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Potential Impact of Price Negotiation Provision in the Inflation Reduction Act

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OVERVIEW OF INFLATION REDUCTION ACT (IRA)

Signed into law on August 16, 2022.

Slimmed down version of the Build Back Better bill.

The law aims to curb inflation by reducing the deficit, lowering prescription drug prices, and investing into domestic energy production while promoting clean energy.

The main provisions include:

Creation of a 15% corporate minimum tax rate;

Prescription drug price reform;

IRS tax enforcement;

Affordable Care Act subsidy extension; and

Energy security and climate change investments.

BACKGROUND RELEVANT TO PRICE NEGOTIATION PROVISION

Medicare Part B program covers drugs administered by physicians.

Prior to the IRA, the Secretary of HHS did not negotiate prices for drugs covered under Part B.

Instead, Medicare reimbursed providers based on a formula set at 106% of the average sales price.

Medicare Part D program covers retail prescription drugs.

Under Part D, Medicare contracts with private plan sponsors to provide a prescription drug benefit.

Prior to the IRA, the Secretary of HHS was not allowed to interfere with price negotiations between drug manufacturers and prescription drug plans.

UNDERSTANDING THE PRICE NEGOTIATION PROVISION

This provision requires the federal government to negotiate prices for some drugs covered under Medicare.

The Secretary of HHS will negotiate prices with drug companies for select, single-source, brand-name small-molecules drugs and biologics that are covered under Medicare Part D (starting in 2026) and Part B (starting in 2028).

The number of drugs subject to price negotiation will be 10 Part D drugs for 2026, another 15 Part D drugs for 2027, another 15 Part D and Part B for 2028, and another 20 Part D and Part B drugs for 2029 and later years.

These drugs will be selected from among the 50 drugs with the highest total Medicare Part D and Part B spending.

The number of drugs with negotiated prices available will accumulate over time.

Selection of biologic drugs for negotiation can be delayed by up to two years if a biosimilar product is likely to enter the market in that time.

CATEGORIES OF DRUGS EXCLUDED FROM NEGOTIATION

Drugs that have a generic or biosimilar available

Drugs that are less than 9 years (for small-molecule drugs) or 13 years (for biological products) from their FDA-approval or licensure date

"Small biotech drugs" (until 2029), defined as those which account for 1% or less of Part D or Part B spending and account for 80% or more of spending under each part on that manufacturer's drugs

Drugs with Medicare spending of less than $200 million in 2021 (increased by the CPI-U for subsequent years)

Drugs with a single indication covered by orphan designation

All plasma-derived products

MAXIMUM FAIR PRICE

The IRA establishes an upper limit for the negotiated price (the "maximum fair price") for a given drug.

The limit is the lower of the drug's enrollment-weighted negotiated price (net of all price concessions) for a Part D drug, the average sales price for a Part B drug, or a percentage of a drug's non-federal average manufacturer price:

75% for small-molecule drugs and vaccines more than 9 years but less than 12 years beyond approval;

65% for drugs between 12 and 16 years beyond approval or licensure; and

40% for drugs more than 16 years beyond approval or licensure.

IRA DRUG PRICE NEGOTIATION ROADMAP

SEP 1
CMS Names First 10 Drugs for Negotiation

OCT 1
Deadline for Companies to Agree to Negotiation Process

FEB 1
CMS Initial Maximum Fair Price Offers

MAR 2
Deadline for Counteroffer

SEP 1
CMS Sets Maximum Fair Prices, Effective in 2026

FIRST 10 DRUGS SUBJECT TO PRICE NEGOTIATION

Drug	Treats	Company	Partner	Medicare spend ($billions)	Medicare enrollees treated
Eliquis	Blood clotting	Bristol Myers Squibb	Pfizer	16.5B	3.7M
Jardiance	Diabetes	Boehringer Ingelheim	Eli Lilly	7.1B	1.6M
Xarelto	Blood clotting	Johnson & Johnson		6B	1.3M
Januvia	Diabetes	Merck		4.1B	869K
Farxiga	Diabetes	AstraZeneca		3.3B	799K
Entresto	Heart failure	Novartis		2.9B	587K
Enbrel	Autoimmune conditions	Amgen		2.8B	48K
Imbruvica	Cancer	AbbVie	Johnson & Johnson	2.7B	20K
Stelara	Psoriasis and arthritis	Johnson & Johnson		2.6B	22K
Insulin Aspart	Diabetes	Novo Nordisk		2.6B	777K

Sources: White House and Centers for Medicare & Medicaid Services
Note: Data on Medicare spend and enrollees treated is for the period June 2022 to May 2023

ALL COMPANIES MANUFACTURING SELECTED DRUGS AGREED TO NEGOTIATION

October 3, 2023 HHS Press Release

Biden-Harris Administration Moves Forward with Medicare Drug Price Negotiations to Lower Prescription Drug Costs for People with Medicare

10 companies manufacturing some of the costliest prescription drugs to participate in first-ever direct negotiations with Medicare

Today, the Biden-Harris Administration announced that all 10 drug companies whose drugs were selected for price negotiation with Medicare for the first cycle of the program have decided to participate in those negotiations. These companies manufacture some of the costliest and most commonly used prescription drugs.

CRITERIA TO CONSIDER DURING PRICE NEGOTIATION

The manufacturer's research and development costs, including the extent to which the manufacturer has recouped these costs

The current unit costs of production and distribution

Federal financial support for novel therapeutic discovery and development related to the drug

Data on pending and approved patent applications, exclusivities, and certain other applications and approvals

Market data and revenue and sales volume data in the US

Evidence about alternative treatments

CONSEQUENCES OF FAILURE TO COMPLY

Drug companies that do not comply with the negotiation process will be levied an excise tax.

The tax starts at 65% of a product's sales in the U.S. and increases by 10% every quarter to a maximum of 95%.

- Results in penalty ranging from 186% to 1900% of drug's total national sales revenue

As an alternative to paying the tax, manufacturers can choose to withdraw all of their drugs from coverage under Medicare and Medicaid.

Additionally, manufacturers that refuse to offer an agreed-upon negotiated price will pay a civil monetary penalty equal to 10 times the difference between the price charged and the maximum fair price.

POTENTIAL IMPLICATIONS: INNOVATION AND PORTFOLIO STRATEGY

Under the IRA, biologics will be afforded more time on the market than small-molecule drugs before becoming eligible for price negotiation (13 versus 9 years). This extra time may cause investors and other stakeholders to gravitate more towards companies with biologics rather than small-molecule drugs.

The price negotiation provision may disincentivize additional research because future indications will have less time to generate returns.

Orphan drugs that treat a single rare disease are exempted from price-setting negotiations, which may disincentivize manufacturers from seeking additional indications.

Manufacturers may seek to rebalance their portfolios by moving away from diseases that predominantly affect elderly patients and therefore where Medicare represents a large volume of prescriptions.

The IRA may discourage using federal funding for drug research because receiving such funding is a factor that gets considered in setting the maximum fair price.

POTENTIAL IMPLICATIONS: LITIGATION AND SETTLEMENT

Manufacturers may be incentivized to seek settlements and grant licenses to allow generic and biosimilar companies to enter the market shortly before the reference drug is eligible for negotiation. Doing so will require balancing the benefits and risks, including:

Benefits

- Prevailing in patent infringement suit may no longer be as valuable if reference drug is subject to price negotiation provision.
- Early settlement would eliminate litigation costs.

Risks

- Early settlement may cause the FTC to examine whether the agreement is anticompetitive or otherwise violates antitrust and consumer protection laws.
- Allowing early market entry of a competitor through settlement may drive down the branded drug price to a number that is less than what would have otherwise been set as the maximum fair price after negotiation.
- Settling with one generic or biosimilar may not prevent additional patent challenges (and the associated litigation expenses) from other competitors seeking to enter the market.

CHALLENGES TO IRA DRUG PRICE NEGOTIATION PROVISION

Merck & Co. v. Becerra, 23-cv-01615 (D.D.C. June 6, 2023)

Dayton Area Chamber of Commerce v. Becerra, 23-cv-00156 (S.D. Oh. June 9, 2023)

BMS v. Becerra, 23-cv-03335 (D.N.J. June 16, 2023)

NICA v. Becerra, 23-cv-00707 (W.D. Tx. June 21, 2023)

Astellas Pharma US v. Department of Health and Human Services (HHS), 23-cv-04578 (N.D. Ill. July 14, 2023)

Janssen Pharmaceuticals, Inc. v. Becerra, 23-cv-03818 (D.N.J. July 18, 2023)

Boehringer Ingelheim Pharmaceuticals, Inc. v. Department of Health and Human Services (HHS), 23-cv-01103 (D. Conn. Aug. 18, 2023)

AstraZeneca Pharmaceuticals LP v. Becerra, 23-cv-00931 (D. Del. Aug. 25, 2023)

Novartis Pharmaceuticals Corp. v. Becerra, 23-cv-14221 (D.N.J. Sept. 1, 2023)

Novo Nordisk Inc. v. Becerra, 23-cv-20814 (D.N.J. Sept. 19, 2023)

STATUS OF LEGAL CHALLENGES

Case	Status
Merck & Co. v. Becerra	Parties filed cross-motions for summary judgment with briefing still in progress.
Dayton Area Chamber of Commerce v. Becerra	Defendants moved to dismiss for lack of subject matter jurisdiction. Plaintiffs filed motion for preliminary injunction. The Court denied both motions. Plaintiffs are expected to file motion for summary judgment in December.
BMS v. Becerra	Parties filed cross-motions for summary judgment with briefing still in progress.
NICA v. Becerra	Defendants moved to dismiss for lack of subject matter jurisdiction, with the motion fully briefed. Plaintiffs filed motion for summary judgment with briefing still in progress.
Astellas Pharma US v. HHS	Plaintiffs voluntarily dismissed complaint.

STATUS OF LEGAL CHALLENGES (CONT'D)

Case	Status
Janssen Pharmaceutical v. Becerra	Parties filed cross-motions for summary judgment with briefing still in progress.
Boehringer Ingelheim v. Becerra	Plaintiffs filed motion for summary judgment with briefing still in progress. Defendants are expected to file cross motion for summary judgment in December.
AstraZeneca v. Becerra	Parties filed cross-motions for summary judgment with briefing still in progress.
Novartis v. Becerra	The parties are expected to file cross motions for summary judgment beginning in November.
Novo Nordisk v. Becerra	The parties are expected to file cross motions for summary judgment beginning in December.

CONSTITUTIONAL CHALLENGES TO PRICE NEGOTIATION PROVISION

The negotiation process violates the First Amendment because it coerces manufacturers into stating they agree to the prices that the government has dictated and those prices and fair.

The price negotiation provision violates the Fifth Amendment's due process clause by failing to provide for judicial review for pricing decisions.

The price negotiation provision violates the Fifth Amendment's takings clause because it allows Medicare to obtain manufacturers' patented drugs without paying fair market value under the threat of serious penalties.

CONSTITUTIONAL CHALLENGES TO PRICE NEGOTIATION PROVISION (CONT'D)

The negotiation process violates the Eighth Amendment by levying an excessive fine if drugmakers refuse to negotiate and continue selling their products to the Medicare market.

The price negotiation provision violates the Nondelegation Doctrine because Congress delegated too broad of discretionary authority to HHS.

The price negotiation provision violates the Spending Clause because the IRA does not condition federal Medicare reimbursement on a manufacturer's compliance with the statute.

POTENTIAL GOVERNMENT DEFENSES

Some Plaintiffs lack Article III standing.

The negotiation program is not a taking because participation is voluntary and there is no physical taking.

The negotiation program does not compel manufacturers to speak because negotiation agreements are commercial agreements.

Manufacturers are not required to pay the penalty for refusing to participate because they have the option withdrawing all of their drugs from coverage under Medicare and Medicaid.

The negotiation program is a valid condition on federal funds.

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