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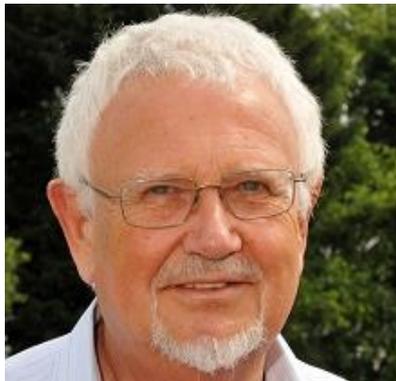
# Staying ahead of the curve: Navigating policy changes and ensuring patient access in the era of IRA and EU HTA

**Educational symposium**

May 6, 2024



# Meet the speakers



**Pr. Michael Drummond**

Professor of Health Economics,  
University of York



**Corey Ford**

Vice President, Reimbursement and  
Policy Insights,  
Cencora



**Casper Paardekooper**

Partner,  
Vintura, part of Cencora



**Kimberly Westrich**

Chief Strategy Officer,  
National Pharmaceutical Council

# Considerations for stakeholders in the wake of IRA implementation

Kimberly Westrich, Chief Strategy Officer, NPC

# Core healthcare components of the IRA

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## Part D Reforms

OOP cap in 2024  
Larger redesign to begin 2025  
Expands LIS eligibility  
\$0 OOP for Part D vaccines

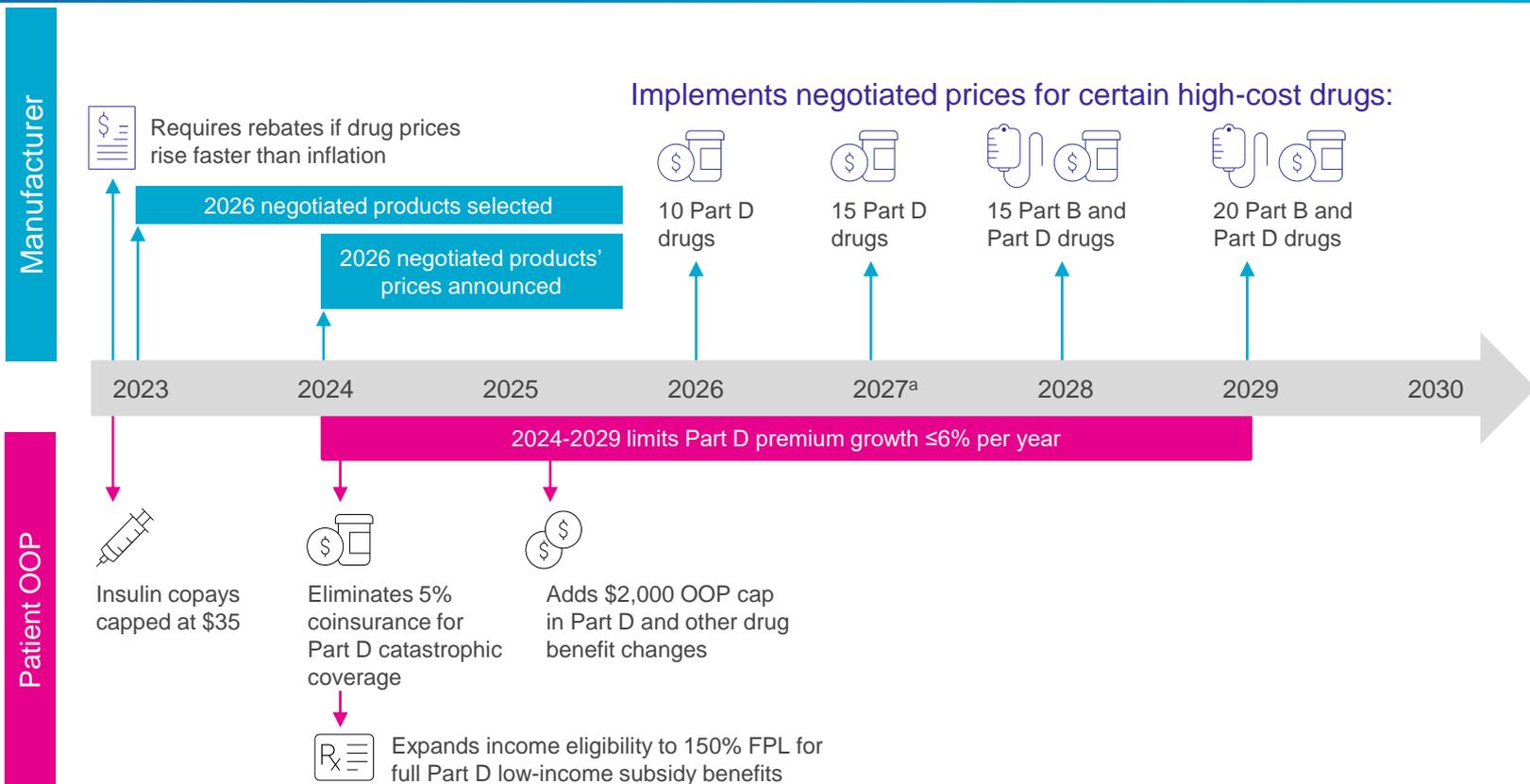
## Inflationary Caps

Medicare Part B and Part D price increases that outpace inflation owe rebates

## Medicare Negotiation

Negotiation starts earlier (2023), implementation in 2026

# IRA implementation timeline for prescription drug provisions



<sup>a</sup> Repeals Trump administration's drug rebate rule until 2031.

Prepared by Cencora. IRA Boot Camp: Navigating the Implementation of the Inflation Reduction Act. July 10, 2023.

# IRA's drug pricing provisions may have unintended consequences for health care stakeholders

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## Future innovation

- May result in **fewer indications** for small molecules
- May **reduce post-approval outcomes research** that informs clinical guidelines



## Patient access to needed medications

- May cause vulnerable patient populations to **wait longer for innovative treatments**
- May create new incentives for payers to **increase utilization management**



## Patient experience

- May **not follow best practices** to incorporate or account for the **patient perspective**

# Understanding the EU Joint Clinical Assessment (JCA)

Pr. Michael Drummond, Professor of Health Economics, University of York

Casper Paardekooper, Partner, Vintura, part of Cencora

# What is the Joint Clinical Assessment (JCA)?

## When & who does it impact?

<9mths to go

New EU-wide HTA process; a single clinical assessment occurring in parallel with the European Medicines Agency (EMA) marketing authorization process.

### Aims:

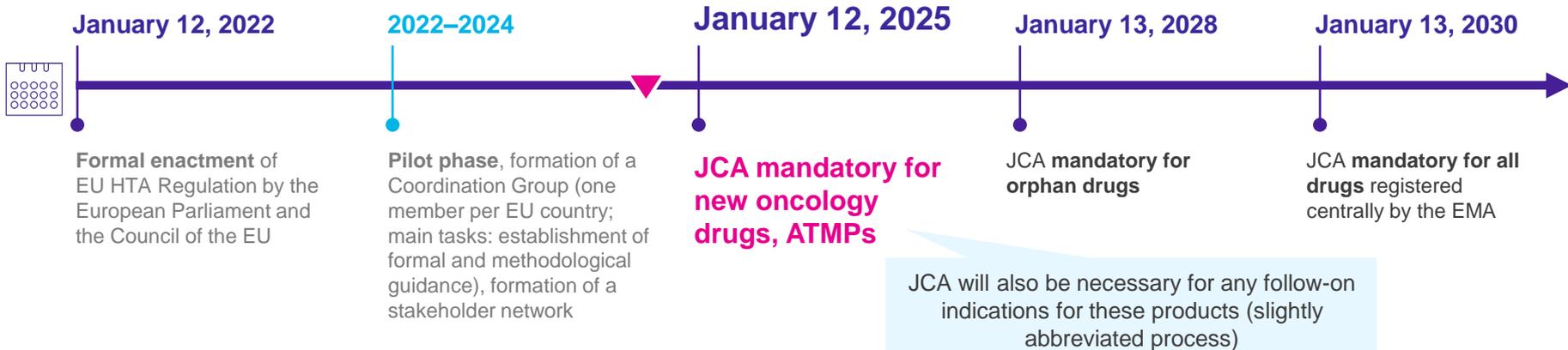
- ✓ Harmonize processes and evidence requirements
- ✓ Avoid duplication of dossier development for manufacturers
- ✓ Accelerate patient access across its member states (“solidarity”)



Comparative effectiveness



Price/ value/ economics



# Key challenges of the new JCA process



## CHALLENGING TIMELINES

- Process aims to publish report just 30 days after EC regulatory decision
- Manufacturers have just 100 days\* to prepare their submission after scope publication
- Expected PICO multiplicity likely to drive early preparation of necessary statistical analysis



## MINIMAL ENGAGEMENT

- Minimal involvement of manufacturers in scoping process (just an “explanation” meeting)
- No sharing of individual member state PICO requirements
- Unclear how patient and clinical organisations will participate



## HIGH TRANSPARENCY

- High demand for sharing of manufacturer materials via process
- Only 7 days to fact check report and mark commercial in confidence
- Unclear process for challenging publishing of confidential material

\*Based on an assumed average clock stop

\*Note: Points on this slide are accurate at the time of writing (1<sup>st</sup> May 2024)

# Thank you

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**Connect with the Cencora team at booth #607**



Thank you धन्यवाद Děkujeme Mange  
takk Vă mulțumesc Gracias Vielen Dank  
شكركم كل Teşekkürler Děkojame jum  
спасибо Merci 谢谢 Obrigado ありがとう  
ございました cảm ơn bạn Paldies 감사합  
Hartelijk dank Thank you धन्यवाद Dě  
Mange takk Vă mulțumesc Gracias  
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