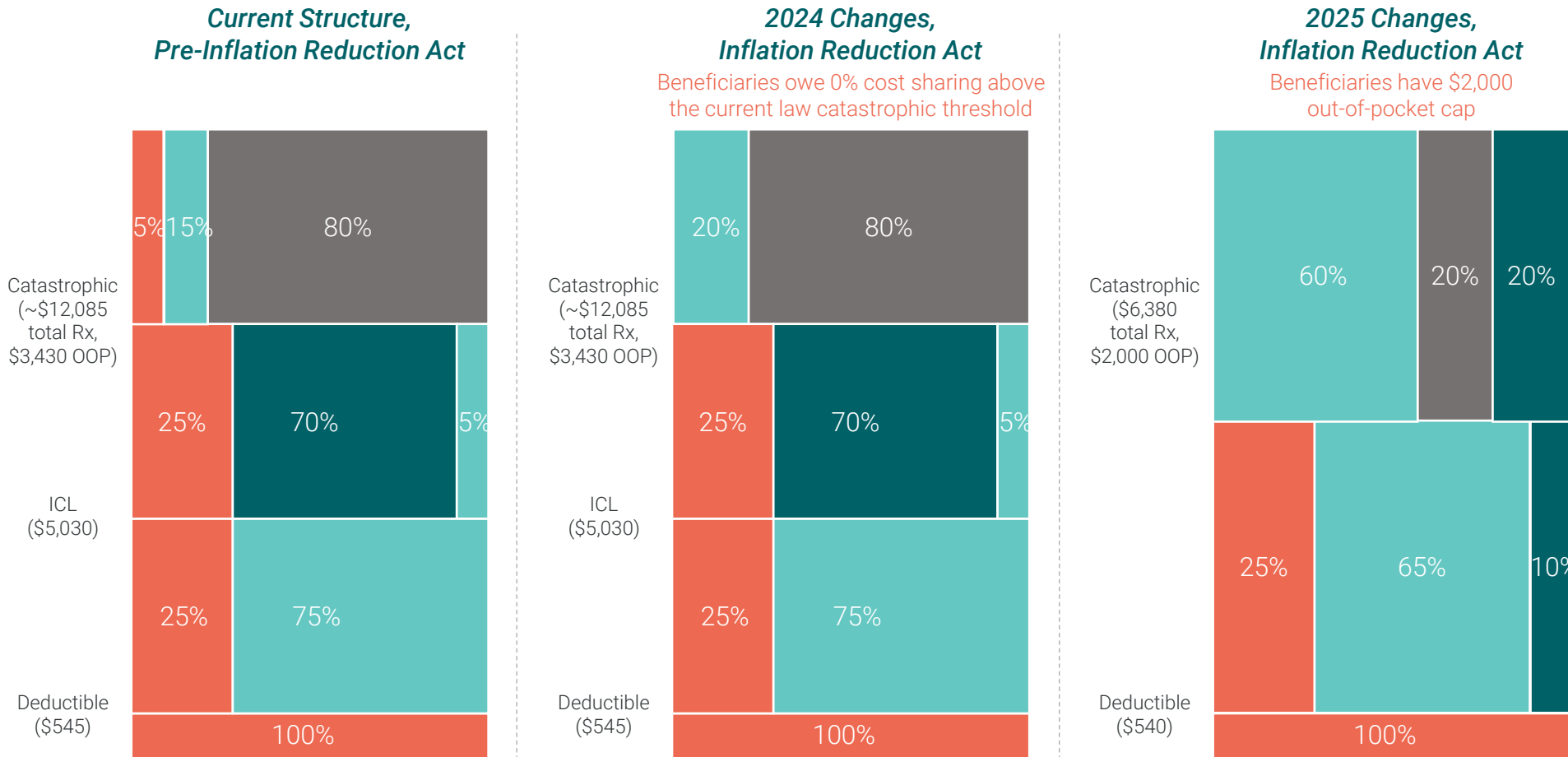
Increase the share of the benefit financed by manufacturers



Limit premium growth to 6% annually through 2029



# Cost sharing changes



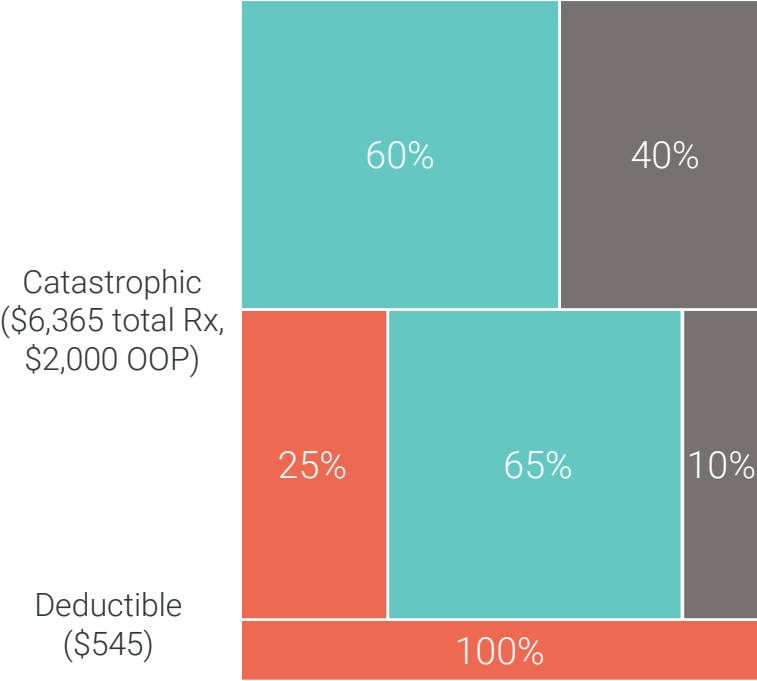
- Replaces coverage gap discount program with new manufacturer discount (10% below catastrophic threshold and 20% above catastrophic threshold) for both LIS and non-LIS beneficiaries
- Financial liability changes for all stakeholders;** liability increases for manufacturers overall while simultaneously decreasing for the federal government and increasing for Part D plans above the catastrophic threshold and eliminating cost-sharing above catastrophic for beneficiaries

# Additional benefit changes once price setting provisions take effect

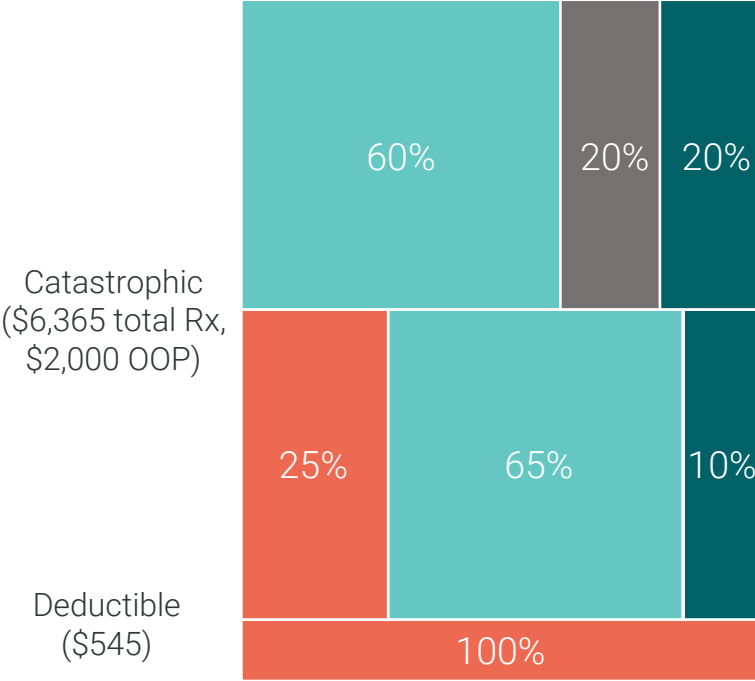


- Beneficiary OOP
- Plan
- Manufacturers
- Government

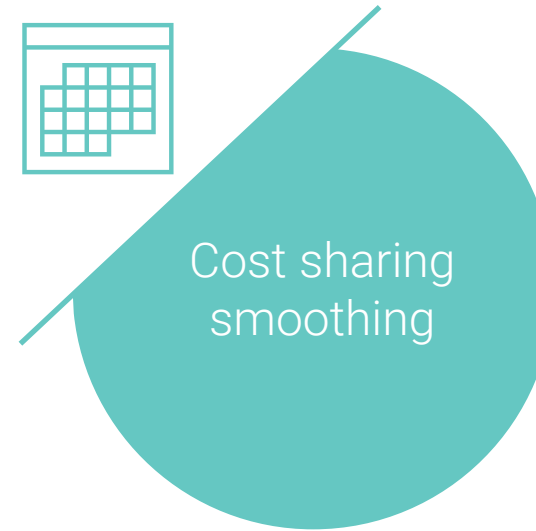
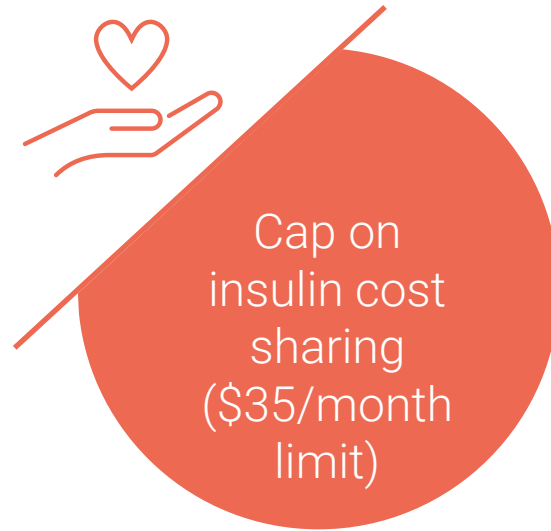
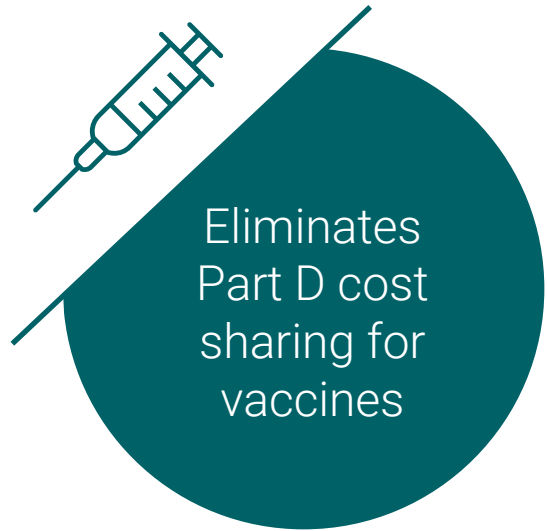
*For Brand Medicines Subject to Price Setting*



*For Brand Medicines NOT Subject to Price Setting*



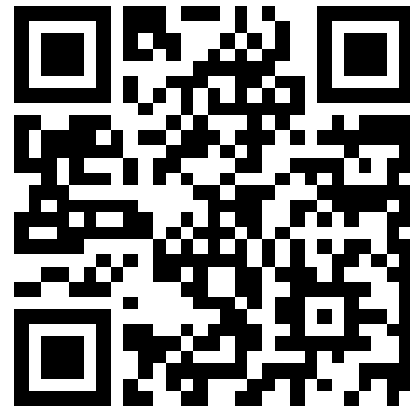
# Additional key provisions include:



# Changes in the low-income subsidy (LIS)



What are some implications of introducing price-setting into the otherwise market-based insurance system that underpins the Medicare drug benefit?



**Live attendees:** Please discuss at your tables and submit a short written summary of your discussion via *Slido*.

**Virtual attendees:** Please submit your thoughts via *Slido*

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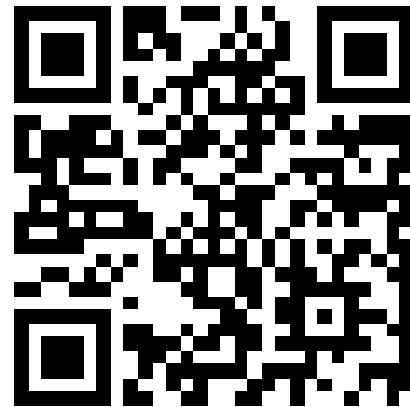
Roundtable  
discussion

BREAK



OHE

# What can the US learn from global experience with price regulation?



**Live attendees:** Please discuss at your tables and submit a short written summary of your discussion via *Slido*.

**Virtual attendees:** Please submit your thoughts via *Slido*

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Roundtable  
discussion



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# Insights on Impact

Dr Amanda Cole, Associate Director, OHE

# Motivation for analysing the impacts of IRA **OHE**

- IRA is an unprecedented policy that sets prices for selected drugs in Medicare.
- The full implications for R&D incentives and innovation are unknown but likely to be far reaching.
- Many of the existing estimates of innovation impacts ignore complexities of the law and many likely consequences.

# How could the IRA impact biopharmaceutical innovation?



## What are the likely impacts on expected revenues?

Potential sources of revenue impact & magnitude

Spillover to other products and markets

*Threat of expansion*

Lower revenue directly impacts *level of innovation*

## What are the implications for R&D decisions?

IRA also impacts *R&D focus*

Undermines existing IP incentives

Reduces incentives to invest in post-approval indications

*Disproportionate impact on small molecules and certain diseases (cancer, chronic, rare)*

# Revenue impact from the perspective of innovative biopharmaceutical companies



**What are the likely impacts on expected revenues?**

Potential sources of revenue impact & magnitude

Spillover to other products and markets

*Threat of expansion*

# Revenue impact from the perspective of innovative biopharmaceutical companies

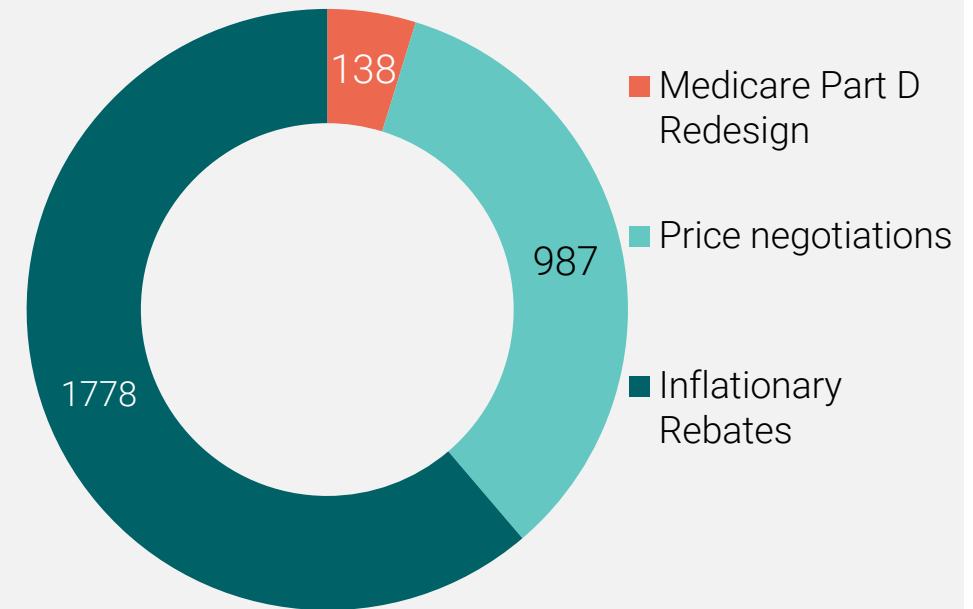


# Published estimates vary but suggest large manufacturer revenue impact



- Philipson and Durie (2021) estimate that policies like the IRA will reduce 2022-2039 manufacturer revenues by 12%, or **\$2.9 trillion**.
- CBO (2021) estimates are more conservative (5.1%), but still significant

Breakdown of foregone manufacturer revenue by IRA provision 2022-2039  
(billions, \$)



Philipson, T.J. and Durie, T., 2021. Issue Brief: The Impact of HR 5376 on Biopharmaceutical Innovation and Patient Health. Available at: <https://bpb-us-w2.wpmucdn.com/voices.uchicago.edu/dist/d/3128/files/2021/08/Issue-Brief-Drug-Pricing-in-HR-5376-11.30.pdf> [Accessed 17 Mar. 2023].

CBO, 2021. CBO's Simulation Model of New Drug Development: Working Paper 2021-09 | Congressional Budget Office. Available at: <https://www.cbo.gov/publication/57010> [Accessed 18 Apr. 2023].

# MFP: Likely unintended spillover effects would increase the IRA's impact on industry revenue



## Potential impacts on competitive dynamics that affect prices of products competing with MFP product

- Impact not limited to the products selected for price-setting. Pricing and formulary access will also be affected for competing products in the therapeutic class that must compete with the government set price.
- In addition, reduced incentives for market entry to compete with the government set price may harm continued innovation within classes impacted by MFP, ultimately reducing competition and treatment options.

## MFP is likely to spillover into other markets beyond Medicare

- MFP to impact Best Price for the Medicaid Rebate Program, the 340B ceiling price, and likely will be reflected in calculation of Average Sales Price, which is typically used as a pricing benchmark in the commercial market, increasing IRA's impact on revenues.

Devane, K., MacDougall, D., Harris, K. and Borrello, E., 2022. Government Price Negotiation & its Anticipated Impact on Contracting Dynamics in Medicare Part D. HCG White Paper Series: The Inflation Reduction Act #3. [HaydenCG] Hayden Consulting Group. Available at: <https://www.haydencg.com/post/hcg-white-paper-series-the-inflation-reduction-act-3> [Accessed 8 Jul. 2023].

Nagar, S., Kesselheim, A.S. and Rome, B.N., 2023. Medicare Drug Price Negotiation: Few Drugs, Big Impact? Health Affairs Forefront. [online] Available at: <https://www.healthaffairs.org/doi/10.1377/forefront.20230605.192390/full/> [Accessed 8 Jul. 2023]

# Further revenue impacts possible as pressure grows for expanding price controls in US

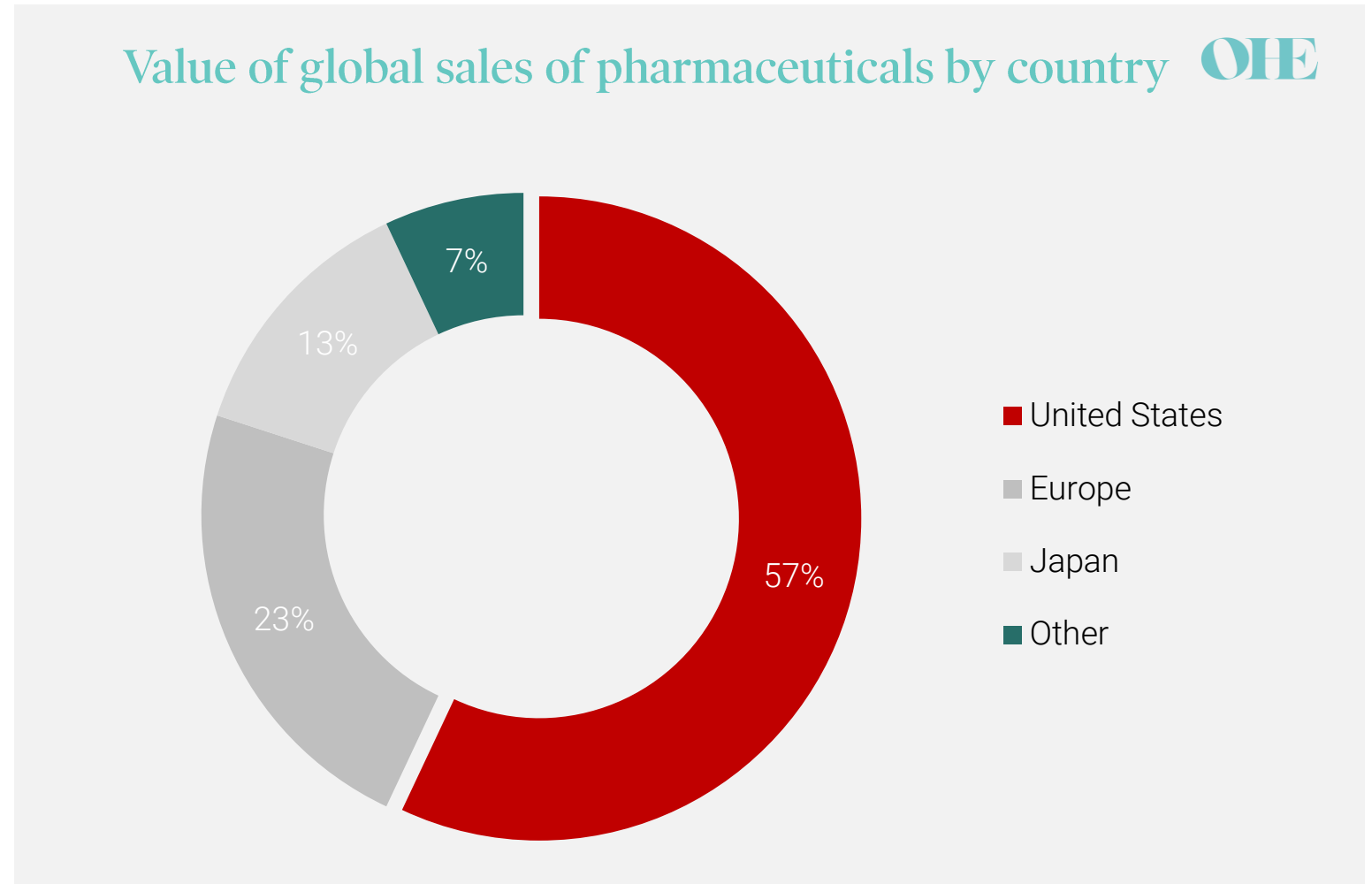


- The precedent set by the IRA may pave the way for policymakers to expand government price controls in the future



My budget will build on drug price reforms by strengthening Medicare's newly established negotiation power, allowing Medicare to negotiate prices for **more drugs** and bringing drugs into **negotiation sooner** after they launch.

# US represents biggest share of global industry revenue



# Impact of reduced biopharmaceutical revenues and R&D



**What are the likely impacts on expected revenues?**

Lower revenue  
directly impacts  
*level of*  
innovation

# Long standing evidence that revenues directly impact innovation



- Several papers consider the “elasticity” of innovation (% change in innovation associated with a 1% change in market size).

Source	Elasticity	Measure of innovation
Acemoglu and Linn (2004)	5	Entry of non-generic and new molecular entities
Blume-Kohout and Sood (2013)	2.8	Preclinical and clinical development
Finkelstein (2004)	2.75	Clinical trials for new vaccines
Kourouklis and Gandjour (2022)	2.2	Early-stage innovation measured by patent applications
CBO (2021)	0.45	Number of new drugs entering the market

Examples of estimates of the elasticity of drug innovation to market size

Source: Adapted from Philipson and Durie (2021)

- But elasticities may oversimplify the complex decision-making process and ignore post approval research (Cookson and Hitch, 2022)

Cookson, G. and Hitch, J., 2022. Limitations of CBO’s Simulation Model of New Drug Development as a Tool for Policymakers. [online] OHE. Available at: <https://www.ohe.org/publications/limitations-cbos-simulation/> [Accessed 22 Jun. 2023].

Philipson, T.J. and Durie, T., 2021. Issue Brief: The Impact of HR 5376 on Biopharmaceutical Innovation and Patient Health. Available at: <https://bpb-us-w2.wpmucdn.com/voices.uchicago.edu/dist/d/3128/files/2021/08/Issue-Brief-Drug-Pricing-in-HR-5376-11.30.pdf> [Accessed 17 Mar. 2023].

# Reduced revenues projected to lead to lower R&D and forgone health benefits



- Philipson and Durie (2021) estimate that every \$2000 in lost R&D spend leads to one statistical life year lost. They conclude that IRA will be associated with 135 fewer drug approvals and the loss of 331.5 million life years in the US by 2039.



# How could the IRA impact biopharmaceutical innovation?



## What are the likely impacts on expected revenues?

Potential sources of revenue impact & magnitude

Spillover to other products and markets

*Threat of expansion*

Lower revenue directly impacts *level of innovation*

## What are the implications for R&D decisions?

IRA also impacts *R&D focus*

Undermines existing IP incentives

Reduces incentives to invest in post-approval indications

*Disproportionate impact on small molecules and certain diseases (cancer, chronic, rare)*

# R&D impact from the perspective of innovative biopharmaceutical companies



**What are the implications for R&D decisions?**

IRA also impacts  
*R&D focus*

# R&D impact from the perspective of innovative biopharmaceutical companies



## What are the implications for R&D decisions?

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Undermines existing  
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Reduces incentives  
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*Disproportionate impact on small molecules and  
certain diseases (cancer, chronic, rare)*

# The IRA undermines existing IP and incentives for small molecule innovation in particular



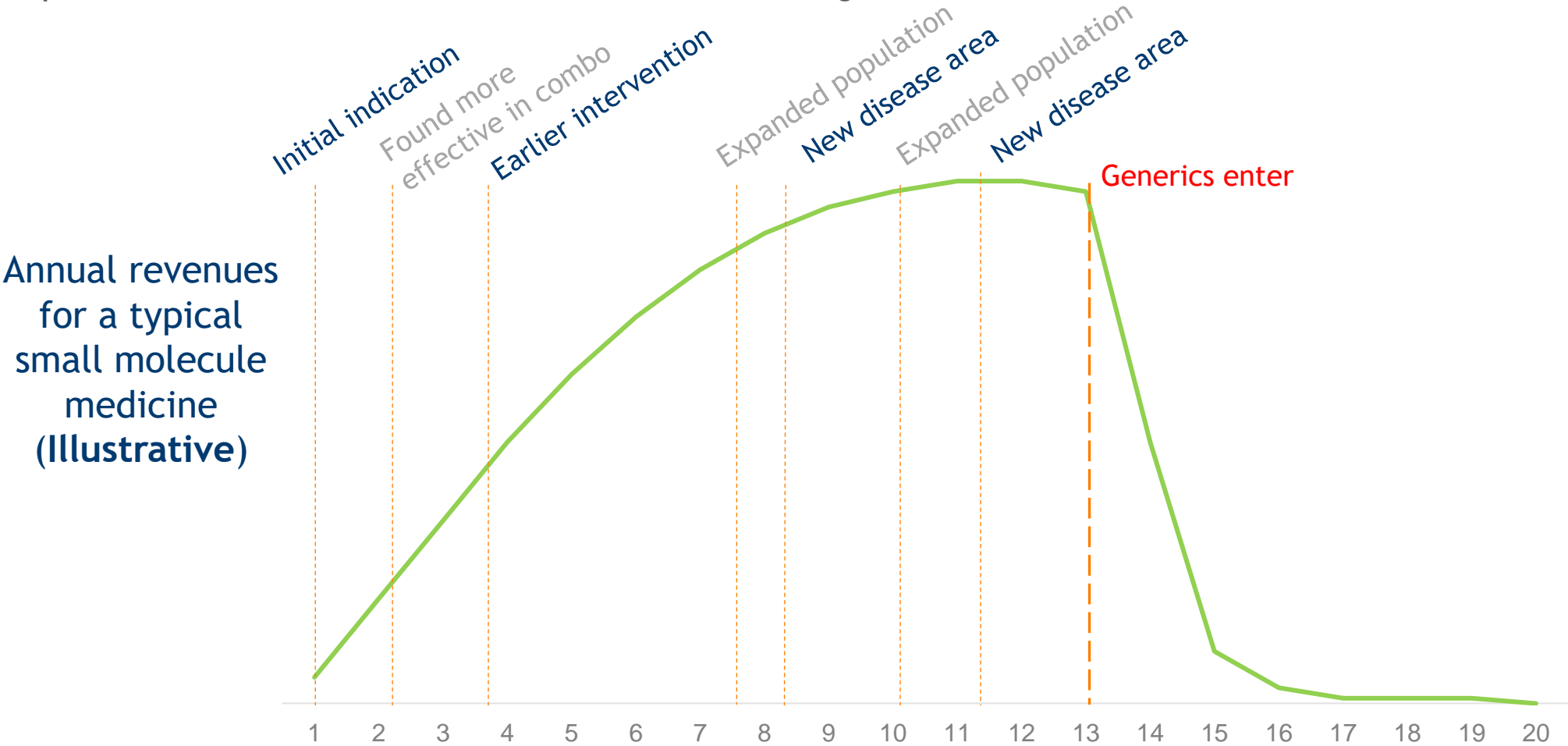
**The Hatch-Waxman Act (1984), is a comprehensive legal framework adopted by Congress to streamline generic pharmaceutical approvals while preserving innovation incentives**

- Existing IP mechanisms have offered an effective patent life of on average 13.6 years for small molecule medicines (Grabowski et al., 2016).
- Under IRA, the time to generate returns is effectively reduced from an average of 13.6 to a max of 9 years for selected small-molecule drugs.

# Pre-IRA, drugs averaged ~14 years before generic competition



Expected revenues enable continued R&D, revealing new uses

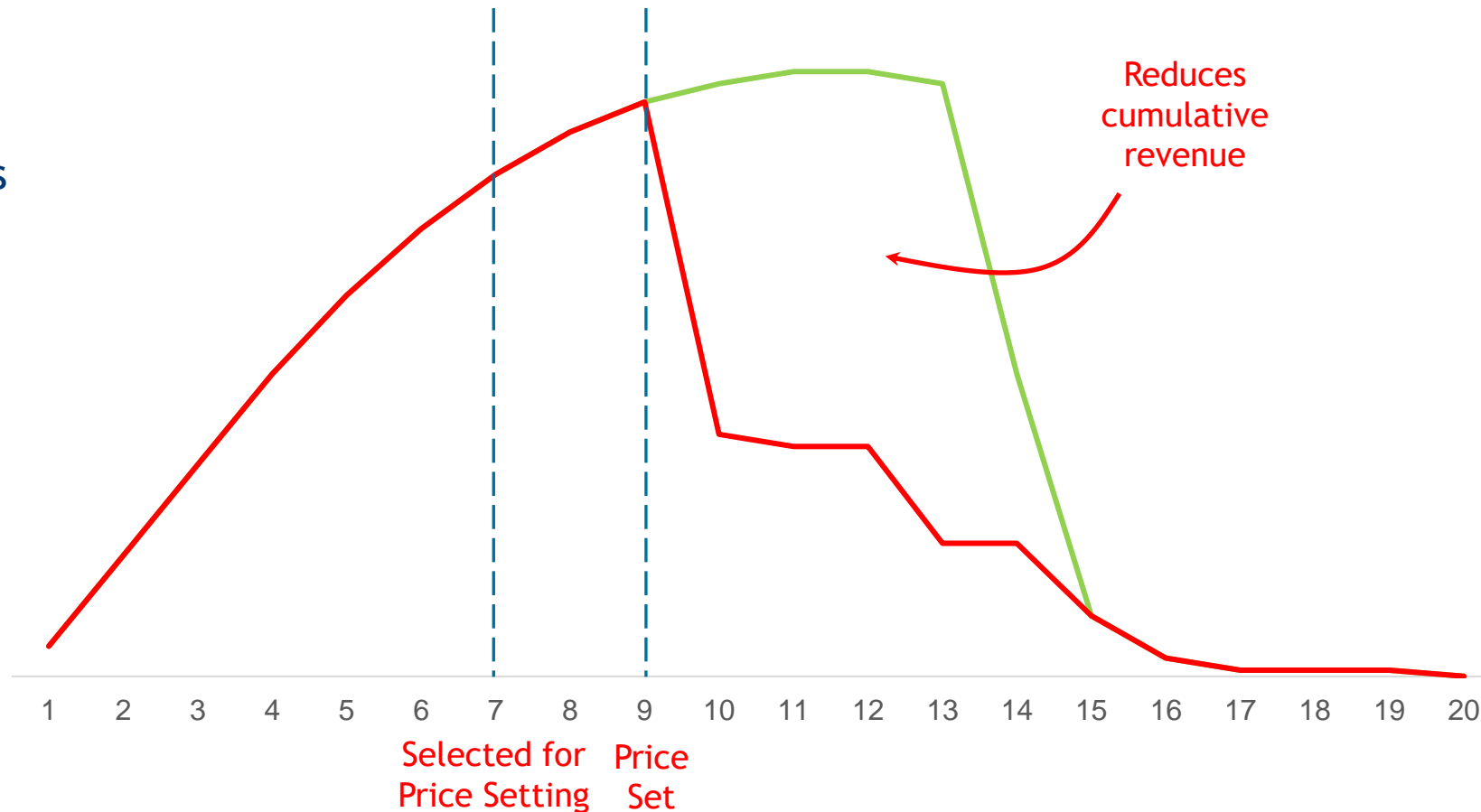


# Under IRA, a small molecule drug can face price setting after 9 years



In the future, the lower expected revenues might mean that a drug not be developed at all – if not high enough to justify the large and uncertain up-front investments

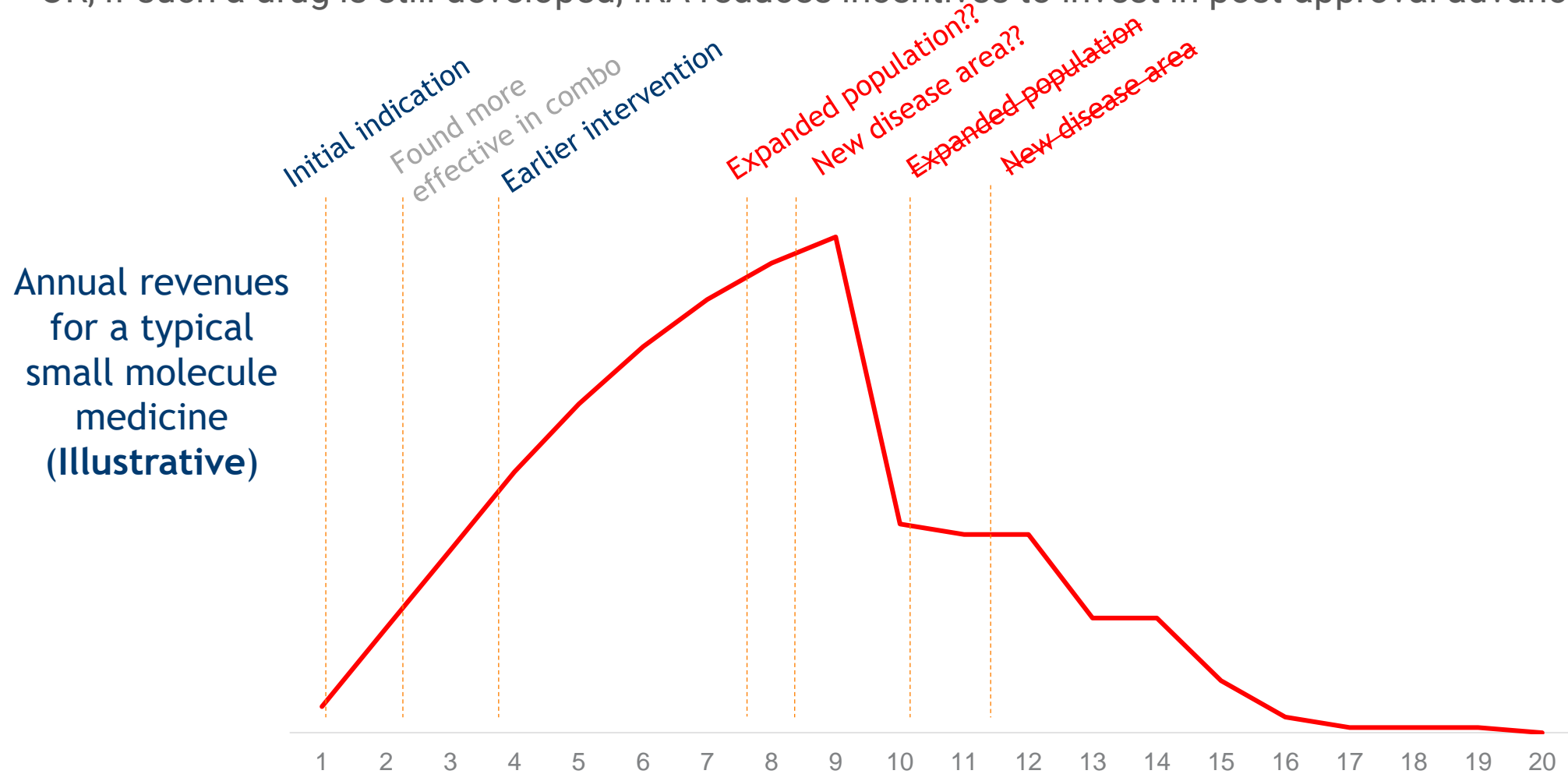
Annual revenues  
for a typical  
small molecule  
medicine  
(Illustrative)



# Under IRA, a small molecule drug can face price setting after 9 years



OR, if such a drug is still developed, IRA reduces incentives to invest in post-approval advances



# IRA would disincentivise R&D into new treatment indications, particularly those arising later in product life



- Research conducted on a drug after its initial approval leads to new disease targets, new patient populations, or earlier stages of disease.
- Particularly problematic for **cancer and rare diseases**, for which many advances stem from discovering uses for already approved drugs.
  - **60%** of cancer products receive new indications after the initial FDA approval and **22% receive 3+** new indications; **44% of new indications occur 7+ years** after the initial (PHAR, 2023)
- Manufacturers could be incentivised to place further emphasis on strategic launch sequencing, prioritising the most commercially successful indication first and smaller indications later, if ever (Gores and Scott, 2023).

# The IRA will shift incentives for innovation away from some disease areas



## Primarily impacts innovation in diseases disproportionately affecting the elderly

- Among the diseases likely to be affected most are neurological conditions, cancers and cardiovascular disease.

## Shift away from small-molecule drugs (e.g. pills)

- Small molecules are subject to price setting sooner at 9 years, while biologics are afforded a longer period (13 years before MFP kicks in).
- Small molecules have advantages over large molecules in ability to be taken at home in pill form, and by penetrating blood-brain barriers or cell membranes needed to target neurological diseases or cancers, which disproportionately impact communities of colour in the US.

# The IRA undermines existing incentives for rare disease drug development



**The Orphan Drug Act (1983) was enacted to encourage the development of drugs for rare diseases by providing incentives in the form of regulatory exclusivity**

- Under IRA:
  - Drugs with a single orphan designation and approved indication(s) only within that designation will be exempt from selection for price setting
  - But as soon as the manufacturer receives additional designations or indications outside the initial designation (whether under a subsequent orphan designation or not) they become eligible for price setting. This will disincentivise follow-on orphan drug development, a key route to new treatment opportunities for patients with rare diseases.

## **IRA reduces incentives to invest in rare disease medicines**

- 9-year price setting timeline incentivizes manufacturers to launch with largest indication, not necessarily in the Medicare population.
- Reduces likelihood of earning a return before potential to be price set will reduce investment in disease areas with high regulatory uncertainty, but with high scientific promise and risk.

# Disproportionate impact on certain therapeutic areas



Oncology	Chronic physical and mental conditions	Rare
<ul style="list-style-type: none"><li>• Cancer often affects people as they get older, so <b>Medicare</b> represents a sizeable market for oncology drugs</li><li>• Most cancer medicines are <b>small molecules</b>, which are penalized by the shorter time to MFP at 9 years.</li><li>• Very many cancer medicines are (or have the potential to be) <b>multi-indication</b>. IRA disincentivises post-approval investments.</li><li>• <b>Launch sequencing</b> likely to become important consideration</li></ul>	<ul style="list-style-type: none"><li>• Chronic physical and mental diseases often affect people as they get older, so <b>Medicare</b> represents a sizeable market for these drugs.</li><li>• Need for <b>small molecule</b> therapy development to treat these conditions and ensure <b>equity of access</b>.</li><li>• High <b>R&amp;D costs</b> and high <b>risk of failure</b> in these areas of significant unmet need: IRA reduces return on investment, and disproportionately affect these high-risk areas of treatment development.</li><li>• <b>Timelines for evidence development</b> can be long and expensive for large population chronic diseases such as cardiovascular disease.</li><li>• Traditionally significant <b>competition</b>, which could be curtailed by MFP and spill over into private markets (Popli et al., 2023).</li></ul>	<ul style="list-style-type: none"><li>• <b>Costly R&amp;D</b> due to difficulties with clinical trials and low treatment volumes.</li><li>• Existing incentives for rare disease therapy development (e.g. Orphan Drugs Act) could be <b>undermined</b> by the IRA.</li><li>• The <b>re-purposing</b> of existing medicines is a significant and efficient source of new treatments, which could be disincentivized by IRA.</li><li>• Companies are <b>already opting to abort opportunities to re-purpose drugs</b> to treat rare diseases with high unmet need, because of the price reforms introduced by the IRA, e.g. vutrisiran for Stargardt disease (Taylor, 2022)</li></ul>

Popli, M., Jiang, J., Saxena, V., Lawless, N. and Stahl, J., 2023. Inflation Reduction Act: Assessment of Impact on Oncology Therapies. [online] ISPOR. . Available at: [https://www.ispor.org/docs/default-source/intl2023/popli-m-2023-us-isporposterinflation-reduction-act-assessment-of-impact-on-oncology-therapies125744-pdf.pdf?sfvrsn=b3de4435\\_0](https://www.ispor.org/docs/default-source/intl2023/popli-m-2023-us-isporposterinflation-reduction-act-assessment-of-impact-on-oncology-therapies125744-pdf.pdf?sfvrsn=b3de4435_0) [Accessed 24 May 2023].

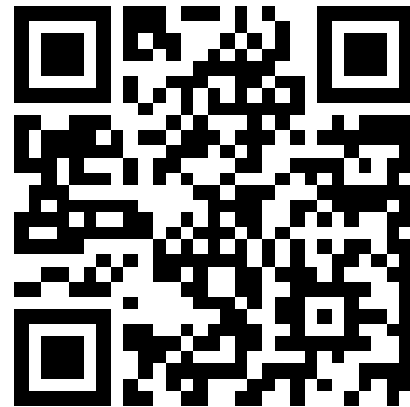
Taylor, P., 2022. Alnylam scraps trial in rare eye disorder, blaming drug price reforms. [online] pharmaphorum. Available at: <https://pharmaphorum.com/news/alnylam-scraps-trial-in-rare-eye-disorder-blaming-drug-price-reforms> [Accessed 22 Jun. 2023].

# Summary



- The potential impact of IRA on drug development and patients is multifaceted.
- IRA discourages innovation of medicines, particularly small molecules and certain disease areas (e.g., cancer, rare, chronic).
- IRA undermines existing IP incentives.
- Implementation of the law should take caution to mitigate harm to sustainability of future R&D.
- Potential for expanding U.S. price controls could increase impact on industry revenue and global implications

If the US adopted price controls at launch for all drugs, what might the impact be on global innovation?



**Live attendees:** Please discuss at your tables and submit a short written summary of your discussion via *Slido*.

**Virtual attendees:** Please submit your thoughts via *Slido*

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Roundtable  
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# Reflections

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THANK YOU