Impact of the Inflation Reduction Act on biopharma portfolio strategies

Introduction

The Inflation Reduction Act (IRA)[1] was passed by Congress and signed by President Joe Biden in August 2022 and provides approximately $740 billion in funding and tax policy changes that will affect industries across the economy. Within healthcare, the act aims to improve affordability and accessibility by lowering prescription drug prices and out-of-pocket costs for Medicare beneficiaries and extending premium subsidies in the Affordable Care Act's (ACA) marketplaces.

Sweeping proposals introduced by the act represent some of the most significant healthcare legislation since the ACA by giving Medicare the ability to negotiate drug prices with manufacturers. In this paper, we discuss potential implications of these policies for how drug manufacturers manage their portfolios, starting in 2023, including:

- Manufacturers of blockbuster drugs may face shortened revenue cycles.
- R&D priorities will continue to accelerate towards innovation (and away from "me-too").
- Drug manufacturers may rethink how they set launch pricing and negotiate with their customers.
- Bioequivalent-focused generics players may see more opportunity in complex generic assets.
- An evolved approach to R&D, clinical, and commercial strategy will be required to navigate nuanced market changes, optimize commercial success, and ensure appropriate access to therapies by patients.

Blockbuster drugs may face shortened revenue cycle

The ability for Medicare to negotiate price is the most impactful change enacted by the IRA for the pharmaceutical industry. Medicare will gain the unprecedented power to negotiate prices of up to 60 drugs by 2029, starting with 10 in 2026. While this provision aims to curb spend on top Medicare drugs [Exhibits 1 & 2] that have been approved for more than 9 or more years (13 or more years for biologics), manufacturers of blockbuster drugs that target broad patient-based conditions such as diabetes, rheumatoid arthritis, and cardiovascular conditions will be limited in ways they previously were not as they now face a shorter period of time to negotiate pricing without IRA-imposed caps. And, for example, for companies focused on dementia indications, the investment thesis now has to be reconsidered because the expectation of a biologic treating Alzheimer's Disease no longer can anticipate an Enbrel-like life-cycle management commercial outcome across different types of dementia.

Beginning in 2026 (2028 for Part B drugs), manufacturers of high-spend drugs may start to re-think indication/label extension and other strategies that can "mark" or "unmark" their products for Medicare price negotiations. This move may inadvertently reduce incentives to bring new drugs or indications, such as those in oncology where a given drug may have several follow-on indications, to market by limiting the potential for revenue maximization.

[1] Source: "Inflation Reduction Act of 2022," Congress.gov

Exhibit 1. Top 10 Medicare Part B drugs by spend in 2020

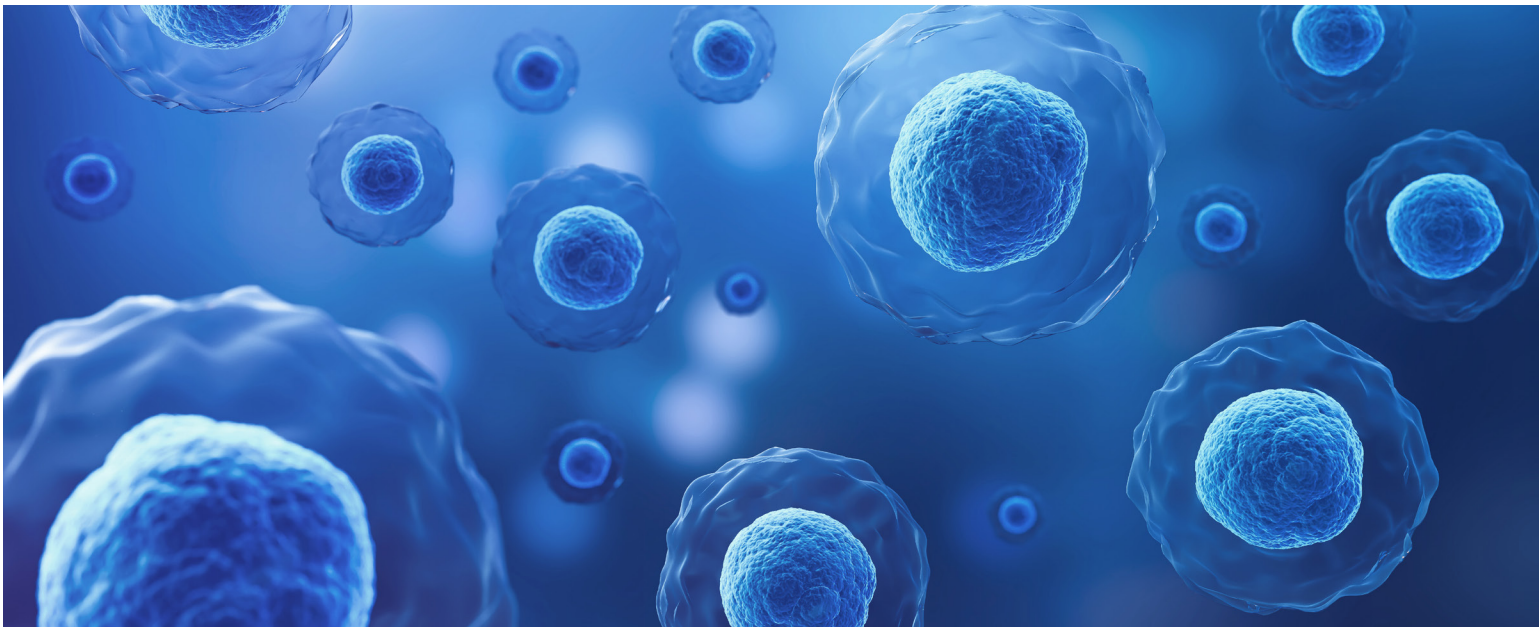
Brand name	Generic name	Manufacturer	Total spending 2020
Keytruda	Pembrolizumab	Merck	$3,500,947,569
Eylea	Aflibercept	Regeneron	$3,013,081,886
Prolia	Denosumab	Amgen	$1,626,844,123
Opdivo	Nivolumab	Bristol Myers Squibb	$1,586,591,103
Rituxan	Rituximab	Genentech	$1,295,821,133
Lucentis	Ranibizumab	Genentech	$1,113,026,180
Orencia	Abatacept	Bristol-Myers Squibb	$1,023,001,524
Neulasta	Pegfilgrastim	Amgen	$899,790,555
Darzalex	Daratumumab	Janssen	$837,400,702
Avastin	Bevacizumab	Genentech	$680,539,026

Source: CMS, accessed Sept 2022

Exhibit 2. Top 10 Medicare Part D drugs by spend in 2020

Brand name	Generic name	Manufacturer	Total spending 2020
Eliquis	Apixaban	Bristol Myers Squibb	$9,936,069,814
Revlimid	Lenalidomide	Bristol Myers Squibb	$5,356,050,275
Xarelto	Rivaroxaban	Janssen	$4,701,314,805
Januvia	Sitagliptin Phosphate	Merck	$3,865,087,773
Trulicity	Dulaglutide	Eli Lilly	$3,284,873,062
Imbruvica	Ibrutinib	Pharmacyclics	$2,962,909,304
Lantus Solorstar	Insulin Glargine	Sanofi-Aventis	$2,663,360,232
Jardiance	Empagliflozin	Boehringer Ingelheim	$2,376,166,292
Humira (Cf) Pen	Adalimumab	Abbvie	$2,169,430,424
Ibrance	Palbociclib	Pfizer	$2,108,937,188

Source: CMS, accessed Sept 2022



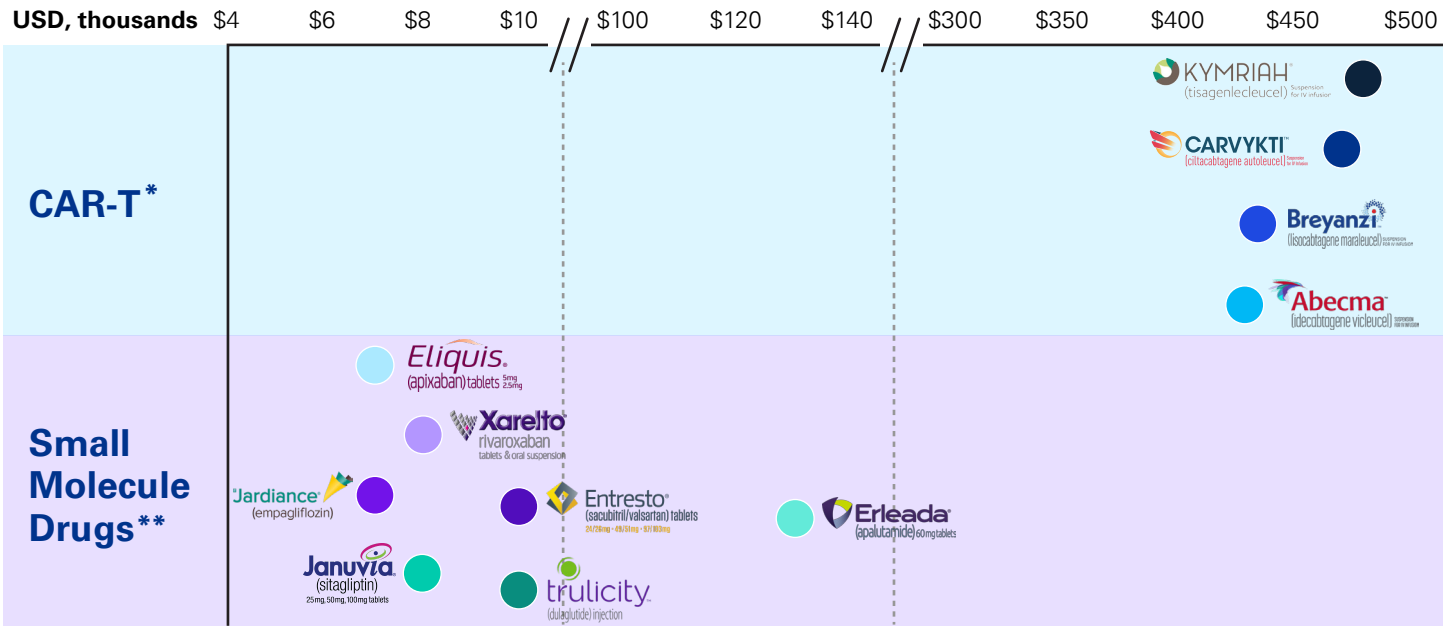
The shift in R&D priorities to innovation (and away from "me-too") will continue to accelerate

Drug manufacturers have already become less inclined to develop high-cost competitive "me-too" therapies. These drugs not only face higher entry hurdles (e.g., a need to demonstrate meaningfully higher efficacy for coverage and/or better formulary placement), but also may receive limited Medicare coverage if clinical profiles are at parity (or worse) vs. incumbents. For example, rather than launching another PD-1/PD-L1 that would compete with established treatments such as Keytruda, Opdivo, and Tecentriq, we expect manufacturers may instead focus on developing newer-generation therapies (e.g., CD47, LAG-3). This trend has already taken root and will likely further accelerate, fuelled by the IRA, in the future.

Furthermore, drug manufacturers that have started or plan to move away from less complex, more competitive market segments that have limited growth potential but are still impactful to patients (e.g., small molecule drugs) now have greater incentive to double down on more scientifically innovative areas. An example would be precision medicine, which includes, but is not limited to, cell & gene and RNA therapies. While innovative, precision medicine assets tend to carry potentially more development risks and require higher investments, once approved for market development activities, they inherently differentiate from existing products or standard of care and in turn often carry a much higher price than many small molecule drugs [Exhibit 3]. For example, Abecma, the first anti-BCMA CAR-T cell therapy for relapsed or refractory Multiple Myeloma, was approved to treat patients with high clinical unmet needs. Differentiation, in turn, provides drug developers considerable leverage–less comparators means fewer, if any, references or less indexed pricing–in pricing and contracting negotiations with plans and/or providers, creating avenues to maximize revenue and profit.

Indeed, market leaders such as J&J, GSK, and others are continuing to invest heavily in precision medicine and cell & gene therapies. An example of this recent trend is GSK's expansion of clinical trial manufacturing capacity to accelerate its cell and gene therapy pipeline. We see that those who have the capabilities and willingness are making sizable investments in pursuing this path. Given the direction and intent of the IRA, we foresee companies continuing to double down on their precision medicine efforts to maintain portfolio leverage with differentiated products across major therapeutic areas.

Exhibit 3. Price comparison of CAR-T vs. Small Molecule Drugs



*Estimated one time treatment cost; **Estimated annual treatment cost; All estimations based on product list price

Sources: CAR-T: Drugs.com, GoodRx.com, BiopharmaDive.com. Small molecule drugs: SingleCare.com, Jardiance.com, Eli Lilly Trulicity website, EndPoint News; KPMG analysis.

All sources accessed in September 2022

Drug manufacturers may evolve launch pricing and negotiation strategies

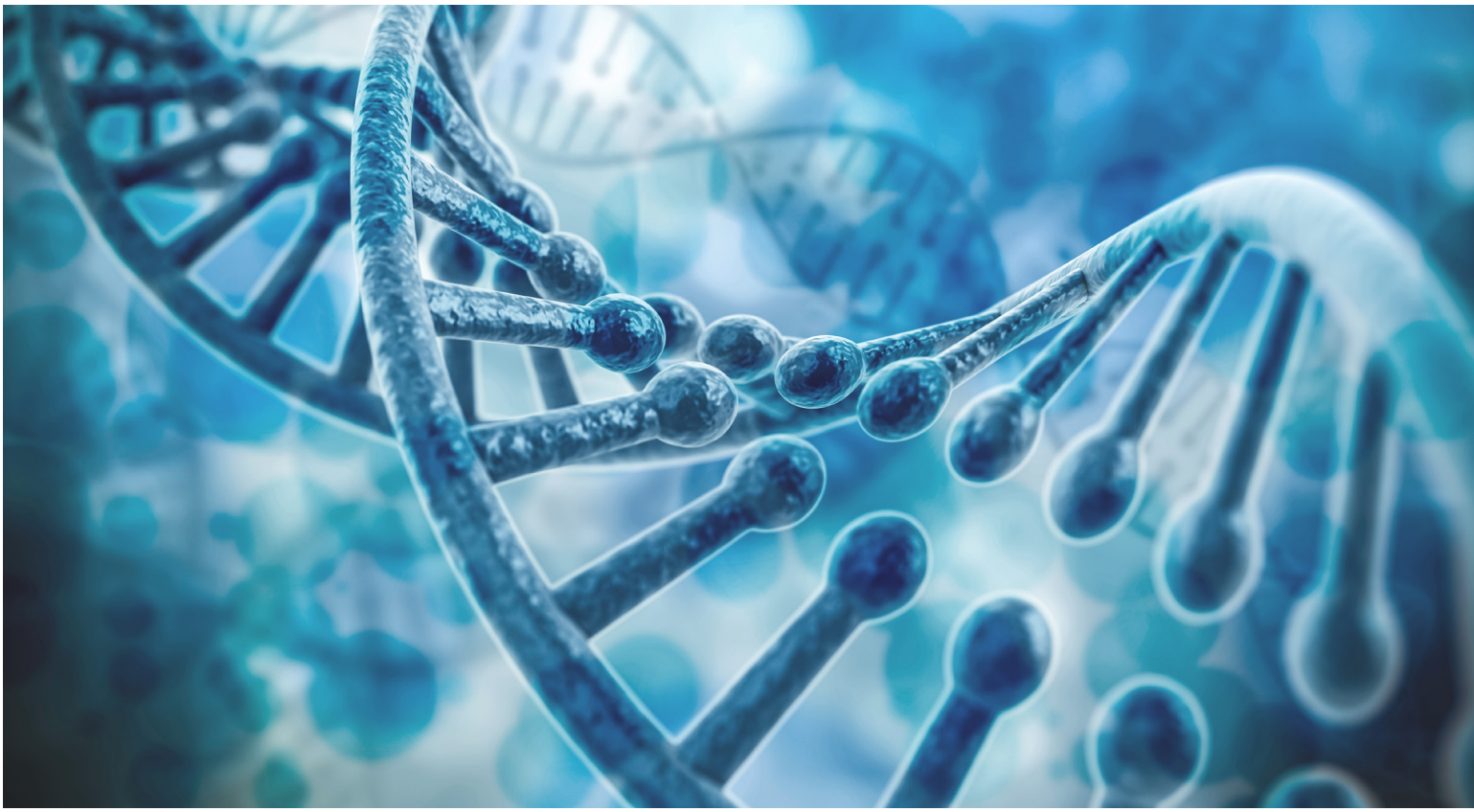
Starting in 2023, the inflationary rebate arm of the IRA will require drug manufacturers to pay rebates if the price of a drug (with no generic equivalent) rises faster than inflation. Given more than 50 percent of all drugs covered by Medicare had price increases above the rate of inflation between 2019 and 2020[2], one of the possible primary outcomes of capitation will be the shrinking margin of manufacturers' existing portfolio and contracts.

Medicare Part D benefit redesign, another pillar of the IRA, will eliminate 5 percent coinsurance for Part D catastrophic coverage (starting in 2024) and cap Medicare beneficiaries' annual OOP at $2,000 (starting in 2025). These changes mean lowering beneficiary spending by reducing coverage gap and shifting costs to plans and drug manufacturers.

In response to price increase capitation and increasing costs (as a result of OOP cap), we anticipate drug manufacturers could explore launching their products with higher initial prices (especially for highly differentiated assets), though clinical, access, and reimbursement considerations would need to be carefully weighed.

Pharma companies may also start scenario planning whether paying inflationary rebates to Medicare can be justified by revenue gains from other "books of business" (e.g., commercial). The overall question boils down to pursuing price increase that is in-line vs. above inflation (and if above, by how much), taking into account relevant factors such as therapeutic area and patient population demographics.

Additionally, manufacturers may start to think on how to adjust how they engage in payer and provider (for Part B/physician administered products) negotiations. There will likely be less willingness to offer significant discounts in negotiations and an attempt to be made "whole" by shifting prospective costs to other "books of business" to buffer for projected revenue reduction from Medicare and Medicaid. There may also be fundamental considerations made at the pre-commercial stage to affect how a manufacturer wants to compete in the marketplace with launch pricing and contracting strategies tailored to commercial versus Medicare markets.



[2] Source: "Prices Increased Faster Than Inflation for Half of all Drugs Covered by Medicare in 2020," KFF.org, Feb. 25 2022

Bioequivalent-focused generics manufacturers may see more opportunity in complex generic assets

To incentivize biosimilar uptake, the IRA temporarily increases Medicare Part B add-on payment for certain biosimilars from 6 percent to 8 percent of the reference product's average sales price (ASP) through the end of 2027. This provision, along with cost saving at the core of the IRA's mission, may create attractive opportunities for bioequivalent-focused Generics manufacturers (e.g., Teva) to turn their focus to higher complexity generics.

Other drivers of this trend include:

- Considerable biosimilar growth potential given 1) the U.S. will remain the largest biologic market in the world and 2) volume share of certain biosimilars may reach over 50 percent[3] by the end of their second year on the market despite an overall slower, initial biosimilar uptake in the U.S.
- Large number of pipeline biosimilar assets are already under development in the U.S. and globally, in response to expected patent expiry of several blockbuster biologic originators such as Humira and Stelara. [Exhibit 4]
- Interchangeability designation, a status that historically has required switching studies (which are lengthier and more expensive), has recently been granted to Cimerli (a biosimilar to Roche's Lucentis for wet AMD) by the FDA in the absence of switching study. This may pave the way for similar approvals in the future and make the space more attractive (e.g., lower R&D investments) to both incumbents and new entrants

Exhibit 4. Select blockbuster biologic originators expected to lose exclusivity during 2023-2026

Originator Brand	Molecule	Originator Company	Potential US Patent Expiry Year	US Sales 2021 ($M)
Humira	Adalimumab	AbbVie	2023	$17,330
Stelara	Ustekinumab	Janssen	2023	$5,938
Eylea	Aflibercept	Regeneron	2023	$5,792
Victoza	Liraglutide	Novo Nordisk	2023	$1,279
Cimzia	Certolizumab pegol	UCB	2024	$1,400
Perjeta	Pertuzumab	Genentech	2025	$1,550
Prolia	Denosumab	Amgen	2025	$2,150
Yervoy	Ipilimumab	Bristol Myers Squibb	2025	$1,265
Prevnar	Pneumococcal conjugate	Pfizer	2026	$2,701
Entyvio	Vedolizumab	Takeda	2026	$3,116

Source: Evaluate Pharma, Company Press Release

[3] Source: "Biosimilars in the United States 2020–2024," iqvia.com, Sept. 29, 2020

Path forward

With the enactment of the IRA where sweeping provisions aim to lower Medicare enrollees' drug costs, we anticipate life sciences companies will rethink their portfolio management and adjust approaches to R&D, clinical, and commercial strategy in order to navigate nuanced market changes, optimize commercial success, and ensure outcome and access to therapies by patients.

KPMG Deal Advisory & Strategy has a full suite of growth and performance improvement services to support clients across the entire product life cycle. KPMG Strategy provides support to biotech and pharmaceutical companies in exploring different value optimization and long-term growth strategy across areas such as precision medicine, portfolio management, pricing, and Gx/biosimilar. KPMG also provides clients with a full suite of due diligence services and advises on appropriate deal multiples.

Examples of engagement we support include:

- Early commercial planning and forecasting
- Pipeline asset forecast verification
- Commercial, financial, and operational due diligence supporting acquisition and divestiture of therapeutic assets and/or small-medium biopharma entities
- Organic and inorganic growth strategy analyzing precision medicine landscape in oncology, neurology, and rare disease
- Portfolio optimization strategy advising investments decisions on clinical stage assets and in-market therapeutics products

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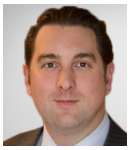

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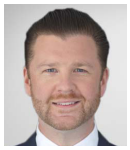

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