Applications for Community Oncology

Business of Oncology

December 12, 2024

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Business of Oncology Symposium

- Provide insights on the current landscape, challenges, and opportunities facing community oncology practices today
- Explore anticipated trends in healthcare delivery, technology, and policy that will shape oncology care in the near future
- Inform network about critical legal and regulatory changes impacting community oncology, ensuring compliance and readiness for upcoming shifts
- Examine how the IRA is influencing pharmaceutical innovation, drug pricing, and accessibility, and its implications for patient care in oncology

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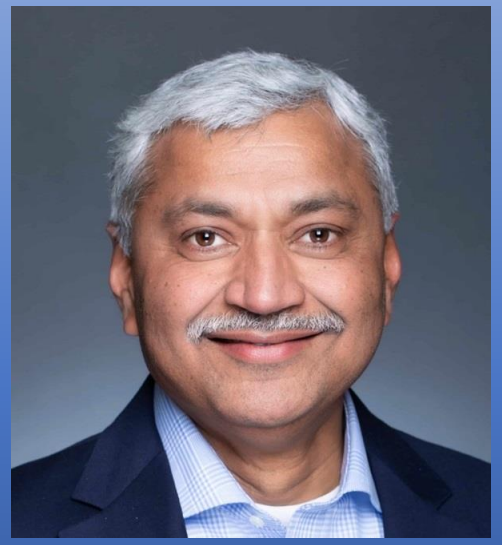

Bimal Patel, MD

Epic Care

Antioch, CA

Edith A. Perez, MD

Mayo Clinic

San Francisco, CA

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2024 Business of Oncology Symposium

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2025 Healthcare Projections	David Kemps, Executive Director Government Relations Will Boffa *Morgan Stanley*	7:55 – 8:25 PM
Compliance Guidance for Community Oncology Practices- Challenges and Opportunities	John Jones Joseph Harrington Brian Wong *Goodwin Procter, LLC*	8:25 – 8:50 PM
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State of Community Oncology

- Oncology landscape consolidation still in full-force
- Increasing Clinical Data: Need for clinical specialization in community setting
- Reducing margins on medication and resulting economic challenges
- Positioning community oncology for continued relevance and success

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Compliance Guidance for Community Oncology Practices- Challenges and Opportunities

John Jones
Joseph Harrington
Brian Wong

December 2024

Significant Challenges in the Oncology Community

- Healthcare Regulations, including privacy and security, reimbursement, fraud and abuse and quality standards (e.g., 2024 updated radiation oncology billing guidelines by CMS)
- Navigating the complexities of modern cancer treatment and range of therapies, including radiation, surgery, chemotherapy and immunotherapy, as well as targeted therapies
- High cost of drugs and supplies, operational expenses and complex reimbursement policies of payors
- Staying current with the development and advancement of complex treatment modalities, including integration of these new treatments in practice to benefit patients
- A focus on patient-centered care and care coordination with a focus on improving outcomes and ensuring access to the latest treatment options, including clinical trials
- Significant administrative burdens, including complex medical billing and coding and technology investment to reduce errors and streamline operations
- Inflation Reduction Act and impact of Medicare Price Negotiations and implementation of Maximum Fair Price, including administrative burdens (managing separate inventory for Medicare beneficiaries), extended timeframe to float difference between acquisition costs and reimbursement (up to two additional months), and decrease in add-on reimbursement because it would be based on negotiated MFP of drug versus current average sales price

Oncology Trends and Opportunities

Global Oncology Trends: 2024*

- Global spending on cancer medicine increased to $223 billion in 2023; projected to reach 409 billion in 2028
- In 2023 – 25 oncology novel active substances launched globally, but large geographic variations exist in availability
- Cancer incidence expected to rise significantly through 2050 (esp. in lower income countries), potentially by more than 12 million new cases annually to 32 million
- More than 2,000 new clinical trials started in 2023 with novel modalities

** Note: Report from IQVIA Institute for Human Data Science, May 28, 2024*

Opportunities for Community Oncology

- Consider expanding operations to provide specialty infusion
- With 2025 reimbursement cuts estimated to be 3.98% under CMS Physician Fee Schedule – Care Plan Oversight services may be available for home health and hospice patients
- Add-on Code 62211 reported with an E&M visit – January 16 Fact Sheet issued by CMS – not appropriate for every visit – 62211 captures the inherent complexity of the visit that's derived from the longitudinal nature of the practitioner and patient relationship. Must provide on-going medical care related to a patient's single, serious condition, or complex condition and be documented
- Affiliations and Joint Ventures for ancillary services (e.g., infusion)

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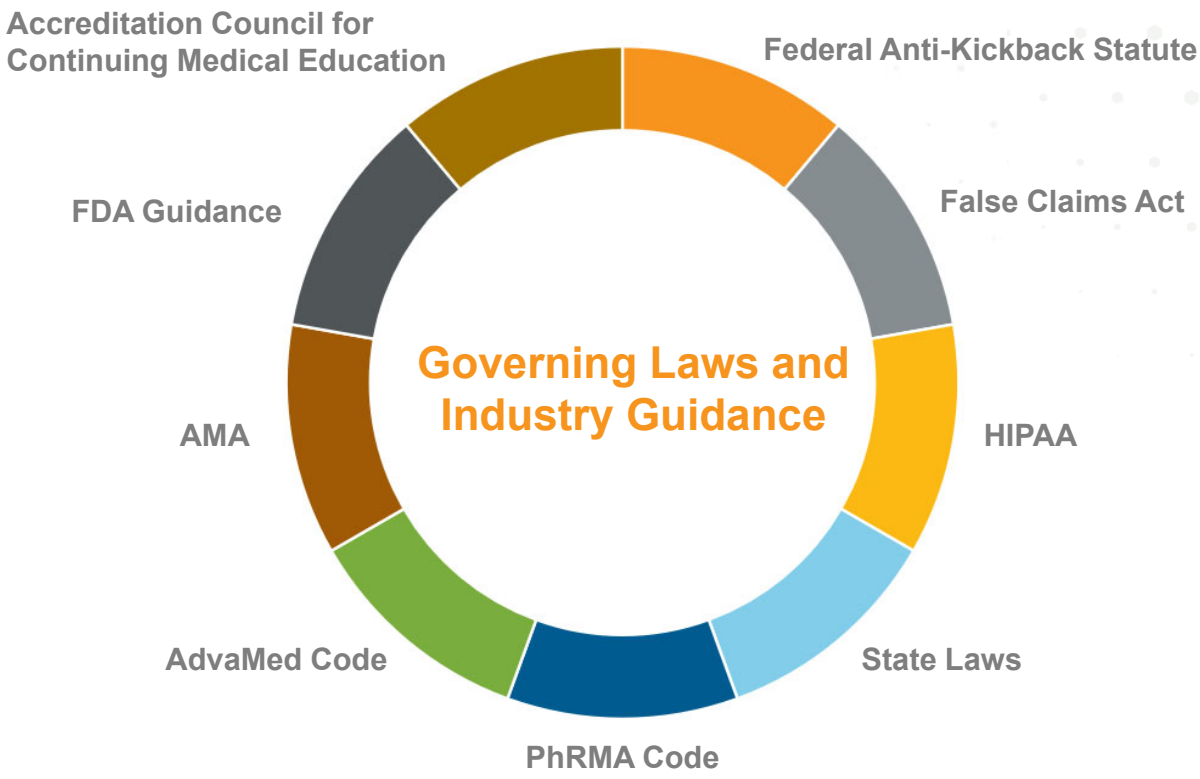
The Regulatory Landscape and Enforcement



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The Regulatory Landscape – HHS Enforcement Arm

Office of Inspector General

MISSION

Under the authority of the IG Act, we improve HHS programs and operations and protect them against fraud, waste, and abuse. By conducting independent and objective audits, evaluations, and investigations, we provide timely, useful, and reliable information and advice to Department officials, the Administration, the Congress, and the public.

VISION

- ✓ Working with management, we will ensure effective and efficient HHS programs and operations
- ✓ Working with decision-makers, we will minimize fraud, waste and abuse in HHS programs
- ✓ Working with our talented and motivated staff, we will manifest the highest standards as a Federal OIG

VALUES

- ✓ Quality products and services that are timely and relevant
- ✓ A service attitude that is responsive to the needs of decision-makers
- ✓ Fairness, integrity, independence, objectivity, proficiency, and due care in performing our work
- ✓ Teamwork and open communication among OIG components
- ✓ A positive environment that supports our personal and professional needs and encourages us to be innovative and reach our full potential

Fraud, Waste & Abuse – Hot Topics of Focus & Settlements & Cases

- ✓ Billing and Coding – use of E/M
- ✓ Excessive Patients
- ✓ Relationship with Manufacturers
  - – HCP Support
  - – Marketing Schemes
  - – Sales support for products vs. education
- ✓ Physician Consulting Arrangements
- ✓ Data Arrangements
- ✓ Patient Support Services
- ✓ Clinical Trials
- ✓ Grants
- ✓ Financial Relationships with Referral Sources

- ✓ Fiscal year 2023 – Highest number of settlements and judgments ever reported by DOJ under the False Claims Act - $1.8 billion from healthcare sector
- ✓ Fiscal year 2022 – HHS Fraud Report
  - – Federal prosecutors filed more than 419 criminal cases
  - – DOJ opened more than 774 civil cases
  - – HHS Office of Inspector General investigations into Medicare and Medicaid fraud resulted in 661 criminal actions and 726 civil actions

Fraud, Waste and Abuse – Enforcement Activity on the Rise

Instructive Cases and Settlements

- **August 26, 2024** – FCA suit filed by USAO for the District of Montana against a Montana oncologist alleging busy schedule led to excessive claims. Theory of case (which is aggressive because E&M codes are complexity codes, not time codes) is the amount of time (or lack of time) oncologist spent with patients relative to standard practice
- **April 2, 2024** – Oncology San Antonio, PA has agreed to pay $1.3 million and CorePath Laboratories, PA has agreed to pay $2,746,275.22 (plus accrued interest) in civil settlements with the US and State of Texas for alleged violations of FCA where CorePath (that provided in-office bone marrow biopsy services) agreed to pay $115 for each biopsy referred by Oncology San Antonio
- **Fall 2023** – Frederick Oncology and Hematology Associates in Maryland settled for approximately $1 million in allegations that the practice improperly submitted E&M claims using CPT modifier 25 (which can only be used when there is a separate and distinct E&M service the same day as another procedure or service)
- **2020** – The H. Lee Moffitt Cancer Center and Research Institute Hospital in Tampa self-disclosed to the government that it had been inappropriately billing Medicare and other federal healthcare programs for over six years for patient care items and services during clinical trials and settled for $19.5 million

Fraud, Waste and Abuse – What is the Risk?

Applicable Federal Statutes

Federal Anti-Kickback Statute

- Basic prohibition
- Safe Harbors
- Penalties
  - Civil fines - $50K per violation
  - Criminal fines - $25K per violation
  - Imprisonment
  - Treble damages

False Claims Act

- Government's weapon of choice
- Basic prohibition - "knowingly" making false claims
- Penalties
  - CMP - $5,500 - $11,000 each claim
  - Treble damages
  - Exclusion
- Qui tam actions
- False certification theory

HIPAA

- New categories of CMP violations:
  - Upcoding
  - Billing medically unnecessary services
  - Patient inducements
- Criminal laws applicable to any health care benefit program, not just FHCPs:
  - Health care fraud
  - Theft or embezzlement
  - False statements
- BBA of 1997
  - Tightened mandatory and permissive exclusions

Stark

- Penalties
  - Disgorgement
  - Civil Penalties
  - Exclusion from Government Programs
  - FCA - Treble Damages
  - Loss of License (States) - Physician / Facilities
- Supports FCA Claim

Fraud, Waste and Abuse – What is the Risk?

Applicable Federal Enforcement Statutes

Federal Anti-Kickback Statute

- Criminal Statute
- Intent Based Statute
- Patient Protection and Affordable Care Act of 2010
  - No Knowledge of Statute or Intent to Violate
- Elements:
  - "Knowing and Willful" - offer or payment or solicitation or receipt
  - Remuneration - anything more than *de minimis* value
  - Referrals - in return for referring or arranging for referrals
  - Government Programs - Medicare and Medicaid
- Greber - "One Purpose" test
- Safe Harbors
- Failure to Satisfy Safe Harbor
  - Does not equate to a violation of AKS
  - Totality of circumstances/aggravating factors

- Safe Harbors
- Failure to Satisfy Safe Harbor
  - Does not equate to a violation of AKS
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- Purposes:
  - Prevent over-utilization
  - Prevent increase in costs of government programs
  - Prevent interface with patient freedom of choice
  - Prevent anti-competitive practices
- Why do we care?
- Costs on Non-Compliance
  - Fines and Penalties
  - Suspension / Exclusion Programs
  - Disgorgement
  - Imprisonment

Fraud, Waste and Abuse – What is the Risk?

Applicable Federal Enforcement Statutes

- False Claims Act
  - Knowingly presents, or causes to be presented, a false or fraudulent claim for payment
    - Civil Fines
    - Treble damages
    - Claims submitted and resulting in violation of AKS constitutes a false claim (f/k/a False Certification Theory)
    - Result: Increase in FCA violations primarily on entities that participate in provision of products and services reimbursable under government programs, but which do not submit claims (HIT Company)
    - Increase in *qui tam* actions

Fraud, Waste and Abuse – What is the Risk?

Applicable Federal Enforcement Statutes

- Stark:
  - Payment Rule
  - If implicate Statue, strict compliance with an exception required
  - Strict liability for failure to comply
- Stark Prohibition

  If a **physician** (or immediate family member) has a **financial relationship** with entity, then the physician may not make a **referral** to the entity for the furnishing of **designated health services** and the entity may not present a cause to be presented a claim for such designated health services unless an exception is satisfied.

Fraud, Waste and Abuse – How to Minimize Risk?

Lessons Learned → **Billing and Coding and Reimbursement is very complex**

- Physicians did not go to school to be billers and coders
- Practice needs to adopt robust compliance program and billing policies – many of these issues could be avoided

How to Minimize Risk of Enforcement? → **Develop and Implement Corporate Compliance Plan**

Origin

- 1991 Federal Sentencing Guidelines and CIAs
- Mitigation of damages in enforcement action

Purpose

- Foster overall ethical behavior of organization
- Promote adherence to applicable federal and state laws
- Ensure accurate, complete and correctly documented billing
- Minimize organization's exposure to fines and penalties

How to Minimize Risk of Enforcement? → **Use OIG Model Compliance**

- October 2000 - Physician Practices
- 7 Elements
- Tailored to needs and resources of organization
- Part of overall mission to foster ethical behavior
- Reaffirm organization's commitment to upholding the law

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Fraud, Waste and Abuse – Effective Compliance Program

OIG Compliance Program for Individual and Small Group Practices

✓ Components of an Effective Compliance Program

- Conducting internal monitoring and auditing
- Implementing compliance and practice standards
- Designating a compliance officer
- Conducting appropriate training and education
- Responding appropriately to detected offenses and developing corrective action
- Developing open lines of communication
- Enforcing disciplinary standards through well-publicized guidelines

Q+A

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Effects of Inflation Reduction Act (IRA) on Drug Development

Edith A. Perez, MD.

Professor Emeritus

Mayo Clinic

December 12, 2024

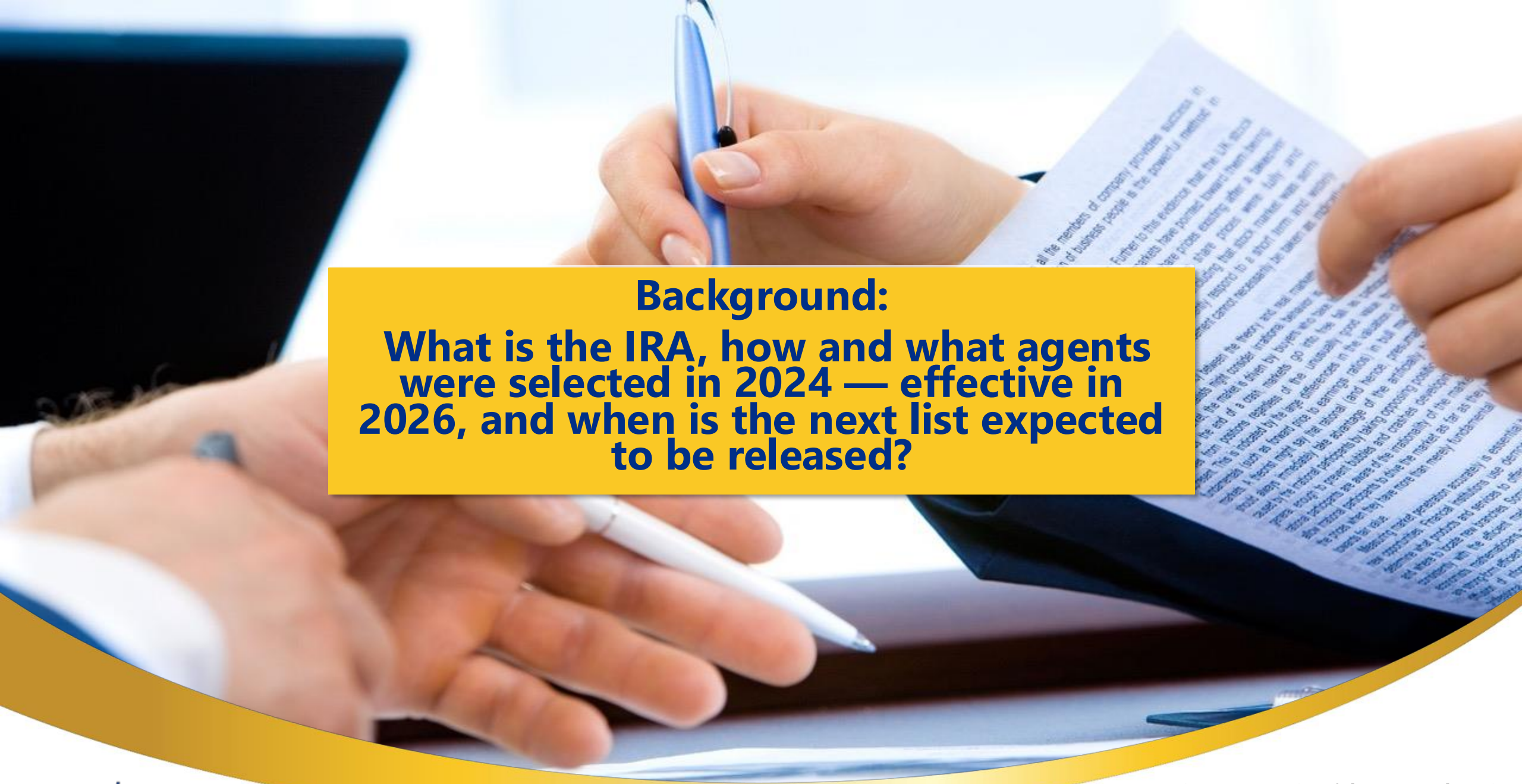
Effects of Inflation Reduction Act (IRA) on Drug Development

What is the IRA, how and what agents were selected in 2024 — effective in 2026, and when is the next list expected to be released?

Impact of IRA on drug development

Impact of the IRA on cancer drug availability

What are the concerns of oncologists regarding the impact of the IRA?

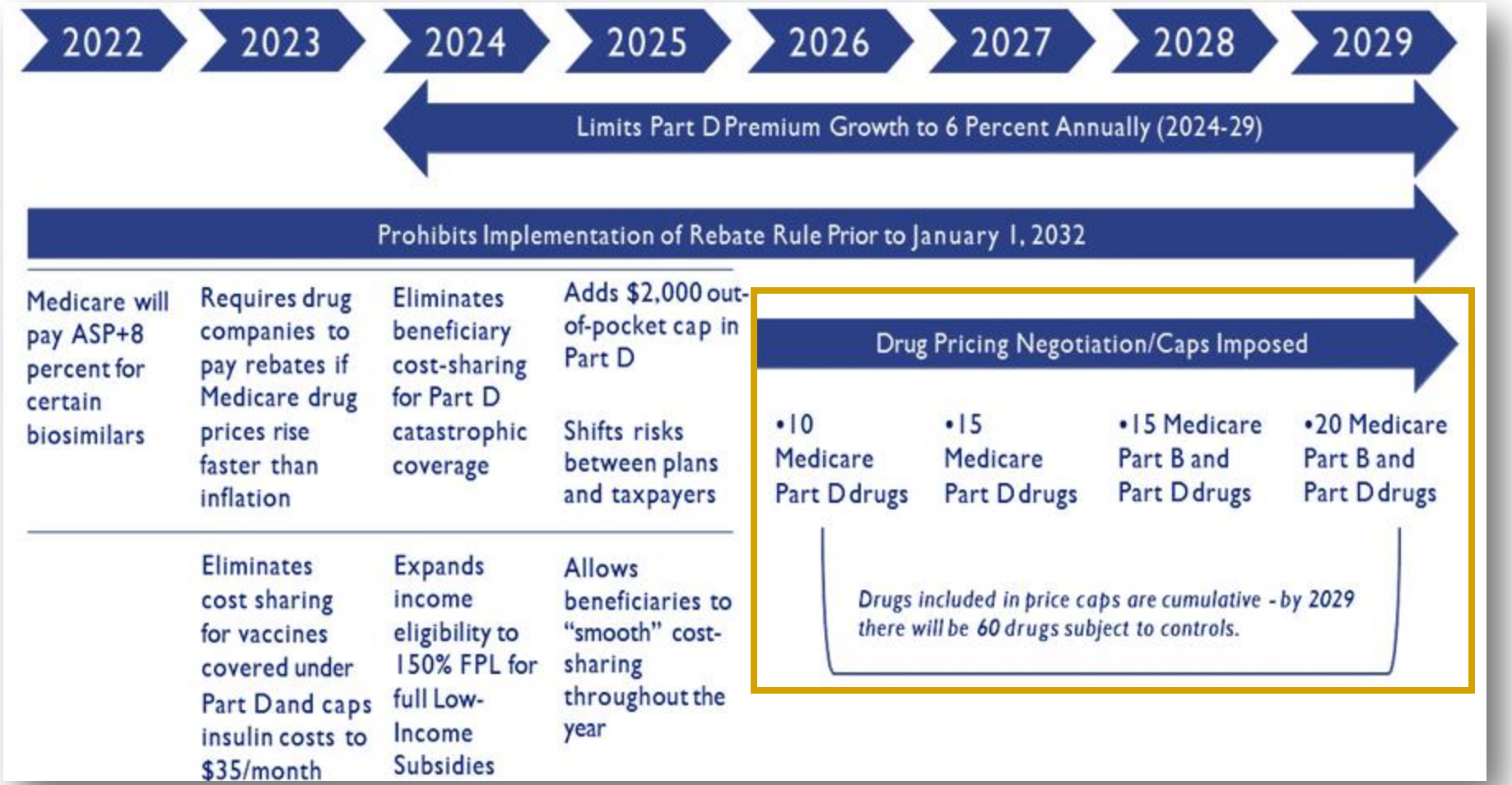


Background:

What is the IRA, how and what agents were selected in 2024 — effective in 2026, and when is the next list expected to be released?

Inflation Reduction Act (IRA)

- *Passed on August 16, 2022, IRA includes major reforms on taxes, climate, energy, and healthcare*
- *Includes several healthcare provisions, including price caps on Medicare Part B and D Drugs*



[A Deep Dive into the Inflation Reduction Act & What It Means for the Future of Healthcare](https://cahc.net/a-deep-dive-into-the-inflation-reduction-act-what-it-means-for-the-future-of-healthcare/)

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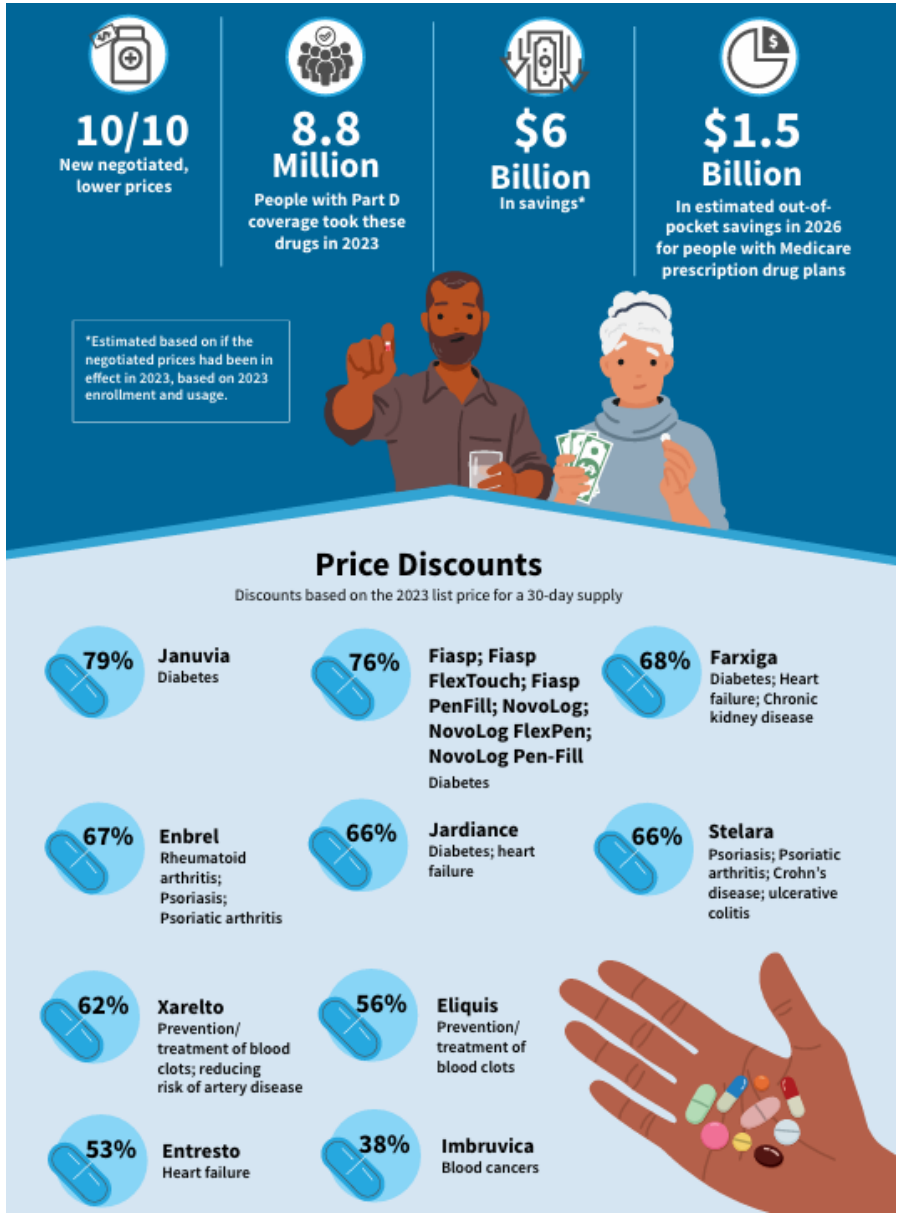
The Inflation Reduction Act—also known as the new prescription drug law—expands Medicare benefits, lowers prescription drug costs, and, for the ***first time ever***, allows Medicare to ***directly negotiate with drug companies*** to lower the prices for certain high-cost prescription drugs

The Centers for Medicare & Medicaid Services (CMS) selected ten drugs for the first cycle of negotiations
Identified single source drugs for which at least 7 years (or 11 years for biologics), had elapsed between FDA approval or licensure and for which there is no generic/biosimilar
Excluded certain orphan drugs, low-spend drugs, or plasma-derived products
Determined and ranked those with highest total Part D gross covered prescription costs, except for small biotech
Selected the top 10, excluding those that are likely to have biosimilar in the market within specified timeframe



New Lower Drug Prices Under the Medicare Drug Price Negotiation Program: What You Need to Kno

https://www.cms.gov/files/document/infographic-negotiated-prices-maximum-fair-prices.pdf

Impact of first round of negotiations

Drug Name	Participating Drug Company	Commonly Treated Conditions	Agreed to Negotiated Price for 30-day Supply for CY 2026	List Price for 30-day Supply, CY 2023	Discount of Negotiated Price from 2023 List Price	Total Part D Gross Covered Prescription Drug Costs, CY 2023	Number of Medicare Part D Enrollees Who Used the Drug, CY 2023
Januvia	Merck Sharp Dohme	Diabetes	$113.00	$527.00	79%	$4,091,399,000	843,000
Fiasp; Fiasp FlexTouch; Fiasp PenFill; NovoLog; NovoLog FlexPen; NovoLog PenFill	Novo Nordisk Inc	Diabetes	$119.00	$495.00	76%	$2,612,719,000	785,000
Farxiga	AstraZeneca AB	Diabetes; Heart failure; Chronic kidney disease	$178.50	$556.00	68%	$4,342,594,000	994,000
Enbrel	Immunex Corporation	Rheumatoid arthritis; Psoriasis; Psoriatic arthritis	$2,355.00	$7,106.00	67%	$2,951,778,000	48,000
Jardiance	Boehringer Ingelheim	Diabetes; Heart failure; Chronic kidney disease	$197.00	$573.00	66%	$8,840,947,000	1,883,000
Stelara	Janssen Biotech, Inc.	Psoriasis; Psoriatic arthritis; Crohn's disease; Ulcerative colitis	$4,695.00	$13,836.00	66%	$2,988,560,000	23,000
Xarelto	Janssen Pharms	Prevention and treatment of blood clots; Reduction of risk for patients with coronary or peripheral artery disease	$197.00	$517.00	62%	$6,309,766,000	1,324,000
Eliquis	Bristol Myers Squibb	Prevention and treatment of blood clots	$231.00	$521.00	56%	$18,275,108,000	3,928,000
Entresto	Novartis Pharms Corp	Heart failure	$295.00	$628.00	53%	$3,430,753,000	664,000
Imbruvica	Pharmacyclics LLC	Blood cancers	$9,319.00	$14,934.00	38%	$2,371,858,000	17,000

Note: Numbers other than prices are rounded to the nearest thousands. List prices are rounded to the nearest dollar and represent the Wholesale Acquisition Costs (WACs) for the selected drugs based on 30-day supply using CY 2022 prescription fills. Drug companies' participation in the Negotiation Program is voluntary; the figures above represent estimates based on continued drug company participation in the Medicare program.

Medcare Drug Price Negotiation Program: Negotiated Prices for Initial Price Applicability Year 2026

Taking the smallest cut of the 10 is the <u>lone cancer treatment</u>, Johnson & Johnson's Imbruvica

List price for 30-day supply, CY 2023

$14, 934.00

38%

$9,319.00

Agreed to negotiated price for 30-day supply, CY 2026

Imbruvica was first approved in November 2013 for mantle cell lymphoma

What's next…?

Drugs anticipated to be selected for the Medicare Drug Price Negotiation Program in 2025

February 1, 2025: *Deadline for CMS to publish the list of 15 Part D drugs selected for negotiation for 2027*

Greater impact on future prescribing decisions and practice management within community oncology

Rank	Brand name	Generic name	Manufacturer	Therapeutic area	Gross Part D spending in 2022	Projected gross Part D spending[a]	Time since approval as of 2/2025[b]
1	Ozempic, Rybelsus & Wegovy[c]	Semaglutide	Novo Nordisk	T2DM	$5,603,055,114	$7,476,655,091	7 yrs 1 mo
2	Trelegy Ellipta	Fluticasone/umeclidinium/vilanterol	GlaxoSmithKline	COPD	$3,340,110,326	$4,259,329,331	7 yrs 4 mos
3	Xtandi	Enzalutamide	Astellas Pharma Inc.	Prostate cancer	$2,436,795,703	$2,740,436,348	12 yrs 5 mos
4	Ofev	Nintedanib	Boehringer Ingelheim	Lung diseases	$1,762,963,783	$2,077,308,575	10 yrs 3 mos
5	Pomalyst	Pomalidomide	Bristol Myers Squibb	Blood cancers	$1,743,892,720	$1,887,642,864	11 yrs 11 mos
6	Ibrance	Palbociclib	Pfizer Inc.	Breast cancer	$1,948,323,854	$1,822,279,057	9 yrs 11 mos
7	Linzess	Linaclotide	AbbVie Inc.	Gastrointestinal disorders	$1,581,669,987	$1,804,032,885	12 yrs 5 mos
8	Calquence	Acalabrutinb	AstraZeneca	Blood cancers	$1,192,914,435	$1,615,471,380	7 yrs 3 mos
9	Creon	Pancrelipase	AbbVie Inc.	Pancreatic insufficiency	$1,310,801,528	$1,478,112,273	15 yrs 9 mos
10	Breo Ellipta	Fluticasone / vilanterol	GlaxoSmithKline	COPD	$1,427,824,950	$1,408,763,895	11 yrs 8 mos
11	Tradjenta	Linagliptin	Boehringer Ingelheim	T2DM	$1,326,573,079	$1,349,012,342	13 yrs 8 mos
12	Janumet	Metformin/sitagliptin	Merck and Co., Inc.	T2DM	$1,212,934,060	$1,246,237,036	17 yrs 10 mos
13	Austedo	Deutetrabenazine	Teva Pharmaceuticals	Neurological diseases	$890,369,750	$1,055,519,879	7 yrs 9 mos
Drugs with uncertain negotiation status							
	Victoza[d]	Liraglutide	Novo Nordisk	T2DM	$ 1,557,800,382	$1,399,269,640	15 yrs 0 mos
	Tagrisso[e]	Osimertinib	AstraZeneca	NSCLC	$1,081,280,466	$1,217,143,163	9 yrs 2 mos
	Xifaxan[f,g]	Rifaximin	Salix Pharmaceuticals	Antibacterial	$969,541,694	$1,026,447,056	20 yrs 8 mos
	Humalog[f,h]	Insulin lispro	Eli Lilly and Co	DM	$2,067,729,284	$954,335,188	28 yrs 7 mos
	Epclusa[f]	Sofosbuvir/velpatasvir	Gilead Sciences	Hepatitis c	$899,944,724	$934,777,002	8 yrs 7 mos
	Xeljanz[f]	Tofacitinib	Pfizer Inc.	Immunological diseases	$886,548,263	$901,642,064	12 yrs 2 mos
	Venclexta[f]	Venetoclax	AbbVie Inc.	Blood cancers	$767,860,286	$876,884,918	8 yrs 9 mos

Drugs anticipated to be selected for the Medicare Drug Price Negotiation Program in 2025 | Journal of Managed Care & Specialty Pharmacy

Effects of Inflation Reduction Act (IRA) on Drug Development

- What is the IRA, how and what agents were selected in 2024 — effective in 2026, and when is the next list expected to be released?
- **Impact of IRA on drug development**
- Impact of the IRA on cancer drug availability
- What are the concerns of oncologists regarding the impact of the IRA?

Impact of IRA on drug development

Opinion by 2 Pharmas

Since Medicare's Part D enactment, over 550 new products have hit the market…With the IRA…price controls on Part B and D drugs are going to ***impact innovation***

*"These long-term projects require sustained investment, **which may no longer be feasible** if price controls are implemented too early in a drug's lifecycle. Davis warned that the biopharmaceutical industry might increasingly shift its focus away from small molecules, which could **limit future treatments for conditions** that rely on these types of therapies, including various forms of cancer and cardiovascular disease."* – **Robert Davis, Merck**

The Inflation Reduction Act (IRA) and Its Broader Impact on Innovation, Access, and Affordability in Healthcare – Policy & Medicine

https://www.policymed.com/2024/10/the-inflation-reduction-act-ira-and-its-broader-impact-on-innovation-access-and-affordability-in-healthcare.html

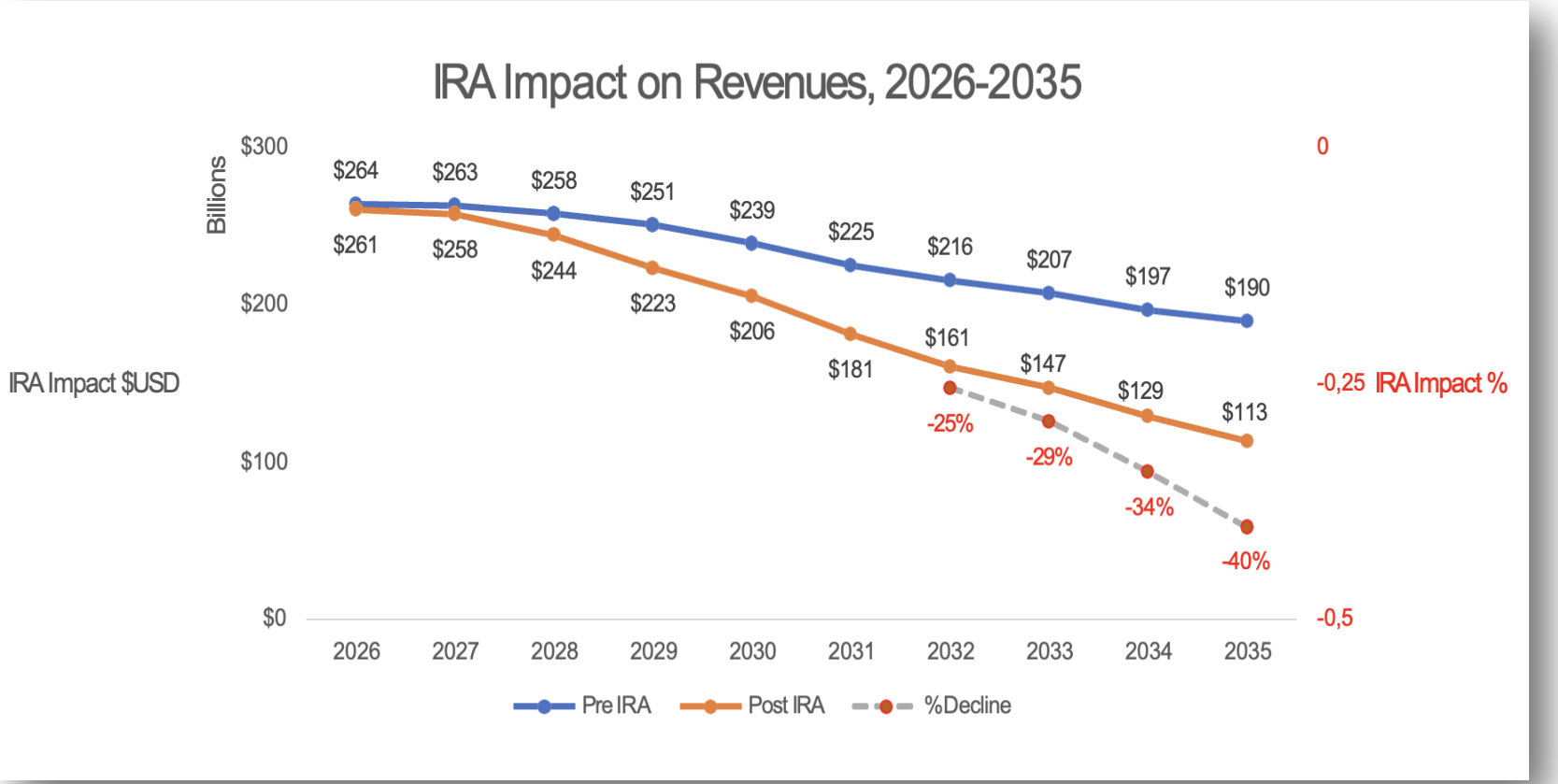
*"At **Novartis**, we have already had to make difficult decisions about studying some potential new treatments because of the IRA price controls. For example, we've **stopped some early-stage cancer drug trials** because we would not have enough time on the market to recoup our investment in them before price controls were implemented. The IRA price controls would inhibit our ability to both bring new medicines to patients in need and also fuel our future research and development."*

Negative impact of the IRA on patient access to innovative treatments | Novartis

https://www.novartis.com/stories/negative-impact-ira-patient-access-innovative-treatments

*"Looking forward, we estimate that because of the IRA pricing provisions, the substantial reduction in revenue will **significantly narrow investment opportunities**. Conservatively, as many as 139 drugs over the next 10 years are at risk of not being developed at all."*

Pharma Industry: Impact on Future Revenue

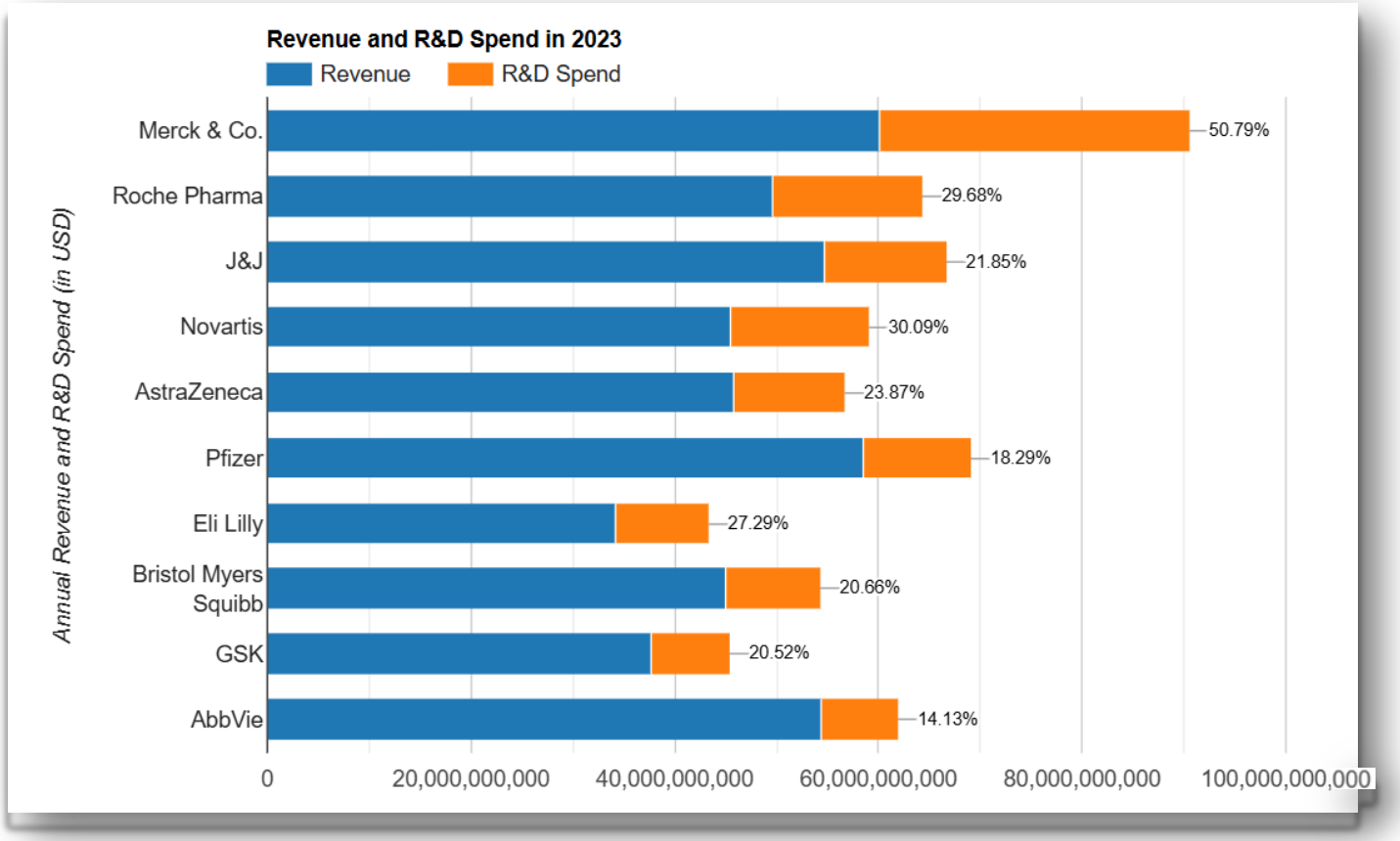


Substantial projected loss of future earnings

Impact on Bio-Pharma Sector; includes 41 firms, 92 therapies

IRA's Impact on the US Biopharma Ecosystem.pdf
https://www.bio.org/sites/default/files/2023-06/IRA%E2%80%99s%20Impact%20on%20the%20US%20Biopharma%20Ecosystem.pdf

Pharma Industry: Less revenue, impact on R&D?



Rounding up the pharma firms investing the most in 2023
https://www.drugdiscoverytrends.com/top-pharma-companies-2023-rd-spend/

IRA has been stated to reduce the ability of companies to reinvest into future pipelines

- *Close research sites*
- *Fewer researchers*
- *Fewer research programs?*

Impact on and access to clinical trials?

Pharma Industry: Impact on Small-Molecule Drugs

	Biologics	Small-molecule
Development Times (median development times)	12.6 years	12.7 years
Clinical Trial Success Rates (median estimates across 5 studies)	Phase 1: 14% Phase 2: 24% Phase 3: 57%	Phase 1: 8% Phase 2: 15% Phase 3: 49%
R&D Costs Research and development spending was publicly disclosed for 63 new therapeutic agents (16 biologics and 47 small-molecule drugs)	Median development costs: $3.0 billion	Median development costs: $2.1 billion

The FDA approved 599 new therapeutic agents from 2009-2023, of which 159 (27%) were biologics and 440 (73%) were small-molecule drugs

Inflation Reduction Act:

Different rules for small-molecules and biologics

- **Small- molecules**:
  - Exempt from negotiation for **7 years**
- **Biologics:**
  - Exempt from negotiation for **11 years**

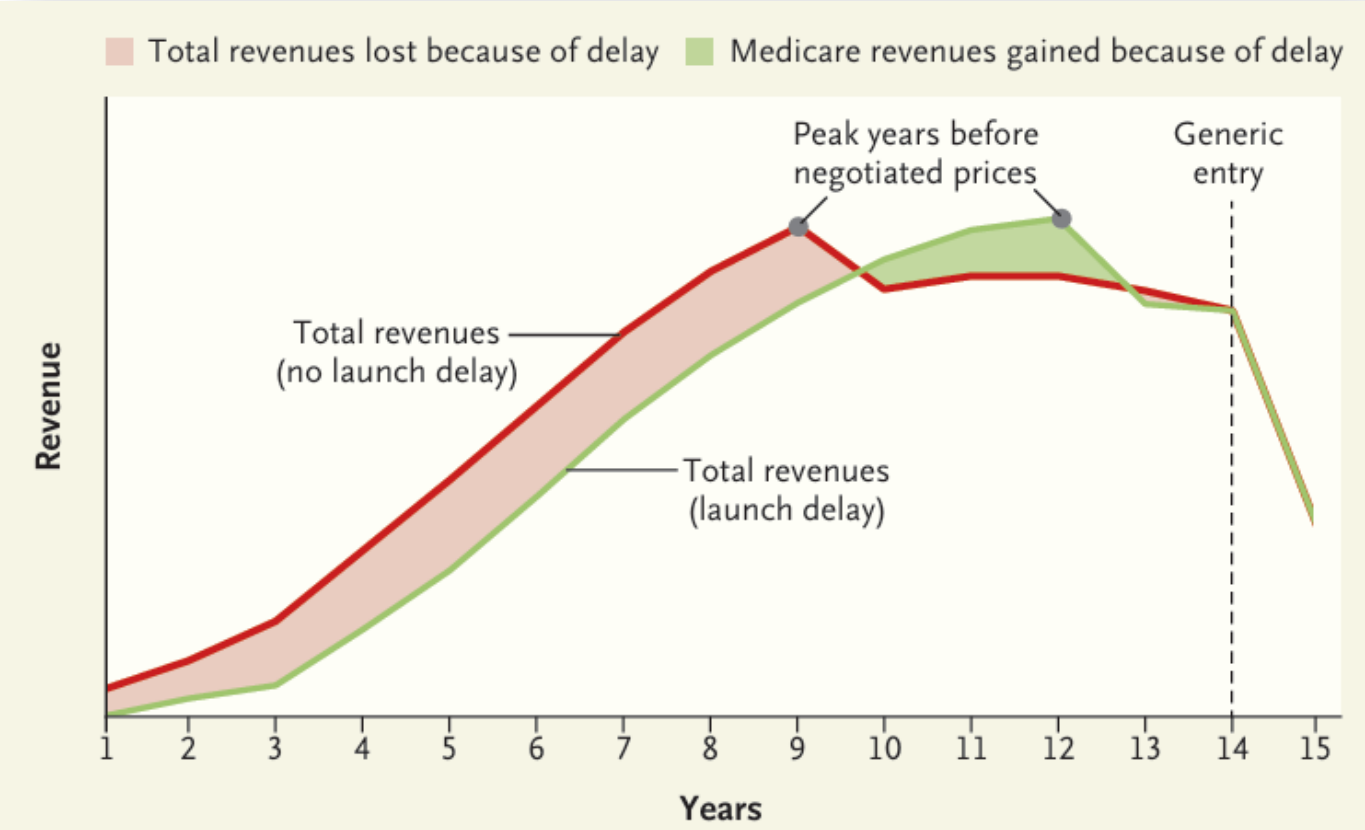
Note: there is a two-year "negotiation period" and the price control then goes into effect at year 9 or year 13.

Greater incentive to develop biologics?

But…biologics are less accessible to patients than small molecules

Pharma Industry: Impact on Drug Launch

Opinion by 1 Pharma



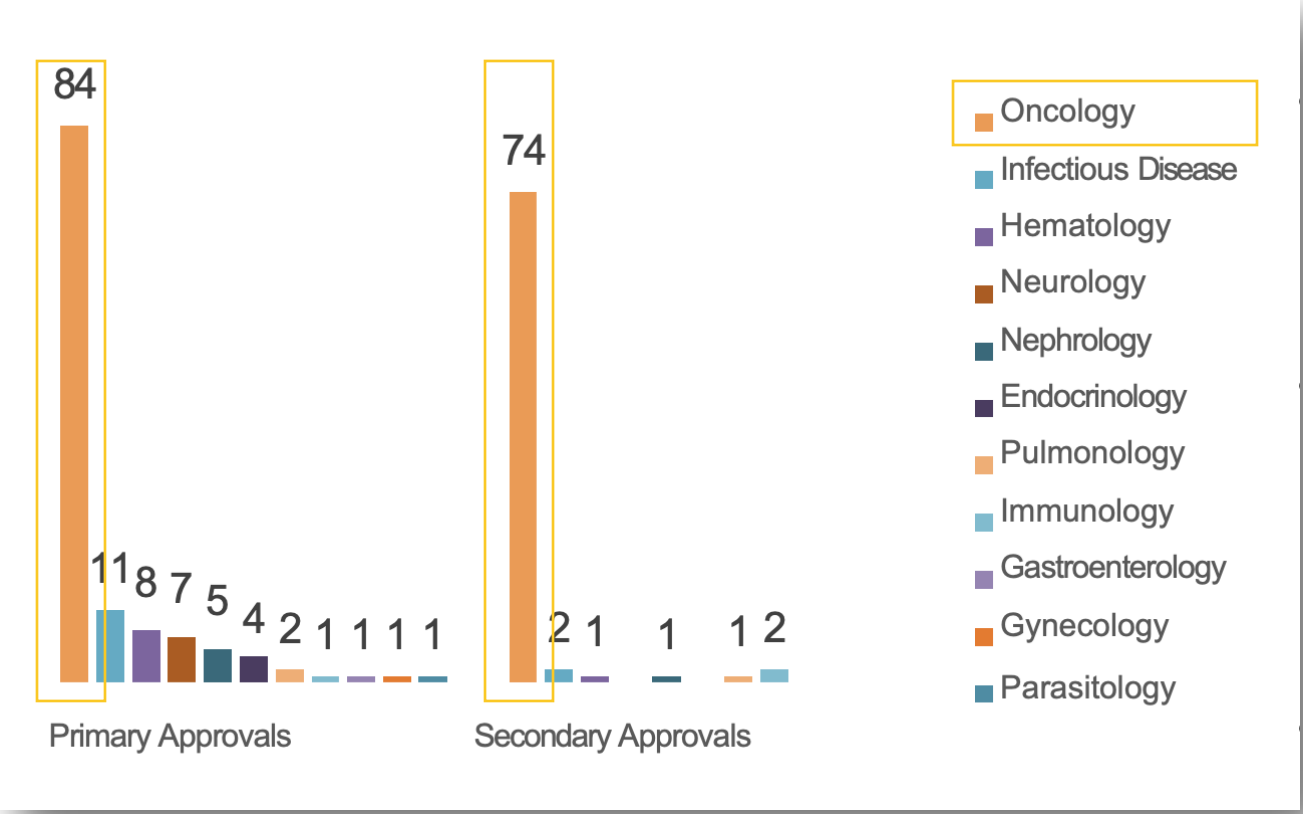
"In August 2023, the chief executive officer of Genentech (now owned by Roche) announced that unless the IRA is repealed or revised, the company may delay seeking approval for a new ovarian cancer treatment until it also completes trials of the same drug in prostate cancer, which will require an additional 3 years."

Will Medicare Price Negotiation Delay Cancer-Drug Launches?
Matthew Vogel, M.B.A., Aaron S. Kesselheim, M.D., J.D., M.P.H., William B. Feldman, M.D., D.Phil., M.P.H., and Benjamin N. Rome, M.D., M.P.H. NEJM 2023 Oct 11

Is delaying launch of cancer therapies the best strategy for managing the impact of the IRA?

Pharma Industry: Orphan Drugs Prior to IRA

IRA's Impact on Orphan Dugs Including Oncology
Accelerated Approvals by Primary and Secondary Indications, 2001 – 2021



N=206 (oncology = 158, non-oncology = 48)

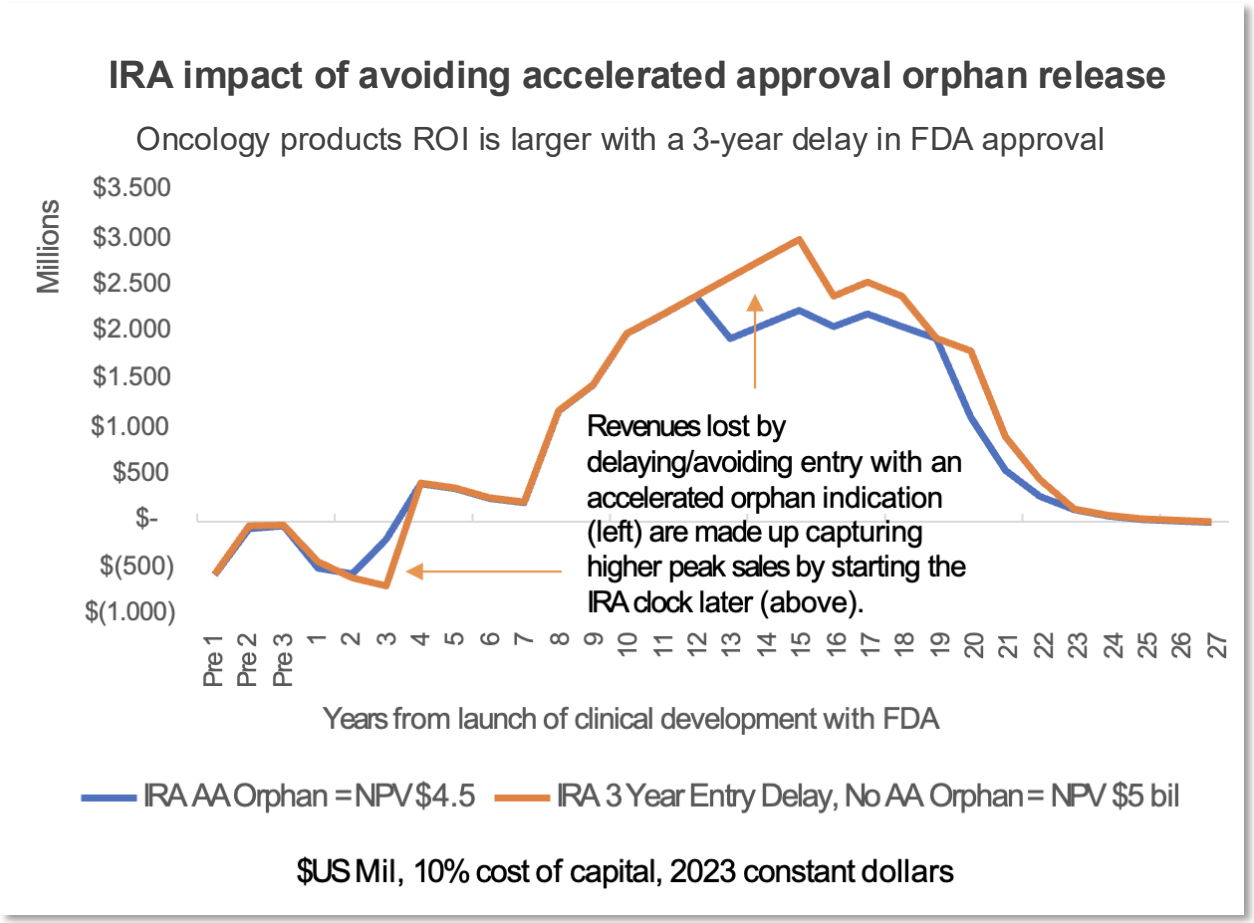
The accelerated approval of orphan oncology products is considered a success of the US innovation and regulatory ecosystems, but it may be impacted by the IRA provisions

IRA's Impact on the US Biopharma Ecosystem.pdf

https://www.bio.org/sites/default/files/2023-06/IRA%E2%80%99s%20Impact%20on%20the%20US%20Biopharma%20Ecosystem.pdf

Pharma Industry: Impact on Orphan Designation of Drugs

Orphan drug designation: Label expansion strategies are a common method for manufacturers to realize the full therapeutic and commercial potential of their product



Entering the market with an orphan approval creates a 'penalty' due to IRA's impact upon peak sales; the IRA clock starts ticking when you have your first approval

1 example: Delaying market entry by three years, and focusing on a non-orphan indication at launch, improves the NPV by $500 mil (USD)

Leading with an accelerated oncology indication to de-risk R&D appears to be a far less favorable strategy under IRA; this may require a radical shift in biopharma's current go-to market paradigm

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https://www.bio.org/sites/default/files/2023-06/IRA%E2%80%99s%20Impact%20on%20the%20US%20Biopharma%20Ecosystem.pdf

Pharma Industry: Potential strategies

Will Pharma risk time and money to make a new drug?

- Drug pricing will have a ceiling but no floor
- Refusal of (government) pricing will result in a confiscatory tax

Revenue and R&D Investments

- Re-allocation of R&D to late-stage products, with continued or increased licensing of early stage
- Biotech investments change with the market, but not correlated to drug prices
- For large companies, lower revenues translate to lower R&D, but do not impact vast majority of biotechs with smaller market caps

For 2026 through 2028, the Inflation Reduction Act specifies that "small biotech" drugs will not be eligible for negotiation.

Shift Focus to Biologics

- e.g., Pfizer: By 2030, the mix of small molecules in its cancer portfolio will drop from the current 94% to 35%
- Proposed bill to address the penalties of small molecules (*EPIC Act)

  Introduced 01/31/2024

*EPIC ACT: To amend title XI of the Social Security Act to equalize the negotiation period between small-molecule and biologic candidates under the Drug Price Negotiation Program.

Strategic Acquisitions

- e.g., Merck: Strengthening oncology portfolio through acquisitions of ADCs and partnerships with Daiichi Sankyo

https://www.statnews.com/2024/02/29/pfizer-cancer-drugs-investor-briefing/

Pros and Cons of the IRA on Drug Development

Pros

- **Improved Health Outcomes**: Lower drug costs can lead to better health outcomes as more patients adhere to their treatment regimens.
- **Transparency in Pricing**: Promotes transparency in drug pricing, allowing consumers to make informed decisions.
- **Support for Chronic Disease Management**: Easier access to medications can improve management of chronic diseases.
- **Public Health Benefits**: Overall public health may improve with increased access to affordable medications.

Cons

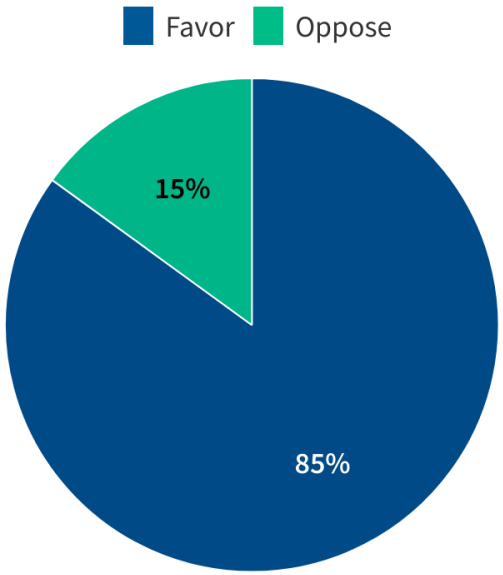
- **Short term focus**: Pharma companies might prioritize short-term gains over long term drug development projects
- **Impact on Small Companies**: Smaller biotech firms may struggle more than larger companies, potentially stifling innovation.
- **Potential Drug Shortages**: Price controls could lead to shortages of certain medications if companies withdraw from the market.
- **Delayed Drug Launches**: New drugs may take longer to reach the market due to increased regulatory scrutiny and pricing negotiations.
- **Legal and Regulatory Challenges**: Pharmaceutical companies may face legal challenges and regulatory hurdles from new pricing policies.
- **Global Competitiveness**: U.S. pharmaceutical companies might lose competitiveness in the global market due to price restrictions

Effects of Inflation Reduction Act (IRA) on Drug Development

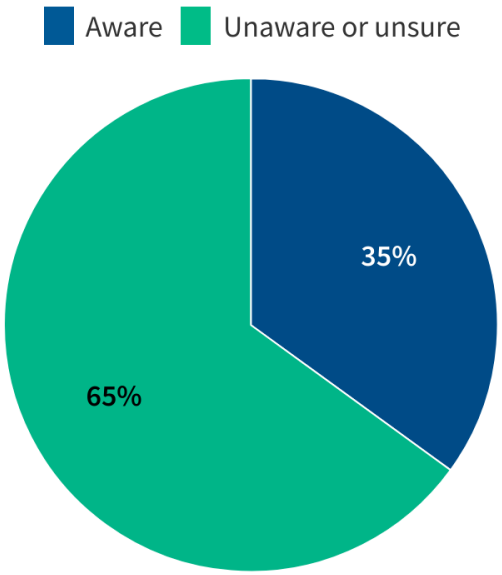
- What is the IRA, how and what agents were selected in 2024 — effective in 2026, and when is the next list expected to be released?
- Impact of IRA on drug development
- Impact of the IRA on cancer drug availability
- What are the concerns of oncologists regarding the impact of the IRA?

Impact on Cancer Drug Availability: Patients

People Overwhelmingly Support Medicare Drug Price Negotiations, but Most Don't Realize It's Happening



Do you favor or oppose allowing the federal government to negotiate with drug companies to get a lower price on prescription drugs for people with Medicare?



As far as you know, is there a federal law in place that requires the federal government to negotiate the price of some prescription drugs for people with Medicare?

Source: KFF Health Tracking Poll (Aug. 26-Sept. 4, 2024).

KFF

Need to educate public on the law that now requires the federal government to negotiate the price of some prescription drugs for people with Medicare

Impact to patients will depend in part on whether they pay flat copayment amounts or a coinsurance rate for the drug in their chosen Part D plan

Impact on Cancer Drug Availability: Patients

Currently the IRA (direct negotiation provision) applies solely to the Medicare population

Benefit for Patients, Part D Redesign:

- Caps out-of-pocket (OOP) drug costs for Medicare patients at $2,000 per year (and $35/month for insulin)
- Shifts most of the financial liability from Medicare to industry players
- Drug manufacturers will have to provide a 20% discount, while payer responsibility will increase fourfold—from 15% to 60%

By 2028, up to 15 additional drugs covered under Medicare Part D or potentially Part B will be selected for price negotiation, followed by up to 20 additional drugs covered under Part D or Part B drugs for 2029 and later years.

Potential to impact greater patient population (commercially insured?)

Impact on Cancer Drug Availability: Payers

Insurers are consistently clear that they plan to restrict access as IRA changes are implemented

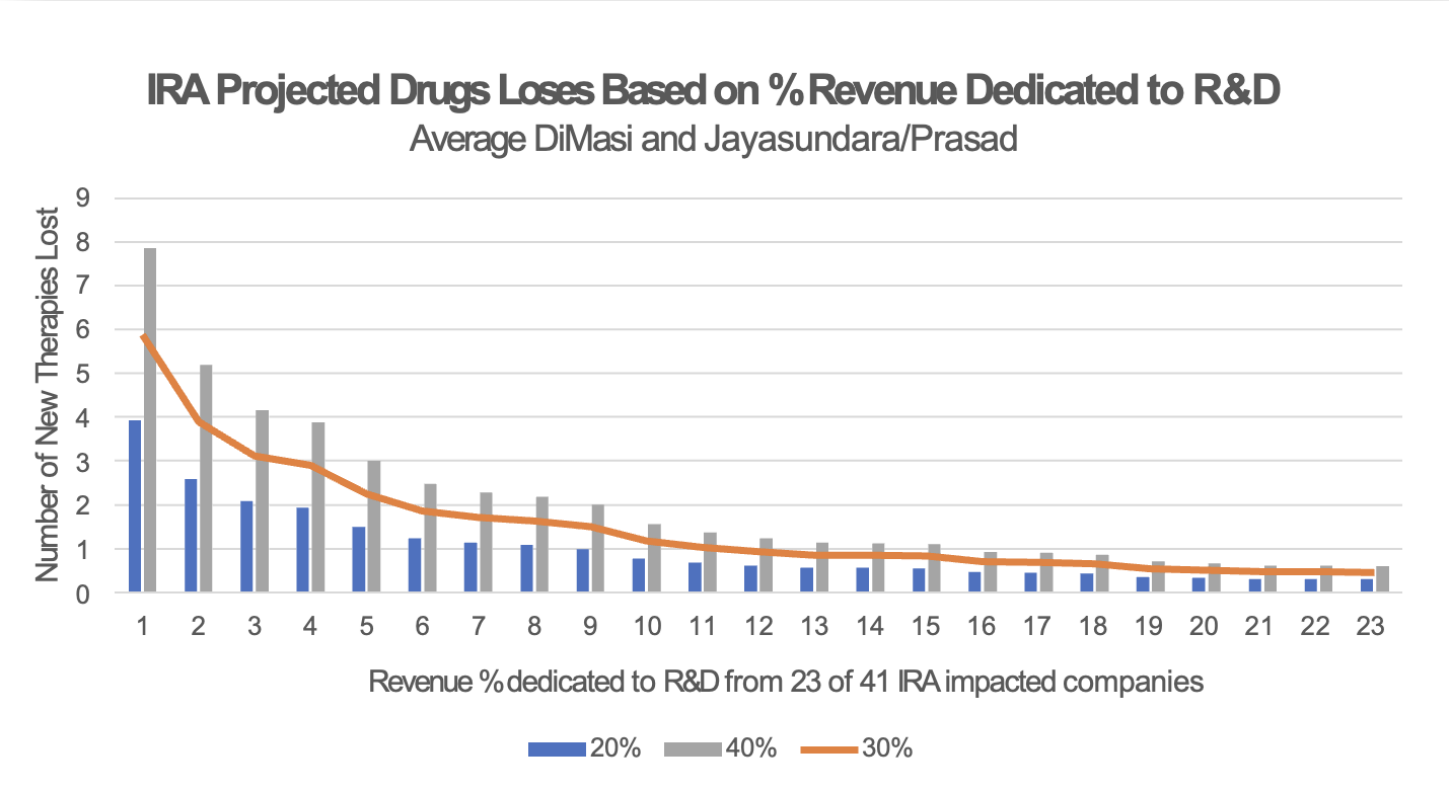
- 89% of insurers plan to **increase utilization management** tools (like prior approval requirements and fail first policies) and pare down formularies
- 78% of insurers expect to create more **stringent utilization management** for new medicines
- 83% of insurers plan to increase the number of **medicines excluded from their formularies**
- 78% of insurers plan **to decrease the number of therapeutic options** in classes with medicines selected for price setting

Significant premium increases, reduced plan choices, and higher out-of-pocket costs for many beneficiaries?

Potential for commercial payers to push for lower prices?

Shift incentives in favor of biologics/Part B drugs?

Impact on Cancer Drug Availability: Future



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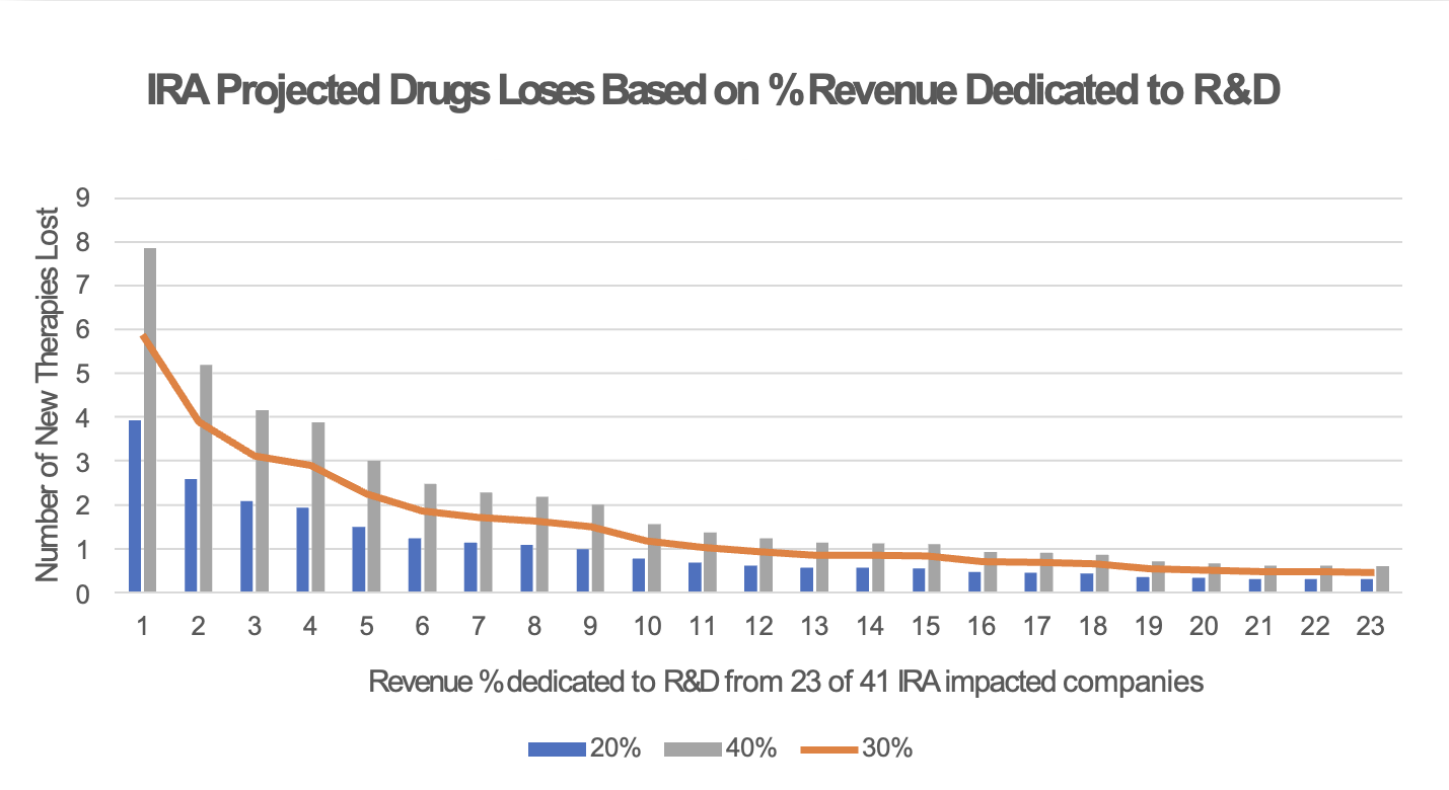
IRA Impact on Pharma Revenue may translate to fewer investments in small molecule drugs:

- ***Small molecule drugs are a category of treatments that are often more affordable and scalable for large populations, including underserved communities***

Impact on patients and access to <u>future</u> medicines

Impact on Cancer Drug Availability: Future



IRA Impact on Revenue may translate to less investment in long term projects:

- ***Many drugs continue to undergo research to expand indications e.g., pembrolizumab even 10 years after its initial approval***

Impact on patients and access to future medicines

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https://www.bio.org/sites/default/files/2023-06/IRA%E2%80%99s%20Impact%20on%20the%20US%20Biopharma%20Ecosystem.pdf

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Effects of Inflation Reduction Act (IRA) on Drug Development

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- **Impact of IRA on drug development**
- **Impact of the IRA on cancer drug availability**
- **What are the concerns of oncologists regarding the impact of the IRA?**

Impact on practices

"…up to a 49% cut in provider reimbursement for the add-on payments there, which is just completely unsustainable for practices" - Community Oncology Alliance (COA)

IRA Negotiated Drug Prices Can't Come "On the Backs of Providers" - September 10, 2024

Drug acquisition

Practices to acquire the negotiated drugs at or below MFP, and practices would then receive the MFP-based reimbursement from patients who have Medicare Part D plans

Lower reimbursement

Through, 2032, 39% to 64% decrease in Medicare add-on payments and a 13% to 21% reduction in commercial and Medicare Advantage (MA) add-on payments

Increased time from acquisition to reimbursement

Practices could be floating the difference between acquisition costs and reimbursement for up to 2 months longer than do currently. These drugs are very expensive, and managing those accounts receivable on our books is a financial burden that costs us quite a bit of money

MFP: Maximum Fair Price

Medicare Drug Price Negotiations Will Have Domino Effect for Community Oncology Practices
https://www.onclive.com/view/medicare-drug-price-negotiations-will-have-domino-effect-for-community-oncology-practices

Part B Losses to Oncologists Due to IRA Could Total $12B Through 2032 Across Medicare, Commercial Plans
https://www.ajmc.com/view/part-b-losses-to-oncologists-due-to-ira-could-total-12b-through-2032-across-medicare-commercial-plans

Impact on administration and management

Product selection	Potential to significantly impact care, especially how treatment decisions are made based on patient affordability
Lower acquisition price is only applicable to drugs for Medicare beneficiaries	Practices will have to manage separate product inventories for MFP- and non-MFP–eligible patients
Administrative burden of duplicative inventory management	Costly, confusing and require additional staffing

What best practices should be implemented in order to prepare?

Medicare Drug Price Negotiations Will Have Domino Effect for Community Oncology Practices
https://www.onclive.com/view/medicare-drug-price-negotiations-will-have-domino-effect-for-community-oncology-practices

MFP: Maximum Fair Price

Understanding and Managing the Short- and Long-term Implications of the Inflation Reduction Act (IRA) is Integral to Community Oncology Sustainability

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