

**2nd BCLT
Advanced Life Sciences Institute**

**Licensing and Deals Update:
Universities and Private
Parties**

May 2024

The Inflation Reduction Act: Mechanics and New Developments

DISCLAIMER

The views expressed herein are solely those of the presenter and do not represent the views of the presenter's employers.

The information presented is for general informational purposes only and should not be construed as specific legal advice.

The Inflation Reduction Act: Mechanics and New Developments

- Enacted on August 16, 2022
- Replacement for the Build Back Better Act
 - IRA introduced via amendment to BBB on August 6, 2022
 - Passed by Congress six days later
- Key provisions:
 - Reforms to ostensibly lower prescription drug prices for drugs without generic or biosimilar competition
 - Continued funding of expanded Affordable Care Act subsidies for a further 3 years
 - Numerous non-pharmaceutical related changes (taxes, climate change, etc.)

The Inflation Reduction Act: Mechanics and New Developments

- IRA provides a framework for direct negotiation of prices paid by Medicare
- Applies to drugs that have no generic or biosimilar competition after: (a) 9 years post FDA approval for small molecules; and (b) 13 years post FDA approval for biologics
- Drugs considered for negotiation will include those on the top 50 spending list for Medicare
- Medicare would start the negotiation process in 2023 and negotiated prices would be effective in 2026
- 10 Medicare Part D drugs would be selected for direct negotiation initially

The Inflation Reduction Act: Mechanics and New Developments

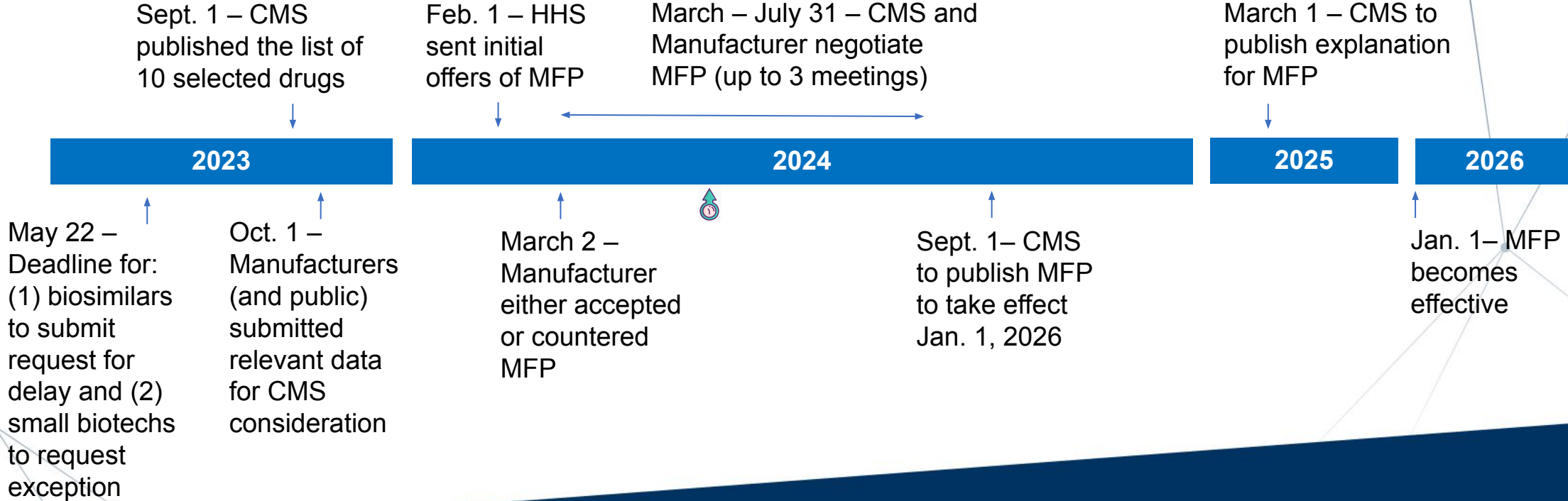
- Price **ceiling** for negotiation to reach “Maximum Fair Price” (“MFP”):
 - 75% of non-federal Average Manufacturer Price (“AMP”) for drugs between 9 and 12 years past FDA approval
 - 65% of the non-federal AMP for drugs between 12 and 16 years past FDA approval
 - 40% of the non-federal AMP for drugs on the market over 16 years past FDA approval, or the net price of the drug, whichever is lower
 - AMP = average price paid to the manufacturer for the drug in the United States by wholesalers for drugs distributed to retail community pharmacies and retail community pharmacies that purchase drugs directly from the manufacturer
 - Net price = list price minus all price concessions and rebates

The Inflation Reduction Act: Mechanics and New Developments

Selection	Number of Drugs	Program	Price Effective Date	Cumulative Total
CY23	10	Medicare Part D	CY26	10
CY25	15	Medicare Part D	CY27	25
CY26	15	Medicare Part B & D	CY28	40
CY27	20	Medicare Part B & D	CY29	60
CY28	20	Medicare Part B & D	CY30	80
CY29	20	Medicare Part B & D	CY31	100

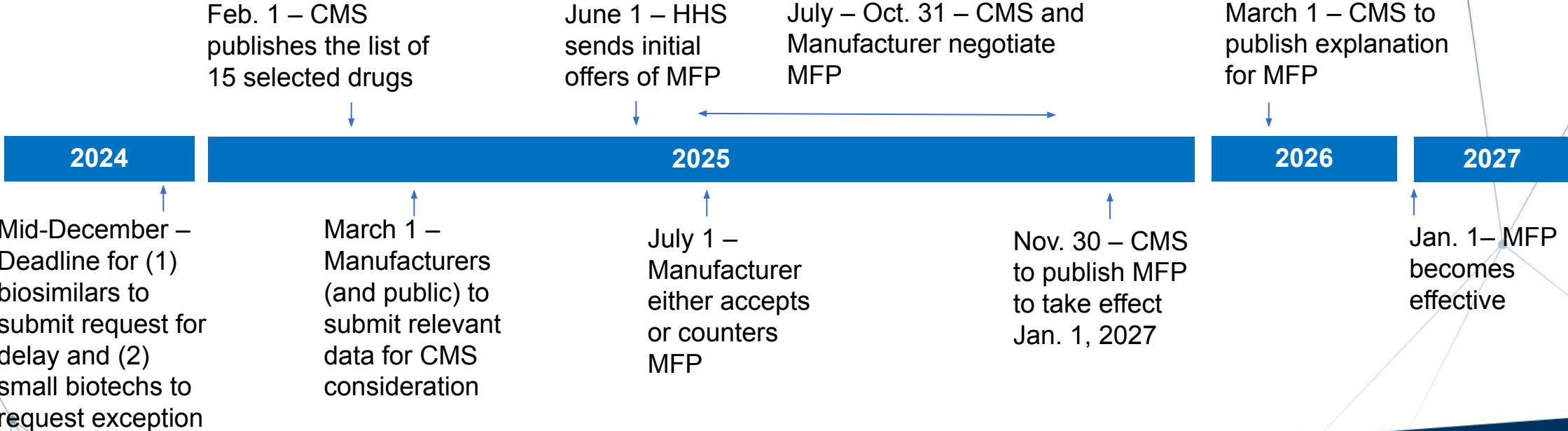
The Inflation Reduction Act: Mechanics and New Developments

Timeline for Initial Price Applicability Year 2026



The Inflation Reduction Act: Mechanics and New Developments

Timeline for Initial Price Applicability Year 2027



The Inflation Reduction Act

Case	Court	Status
<u>Janssen Pharmaceuticals, Inc. v. Becerra et al.</u>	3 rd Circuit (previously D.N.J.)	On appeal, CMS win at district court
<u>Bristol Myers Squibb Co. v. Becerra et al.</u>	3 rd Circuit (prev. D.N.J.)	On appeal, CMS win at district court
<u>AstraZeneca Pharmaceuticals LP et al. v. Becerra et al.</u>	3 rd Circuit (prev. D. Del.)	On appeal, CMS win at district court
<u>National Infusion Center Association et al. v. Becerra et al.</u>	5 th Circuit (prev. W.D. Texas)	On appeal, CMS win at district court
<u>Novo Nordisk et al. v. Becerra et al.</u>	D.N.J.	Argued, decision pending
<u>Novartis Pharmaceuticals Corporation v. Becerra et al.</u>	D.N.J.	Argued, decision pending
<u>Boehringer Ingelheim Pharmaceuticals, Inc. v. U.S. Department of Health and Human Services et al.</u>	D. Conn.	SJ fully briefed, hearing scheduled for June 20
<u>Merck et al. v. Becerra et al.</u>	D.D.C.	SJ fully briefed, decision pending
<u>Dayton Area Chamber of Commerce et al. v. Becerra et al.</u>	S.D. Ohio	Preliminary injunction denied, case ongoing
<u>Astellas Pharma US, Inc. v. U.S. Department of Health and Human Services et al.</u>	N.D. Illinois	Voluntarily dismissed

Thank you!

2024 Advanced Life Sciences Institute Agenda: [LINK](#)