How will Europe's Pharmaceutical Policy and HTA Stakeholders Respond to Medicare Price Negotiation?

THE CHOICE INSTITUTE

School of Pharmacy

Moderator and Speakers

- Introduction and Background
  - Sean D. Sullivan, PhD, Professor, CHOICE Institute, University of Washington, Seattle WA
- Lessons from the First Ten Negotiated Drugs
  - Inmaculada Hernandez, PharmD, PhD, Professor, University of California, San Diego
- Will Medicare Price Negotiation Impact Innovation?
  - Jens Grueger, PhD, Affiliate Professor, CHOICE Institute, University of Washington, Seattle WA
- How will Europe respond to the IRA and EU Legislative Challenges?
  - Ansgar Hebborn, PhD, MBA; Head of Access Policy Affairs, Europe, Roche, Basel, Switzerland
- Moderated Discussion - All

Health Care Provisions in the Inflation Reduction Act of 2022

- Prescription Drug Inflation Rebates (Controls Price Increases)
  - Discounts to Medicare if prices rise faster than inflation (CPI-U) (implemented - Jan 2023)
- Medicare Part D Benefit Redesign
  - Caps on co-payment for insulin ($35)
  - $2,000 Cap on OOP (January 1, 2025)
- Medicare Price Negotiation Program
- Other Health Care Provisions
  - Extends Affordable Care Act subsidies, Expands access to vaccines for Adults in state Medicaid programs, Increases Part B payments for biosimilars, Extends low-income subsidies for Medicare patients

Policy Target for Medicare Price Negotiations

- **Part B** – Covers physician services and office-administered pharmaceuticals
  - $43.6 Billion – 2023 total spending (ASP)
- **Part D** – Outpatient pharmaceuticals, administered by private sector insurance companies
  - $230 Billion – 2023 gross spending (not accounting for rebates, discounts paid to PBMs and Part D Plans)
  - Top 10 drugs account for ~$50 Billion

Selection of Negotiation-Eligible Drugs

How Many Drugs?

- 10 Part D drugs published August 29, 2023 (MFP Implemented in 2026)
- Up to 15 Part D drugs selected - **February 1, 2025** (MFP Implemented in 2027)
- Up to 15 Part B and D drugs selected in 2026 (MFP Implemented in 2028)
- Up to 20 Part B and D drugs selected in 2027 and beyond (MFP Implemented in 2029)

10 drugs selected by CMS in August 2023 for direct price negotiations effective 2026

CMS list				
Rank	**Product**	**Company**	**TA/ Indication**	**GME (actual)**
1	Eliquis	BMS	Cardiovascular	$16.5B
2	Jardiance	BI	Cardiovascular, Diabetes	$7B
3	Xarelto[1]	Janssen	Cardiovascular	$6B
4	Januvia	MSD	Diabetes	$4.1B
5	Farxiga	AstraZeneca	Diabetes, Cardiovascular	$3.3B
6	Entresto	Novartis	Cardiovascular	$2.8B
7	Enbrel	Immunex (Amgen)	Immunomodulators	$2.8B
8	Imbruvica	Pharmacyclics (Abbvie)	Oncology	$2.6B
9	Stelara[1]	Janssen Biotech	Immunomodulators	$2.6B
10	Novolog, Fiasp	Novo Nordisk	Diabetes	$2.6B

Factors for Negotiating the Initial Offer and Final MFP

Manufacturer Specific Data for the Selected Drug

- Research and Development Costs and Recoupment
- Current Unit Costs of Production and Distribution
- Prior Federal Financial Support
- Patents, Exclusivities, and Approvals
- Market Data, Revenue, and Sales Volume Data
- non-Federal Avg Mfr Price (non-FAMP)

Factors for Negotiating the Initial Offer and Final MFP

Negotiation-eligible drugs will be subject to an MFP negotiated between CMS and the manufacturer, with 3 potential rounds of negotiation meetings. MFP will be adjusted annually based on CPI-U.

To formulate an initial offer, CMS intends to:

1) Identifying therapeutic alternative(s), if any, for the selected drug;
2) Use the Part D net price for the therapeutic alternative(s) that are Part D drugs and/or Part B average sales price (ASP) for the therapeutic alternatives that are Part B drugs to determine a starting point in developing an initial offer; and
3) Evaluate the clinical benefit of the selected drug (including compared to its therapeutic alternative(s)), including productivity, independence, quality of life, and whether the selected drug meets an unmet medical need and the selected drug's impact on specific populations;
4) Consider costs and outcomes, so long as the QALY is not part of the evidence package;
5) Apply further adjustments by the manufacturer specific factors outlined in the law to determine the initial offer price.
6) CMS will not make or accept any offers for the maximum fair price that is above the statutorily defined ceiling price in the law.

UC San Diego

Medicare Drug Price Negotiation: Insights from the First Ten

November 18, 2024

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Ceiling for Negotiation

- The Inflation Reduction Act establishes a cap (or ceiling) for the negotiated price

Ceiling is lower of

- Price based on minimum discount based on drug age (25% for 9-16 years, 60% for 17+years)
- Net price paid by plans after confidential discounts

(How much we were paying before new law)

Take-away #1

What set the ceiling for negotiation

(minimum statutory discount based on age vs net price)

mattered

Take-away #1: What Set the Ceiling Mattered

Minimum Statutory Discounts

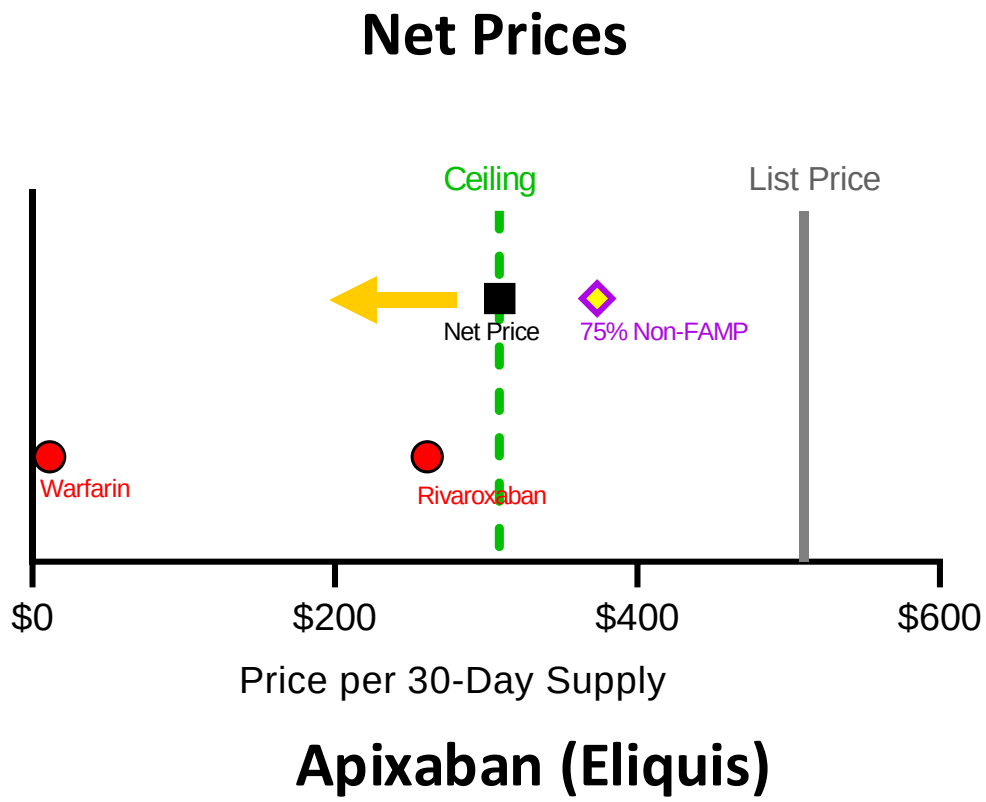
Ustekinumab (Stelara)

- 3 drugs: Stelara, Imbruvica, Enbrel
- In all 3 cases, negotiated price was the ceiling set by the minimum discount

Take-away #1: What Set the Ceiling Mattered

- Remaining 7 products
- Negotiation below the ceiling in most cases

Brand Name	Estimated Part D Rebates (2023)	MFP vs. Net Price	
		Absolute Difference	Relative Difference
Eliquis	**45%**	-11%	**-20%**
Jardiance	**63%**	-3%	**-9%**
Xarelto	**53%**	-9%	**-18%**
Farxiga	**68%**	0%	**0%**
Januvia	**70%**	-9%	**-30%**
Entresto	**27%**	-26%	**-36%**
Novolog/Fiasp	**76%**	0%	**0%**

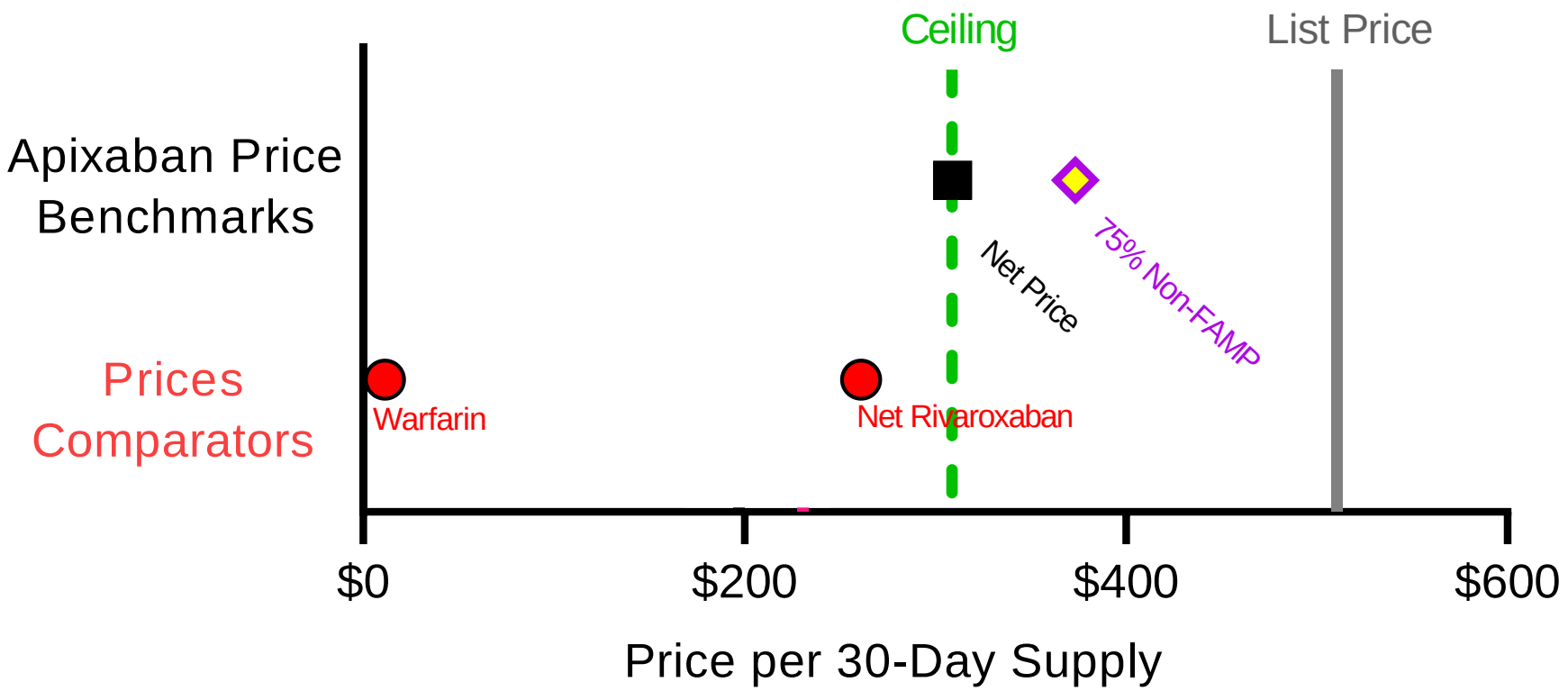


Take-away #2

Drugs with superior clinical profile had higher negotiated prices

Comparative effectiveness research data matters!

Apixaban (Eliquis) and Rivaroxaban (Xarelto)



Hernandez et al. Health Affairs Forefront 2024

Take-away #3

Negotiation generated modest savings (at best)

On “Savings”

- CMS press release stated that, if negotiated prices had been in effect in 2023, they would have resulted in:
  - $6bn in savings
  - Or 22% lower net spending

- This figure overestimates savings
  - Patent expirations
  - Likely decreases in net prices absent negotiation
  - Offset mandatory discounts

Hernandez et al. Health Affairs Forefront 2024

Take-away #4

The negotiation process had many elements of uncertainty,

but the outcome was largely predictable

Predictions vs Negotiated prices

Brand Name	Generic Name	Sullivan et al. Value in Health 2024 Prediction	MFP	Difference
		30-day supply		
Eliquis	Apixaban	$241.31	$231.00	-4%
Jardiance	Empagliflozin	$190.70	$197.00	3%
Xarelto	Rivaroxaban	$209.04	$197.00	-6%
Farxiga	Dapagliflozin	$155.04	$178.50	13%
Januvia	Sitagliptin	$156.48	$113.00	-38%
Entresto	Sacubitril/ valsartan	$366.72	$295.00	-24%
Stelara	Ustekinumab	$4,605.97	$4,695.00	2%
Enbrel	Etanercept	$624.29	$2,355.00	73%
		Unit		
Novolog/ Fiasp	Insulin aspart	$7.87	$8.39	6%
Imbruvica	Ibrutinib	$225.84	$257.37	12%

Sullivan et al. Value in Health 2024

Take-away #5

Negotiation marginally narrowed the gap between US and international prices

Negotiated Prices vs. International Prices

- On average, prices dropped from 4.2 times to 2.9 times those in other countries

Brand Name	Active Ingredient	Initial Net Price	Negotiated Price							Mean Ratio of Foreign to Initial Net Price	Mean Ratio of Foreign to Negotiated Price
Stelara	Ustekinumab	7,859.9	4,695.0	1341.6	1813.1	1219.9	2504.0	1730.0	1291.7	5.1	3.0
Enbrel	Etanercept	3,571.6	2,355.0	754.4	1135.4	646.5	974.3	1176.5	851.9	4.0	2.7
Entresto	Sacubitril / valsartan	458.4	295.0	138.9	181.9	156.6	150.4	145.1	117.9	3.1	2.0
Imbruvica	Ibrutinib	385.7	257.4	71.2	77.3	82.4	164.8	172.4	148.2	4.5	3.0
Eliquis	Apixaban	309.0	231.0	57.1	80.4	63.8	68.7	82.2	68.6	4.5	3.3
Xarelto	Rivaroxaban	261.3	197.0	51.2	70.7	58.7	86.4	86.4	65.0	3.9	2.9
Jardiance	Empagliflozin	251.7	197.0	33.5	67.1	38.3	50.6	50.9	47.2	5.5	4.3
Januvia	Sitagliptin	195.6	113.0	30.5	75.8	26.4	35.9	43.6	42.9	5.1	3.0
Farxiga	Dapagliflozin	193.8	178.5	33.5	64.9	38.6	41.9	48.9	47.1	4.4	4.1
Novolog / Fiasp	Insulin aspart	13.0	9.0	5.4	9.9	6.9	11.1	9.6	7.4	1.6	1.1

Wouters OJ et al. JAMA In Press

Take-away #6

First round not necessarily generalizable of future iterations of the negotiation process

Predictions 2nd Round

Rank	Brand Name	Generic Name	Manufacturer	Therapeutic Area	Gross Part D Spending in 2022	Projected 2023 Gross Part D Spending
1	Ozempic/ Rybelsus/ Wegovy	Semaglutide	Novo Nordisk	T2DM	$5603.1 M	$7476.7 M
2	Trelegy Ellipta	Fluticasone/ Umeclidinium/ Vilanterol	GlaxoSmithKline	COPD	$3340.1 M	$4259.3 M
3	Xtandi	Enzalutamide	Astellas Pharma	Prostate cancer	$2436.8 M	$2740.4 M
4	Ofev	Nintedanib	Boehringer Ingelheim	Lung diseases	$1763. M	$2077.3 M
5	Pomalyst	Pomalidomide	Bristol Myers Squibb	Blood cancers	$1743.9 M	$1887.6 M
6	Ibrance	Palbociclib	Pfizer Inc.	Breast cancer	$1948.3 M	$1822.3 M
7	Linzess	Linaclotide	Abbvie Inc.	Gastrointestinal disorders	$1581.7 M	$1804. M
8	Calquence	Acalabrutinb	AstraZenaca	Blood cancers	$1192.9 M	$1615.5 M
9	Creon	Pancrelipase	Abbvie Inc.	Pancreatic insufficiency	$1310.8 M	$1478.1 M
10	Breo Ellipta	Fluticasone / Vilanterol	GlaxoSmithKline	COPD	$1427.8 M	$1408.8 M
11	Tradjenta	Linagliptin	Boehringer Ingelheim	T2DM	$1326.6 M	$1349. M
12	Janumet	Metformin/ Sitagliptin	Merck and Co., Inc.	T2DM	$1212.9 M	$1246.2 M
13	Austedo	Deutetrabenazine	Teva	Neurological diseases	$890.4 M	$1055.5 M
Drugs with Uncertain Negotiation Status						
	Tagrisso	Osimertinib	AstraZeneca	NSCLC	$1081.3 M	$1217.1 M
	Victoza	Liraglutide	Novo Nordisk	T2DM	$1557.8 M	$1399.3 M
	Xifaxan	Rifaximin	Salix Pharmaceuticals	Antibacterial	$969.5 M	$1026.4 M
	Humalog	Insulin lispro	Eli Lilly and Co	DM	$2067.7 M	$954.3M
	Epclusa	Sofosbuvir/ Velpatasvir	Gilead Sciences	Hepatitis C	$899.9 M	$934.8 M
	Xeljanz	Fofacitinib	Pfizer Inc.	Immunological diseases	$886.5 M	$901.6 M
	Venclexta	Venetoclax	Abbvie Inc.	Blood cancers	$767.9 M	$876.9 M

Cousin E et al. JMCP 2024

Thank you!

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Impact of Medicare Drug Price Negotiations on Global Access Strategies and Innovation

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ISPOR Europe, Barcelona, November 2024

During April and May 2024, we conducted **interviews with senior Access leaders from 11 major pharma companies:**

- 5 headquartered in the US
- 5 headquartered in Europe
- 1 headquartered in Japan

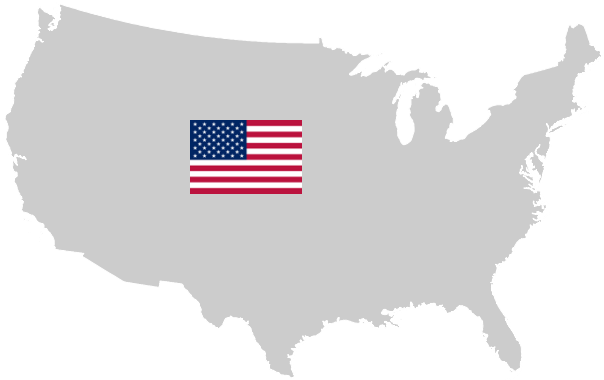
Discussions around the impact of Inflation Reduction Act and Drug Price Negotiations on:

- Implications for global access strategies and innovation
- Operational implications
- Specific considerations for Orphan Drugs

IRA has further strengthened the focus on the US in portfolio decisions

PAST

Traditionally the focus of the US has been on fast regulatory approval with competitive label



FUTURE

- IRA will encourage consideration of US access needs in strategic decisions around LCM and evidence generation
- "The US may look more like Europe", where comparative effectiveness and economic impact need to be translated into a compelling value narrative
- However, major difference in when comparative effectiveness is assessed:
  - EU: at launch based on clinical trials
  - US: several years later based on RWE

Most companies have introduced specific access considerations in their global portfolio and asset evaluations to reflect IRA

Indication sequence	• Selection of initial indication • Selection and timing of subsequent indications
TA/population focus	• Large impact expected in oncology • Expected use of the product in Medicare populations
Competitor dynamics & LCM	• Timing of price negotiations for competitor products • Future modifications of the product presentation or administration

Differentiation based on strong clinical evidence will become even more important

Source of differentiation	IRA impact
Market position & timing	• Increased importance of going for first in class (FIC) or best in class (BIC) products • Reduced appetite to invest into less differentiated assets that are coming late to market
Life Cycle Management	• Increased interest in separating assets into distinct entities (and fixed combinations) optimized for specific indications & populations • Less incentive to explore smaller indications later in life cycle
Evidence generation	• Increased importance of comparative effectiveness evidence in the US, in particular in elderly population

IRA has reduced the incentives for orphan drugs that address unmet needs in rare diseases

TODAY

~50%

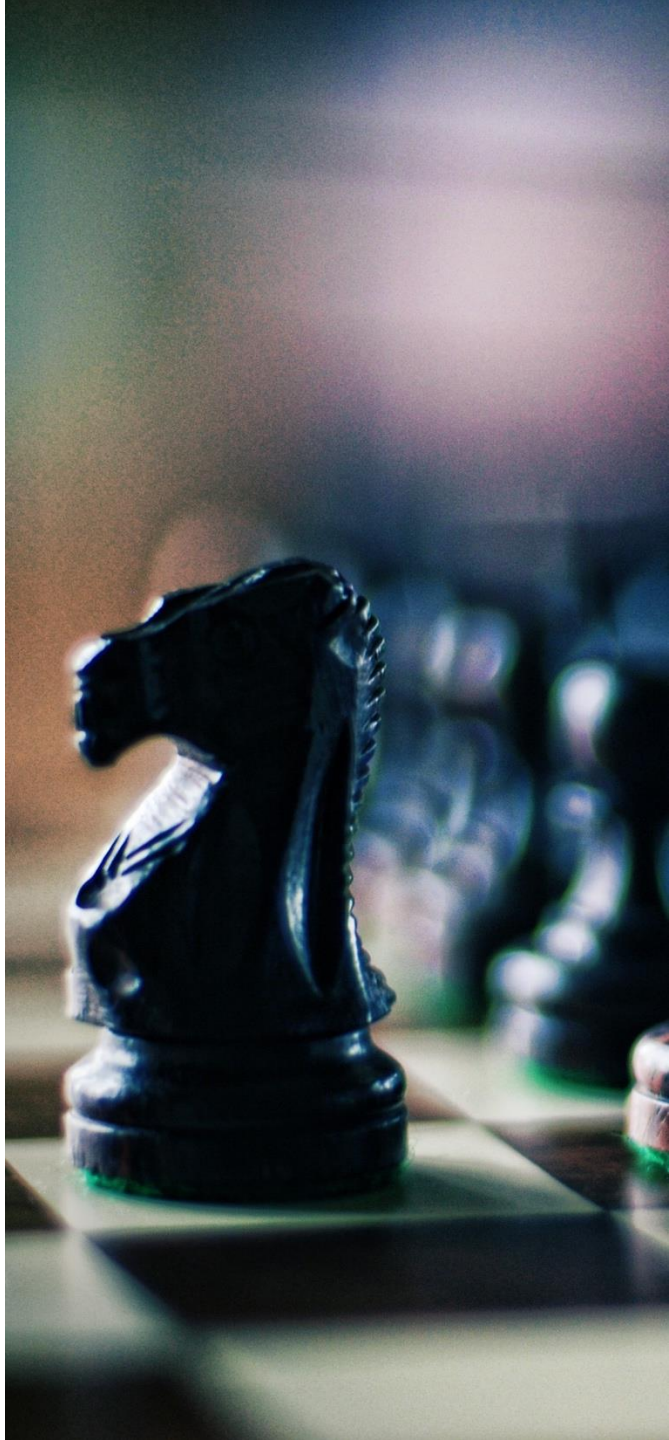
New drug approvals are orphan drugs

EXPECTED POST-IRA EVOLUTION

- The IRA Orphan Exemption only applies to drugs that are approved for a single orphan indication
- Companies will prioritize larger indications (at least in the US) to start the clock
- Orphan indications, which are often developed at a later life cycle stage, will be less attractive

Impact of IRA on innovation

- Less revenue may translate into lower development budgets
- First in class and best in class medicines remain highly attractive
- Orphan drugs and new indications late in life cycle will suffer



Moderated Discussion