EXECUTIVE INSIGHTS

Pharma's New Normal: How the Inflation Reduction Act Will Impact the Biopharmaceutical Industry

The business model for biopharmaceutical research and manufacturing is unique among industries. Manufacturers invest in research and development (R&D) at high cost and with high risk and long-time horizons. In fact, the biopharmaceutical industry has the highest R&D intensity[1] of any industry as of 2019. As a result, in the past decade, the industry has brought to market transformative treatments including immune checkpoint inhibitors for solid tumor cancers, a new curative treatment for hepatitis C, cell therapy for leukemia and lymphoma, and, most recently, vaccines and treatments for COVID-19. U.S. companies led the world[2] in the number of new chemical and biological entities launched from 2000 to 2020, and the U.S. is widely considered the most critical market for biopharmaceutical manufacturers, accounting for nearly 50% of branded prescription biopharmaceutical net revenues.[3,4] This is due to a range of factors, including access to capital and talent, regulatory frameworks that promote innovation, and favorable pricing conditions.

On Aug. 16, President Biden signed the Inflation Reduction Act into law, marking the most significant healthcare reform since the Affordable Care Act. Several provisions of the act are a step forward in improving affordability of and access to innovative treatments, which is of benefit to patients and biopharmaceutical manufacturers alike. These include a limit on copayments for insulin covered under Part D or furnished through durable medical equipment (DME) under Part B; elimination of out-of-pocket cost sharing for adult vaccines covered under Part D, Medicaid and CHIP (Children's Health Insurance Program) programs; expanded eligibility for low-income subsidies; and, importantly, a $2,000 annual cap on Part D patient out-of-pocket costs for the first time ever. However, several of the act's key provisions will

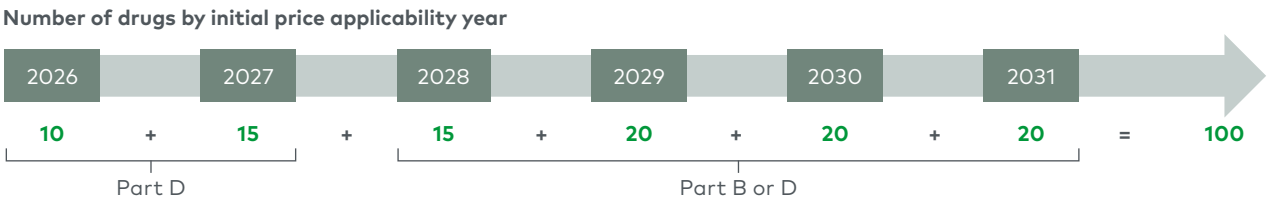
directly lead to lost revenue for biopharmaceutical manufacturers and require them to reevaluate their R&D budgets and portfolio priorities as a result. In this *Executive Insights*, L.E.K. Consulting discusses how this legislation is expected to impact biopharmaceutical manufacturers and how manufacturers can respond as they navigate this new normal.

Several key provisions of the Inflation Reduction Act focus on drug pricing

The law contains several key provisions related to Medicare that will directly impact drug pricing:[5]

- **Medicare drug price negotiation:** The secretary of Health and Human Services will be empowered to negotiate the prices of selected drugs with high budget impact on Medicare Parts B and D, with the first negotiated prices going into effect in 2026. The act's penalties for noncompliance (including up to a 95% excise tax and fines) effectively mandate that biopharmaceutical manufacturers participate in this program (see Figure 1).

Figure 1
Timeline and eligibility criteria for Medicare drug price negotiation



Negotiation eligibility criteria

- ✓ **Among the top 50 Part D and top 50 Part B drugs by spend** meeting all the below criteria
- ✓ **Single-source** branded (i.e., no generic or biosimilar)
- ✓ **Nine (small molecules) or 13 years (biologics)** post-approval when prices take effect
- ✓ **>$200 million total expenditures** under Parts B and D*
- × Are NOT **orphan drugs designated** for only one disease or condition and **only approved for that disease or condition**
- × Are NOT derived from **plasma or human whole blood**
- × In initial price applicability years 2026-28, are NOT "small biotech drugs,"** defined as:
  - **<1% of total expenditures** under Part D or Part B AND
  - **≥80% of manufacturer's total Part D or Part B expenditures**
- × Does NOT meet criteria for delayed selection and negotiation of biologics with **upcoming biosimilar entry**

*$200 million in expenditures from 6/1/2022 to 5/31/2023 for 2026 initial price applicability year; threshold adjusted for inflation annually
**Exception does not apply to new formulations of qualifying single-source drugs
Source: Inflation Reduction Act; L.E.K. analysis

- **Prescription drug inflation rebates:** Beginning in 2023, this law requires pharmaceutical manufacturers to pay rebates to the federal government if Medicare annual prices (Medicare payment rate for Part B, average manufacturer price for Part D) increase above the rate of inflation.
- **Medicare Part D plan redesign:** Beginning in 2025, manufacturers will now be required to give mandatory discounts of 10% of drug costs in the initial coverage period and 20% of

drug costs in the catastrophic coverage period,[6] as opposed to 70% discounts in the "donut hole" coverage gap, among other adjustments to the plan design. This redesign ultimately creates a dichotomy in which manufacturers will see lower value of discounts paid for lower-cost drugs and higher value of discounts for higher-cost drugs.

These provisions will substantially impact pharmaceutical manufacturer revenue

These provisions will have a significant direct and indirect effect on manufacturers' revenues, likely across payer channels.

- In the Medicare channel, which represented over 30% of national retail prescription drug expenditures in 2020,[7] revenue will be directly reduced through the above mechanisms. In its latest assessment,[8] the Congressional Budget Office (CBO) estimates that the prescription drug price inflation rebates and Medicare drug price negotiation provisions will result in combined cumulative government savings by 2031 of ~$200 billion, directly at the expense of manufacturer revenues, though the Committee for a Responsible Federal Budget[9] expects the CBO's final estimate to be lower. There remain significant uncertainties as to the extent of the impacts, including how much lower Medicare negotiated prices will be when compared to the established price ceilings.
- Medicare plan sponsors also now have more incentive to manage discounts and utilization for high-priced therapies, since the act increases the proportion of drug costs they are responsible for in the catastrophic coverage phase from 15% to 60%. They could seek more significant rebates from manufacturers to offset this.
- Medicare negotiated prices will be factored into best price calculations for Medicaid rebates and will also be given to 340B covered entities for entitled individuals if the negotiated price is lower than the 340B ceiling price, which may lead to revenue reductions for manufacturers in these channels as well.
- Commercial payers and pharmacy benefit managers representing them will likely seek to negotiate more significant discounts for drugs subject to Medicare negotiation, as they are unlikely to accept large discrepancies from published Medicare prices.
- One piece of Medicare Part D benefit redesign that is of particular benefit to manufacturers is the $2,000 patient out-of-pocket maximum, which is expected to increase access to therapies and offset some of the revenue impacts by driving greater volumes.

While the totality of these impacts is nearly impossible to quantify, it will almost certainly represent a substantial reduction in biopharma revenue. The legislation will affect some

companies more than others, particularly those with a higher concentration of high-Medicare-spend products in their portfolio. The risk of revenue declines contrasts significantly with the industry's strong historical revenue growth, which averaged ~30% in aggregate worldwide for top biopharma companies between 2014 and 2021.[10]

It is also worth noting that there are several additional potential consequences of these provisions. First, manufacturers may try to mitigate their revenue loss by setting higher list prices than they otherwise would have for newly launched drugs. Additionally, these provisions may disincentivize generics manufacturers from entering the market, given their pricing advantage relative to Medicare-negotiated branded drugs may not be sufficiently attractive for them to generate significant volume and revenue. As of 2018, unbranded generics represent 84% of prescription drug volume[11] in the U.S. but only 35% in a group of 32 other OECD (Organization for Economic Cooperation and Development) countries.

The pricing provisions and resulting net revenue loss will directly impact innovation and portfolio decisions

L.E.K. expects these revenue reductions to have immediate and long-lasting consequences for biopharma R&D investment levels and portfolio strategy, resulting in lower overall levels of innovation. The CBO estimates that the act would lead to approximately a 1% decline in newly approved drugs over the next three decades.[12] Pharmaceutical Research and Manufacturers of America (PhRMA), however, has noted that this significantly underestimates the impact due to several methodological limitations.[13] These include (perhaps most importantly) that the CBO study only examines newly approved drugs and does not account for reduced investment in life cycle management (LCM), it assumes any positive return on investment (even if marginal) would result in a decision to invest, and it does not account for an increased number of new approvals over time.

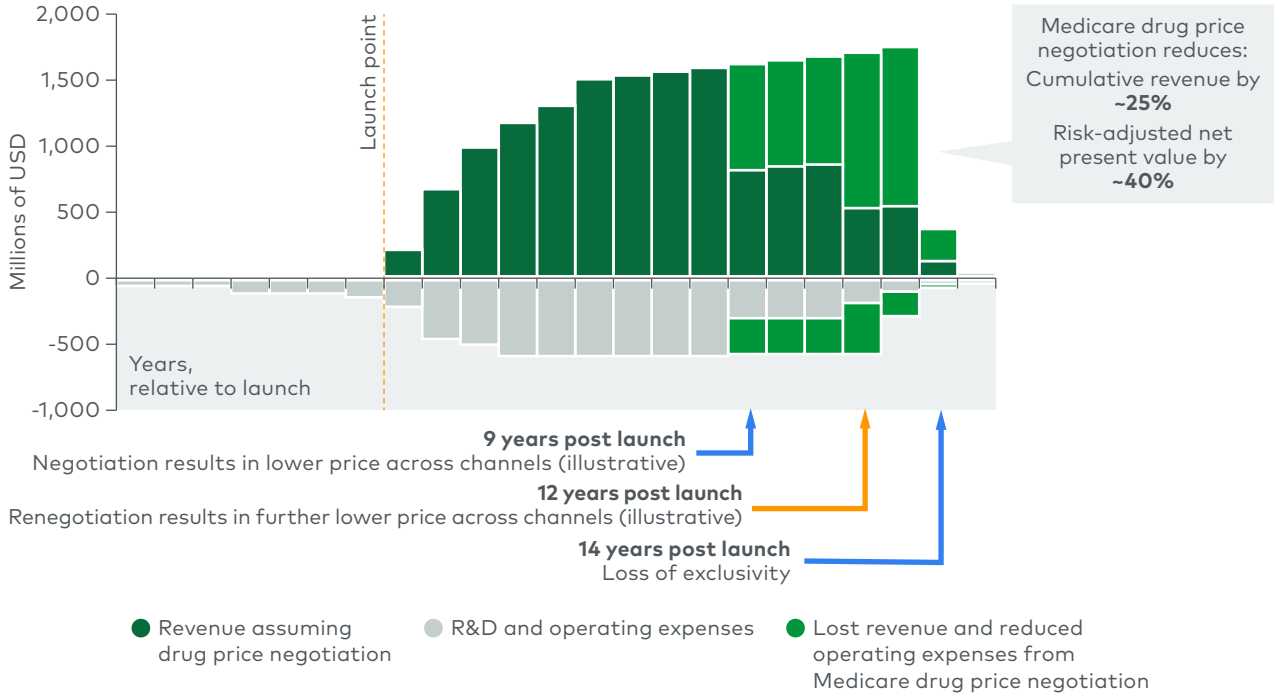
The types of programs that would likely be the most impacted are concentrated in three areas: small molecules, LCM programs and diseases disproportionately affecting the elderly. The effects will be felt not only by large- and mid-cap biopharmas, but also by emerging (often pre-revenue) biopharma companies. In fact, many from the healthcare investing community[14] publicly stated in July that even before the act was passed, it made them "extremely cautious and hesitant to fund any new small molecule projects for diseases of aging."

- **Small molecules:** Small molecule drugs may be subject to negotiated drug prices nine years after Food and Drug Administration (FDA) approval if selected, compared to 13 years after approval for biologics. This nine-year pre-negotiation period is over 35% shorter than the average 14.4-year period[15] that small molecules have recently enjoyed prior to generic

competition.[16] That ~5.5-year difference can significantly reduce the net present value of small molecules, as illustrated in Figure 2. The extent to which net present value is impacted will be highly sensitive to what level of rebating is already occurring prior to negotiation, the extent to which the Medicare-negotiated rebate is lower than the ceiling for maximum fair price and the extent to which commercial insurers are able to negotiate similar rebates. The industry likely cannot move away from small molecules entirely, as they can reach many targets (particularly intracellular targets) that traditional biologics like monoclonal antibodies cannot. Nonetheless, these dynamics may accelerate the industry-level pipeline shift toward biologics, particularly in conditions that are concentrated in the Medicare population.

Figure 2

Illustrative impact of small molecule price negotiation on asset financial performance for a lead indication

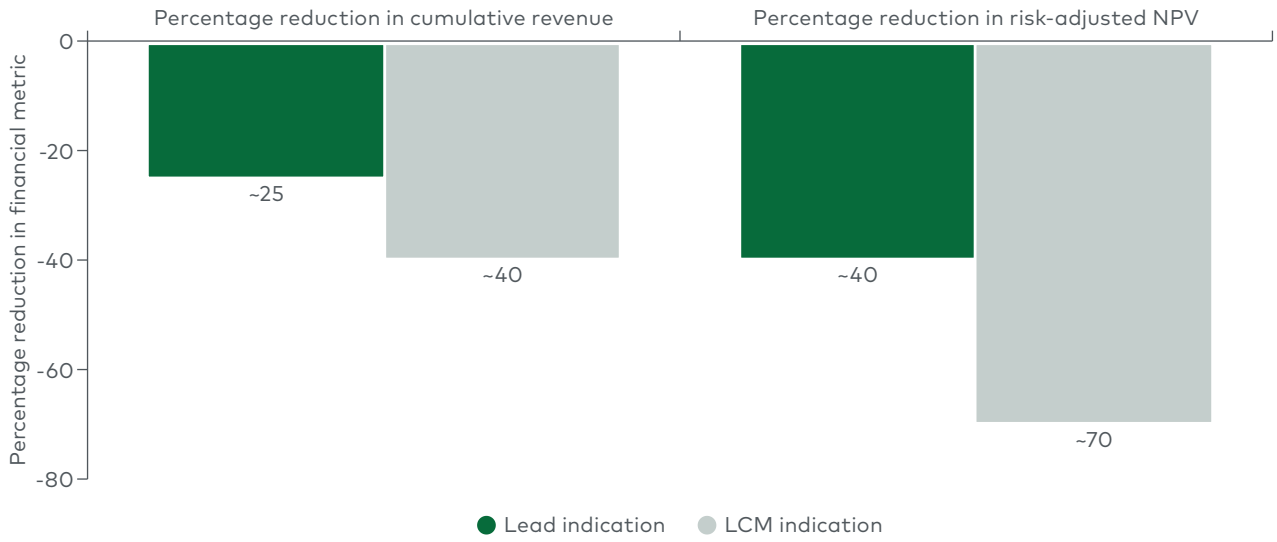


Source: Biotechnology Innovation Organization/PharmaIntelligence Informa/Quantitative Life Sciences; L.E.K. analysis

- **Life cycle management programs:** Some of the most successful drugs have launched into multiple diseases, patient segments and/or lines of therapy over their life cycles. Particularly in oncology, the first-launched indication is typically in a later line of therapy where clinical trials may be first run on patients who have no proven therapeutic alternatives, and then the manufacturer runs post-approval trials to expand the use of the drug into earlier lines of therapy, providing a more effective treatment option for a greater number of patients. It is the investments from these indications that may be most severely impacted by drug price negotiations, as these will have the least time to generate returns (see Figure 3). Instead,

manufacturers may seek to progress multiple molecules with the same mechanism through development for separate indications.

Figure 3
Illustrative impact of small molecule price negotiation on asset financial performance for a life cycle management indication



Note: LCM=life cycle management; NPV=net present value
Source: Biotechnology Innovation Organization/PharmaIntelligence Informa/Quantitative Life Sciences; L.E.K. analysis

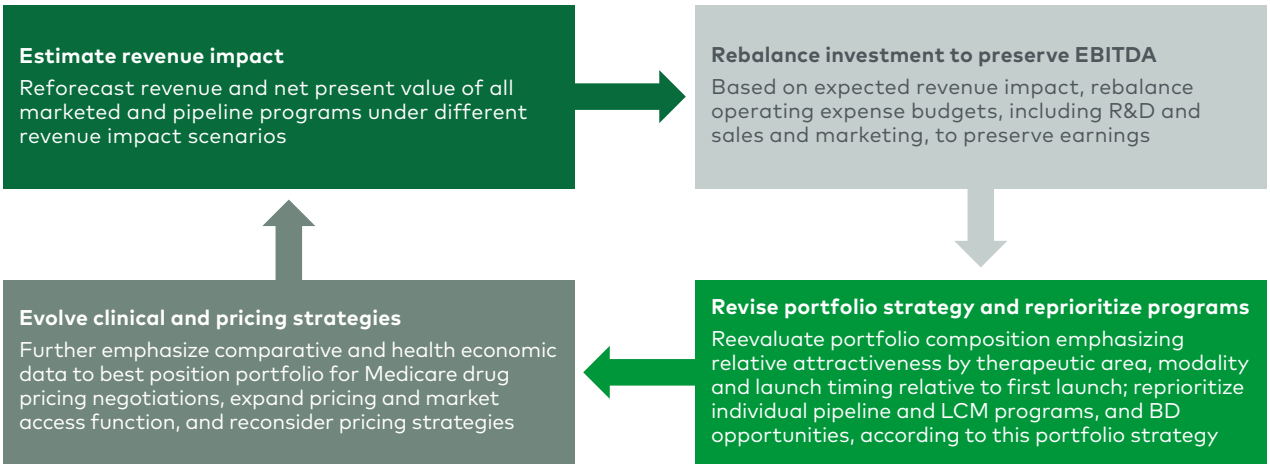
- **Diseases disproportionately affecting the elderly:** Particularly within cuts to small molecule and LCM programs, manufacturers may seek to rebalance their portfolios away from diseases that predominantly affect elderly patients and therefore where Medicare represents a large script volume. These include some of the diseases with the highest morbidity, mortality and unmet medical need — like cancer, heart disease, cerebrovascular diseases, chronic lower respiratory disease and Alzheimer's disease, which together comprised nearly 60% of U.S. deaths[17] in 2019.

There are several specific steps manufacturers should take to best position themselves for sustained growth in the era of the Inflation Reduction Act

While it is difficult to estimate the extent of the Inflation Reduction Act's impact at an industry level, there are several specific steps that pharmaceutical manufacturers should take today to better prepare themselves to navigate the new normal that it has established (see Figure 4).

- **Reassess revenue projections:** Manufacturers will not be equally affected by the drug pricing provisions, given the different compositions of their marketed portfolio and pipeline programs. Each will need to revise its long-range revenue forecasts based on a detailed evaluation of the range of potential impacts to revenue for each of its programs. The

Figure 4
Proposed manufacturer steps to respond to the Inflation Reduction Act



Note: LCM=life cycle management; BD=Business development
Source: L.E.K. analysis

considerations for estimating these impacts are complex and must take into account how the law applies not only to a manufacturer's own products, but also to competitor products, which can drive large changes in market share.

- **Rebalance investment to preserve EBITDA:** Even a modest decrease in revenue can have an outsized impact on EBITDA. With many segment leaders prioritizing continued EBITDA growth, manufacturers will need to thoroughly reassess long-range development to preserve continued EBITDA growth in the face of lower-than-expected revenues as pricing controls come online. Beyond EBITDA preservation, companies may also require a higher expected return-on-investment threshold for investing in new programs due to the increased risk from potential Medicare negotiations or even further legislative reforms.
- **Revise portfolio strategy and reprioritize programs:** With revised revenue forecasts and R&D budgets in hand, manufacturers will need to evaluate their R&D portfolio's composition by therapeutic area, modality, and balance between LCM and first-approval programs. Manufacturers may attempt to shift their portfolio balance more toward biologics. Additionally, the pricing negotiation program may incentivize companies to prioritize multiple assets with few targeted indications rather than "pipeline-in-a-product" development programs, since LCM indications would be disproportionately impacted, and multi-indication blockbusters are likely to face increased pricing scrutiny. Instead, manufacturers may advance multiple molecules with the same mechanism of action through development, each targeting different indications. Manufacturers may also consider greater investment in precision medicines, with more-defined patient populations,

and single-disease orphan medicines, which are excluded from pricing negotiation eligibility. It will likely take months for some of the initial portfolio reprioritization decisions to be made, given the complexity of the decision-making process.

- **Evolve the organization to prepare for future negotiations:** The Inflation Reduction Act will alter the way in which manufacturers can best position themselves from a pricing and market access standpoint. While the concept of value-based pricing has been gaining traction over the past several years, comparative data and real-world cost-effectiveness evidence will become more important than ever as manufacturers seek to defend their pricing decisions both in Medicare negotiations and across payer channels. Success in future negotiations will be dependent on clinical data being developed today and in the near future. Manufacturers are advised to take a cross-functional approach to clinical trial design, integrating pricing/market access insight into clinical planning to ensure clinical trials will both generate the data required for approval and evaluate the value metrics that will support future pricing potential.

The priorities are slightly different for emerging biopharma companies. They too will need to assess revenue impacts, reevaluate their portfolio strategy and investments, and emphasize comparative data in their clinical programs. But beyond that, they will also need to reevaluate their partnership strategy, invest earlier than before in a pricing and market access function and strategy, and reevaluate their strategy for capital raising in the face of some investment headwinds.

Despite the progress the Inflation Reduction Act makes in reducing cost and increasing access to innovative medicines, it also introduces a considerable degree of uncertainty for biopharmaceutical manufacturers. Amid this uncertainty, there are clear steps that manufacturers should take to plan and move forward in this new reality they are facing.

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Endnotes

[1]Publications Office of the European Union

[2]European Federation of Pharmaceutical Industries and Associations

[3]Evaluate Pharma

[4]2021 net revenues excluding over-the-counter products, generics, biosimilars and diagnostic imaging agents

[5]Inflation Reduction Act, 2022

[6]The mandatory discount is a percentage of the negotiated price as defined by the Social Security Act as "taking into account negotiated price concessions, such as discounts, direct or indirect subsidies, rebates, and direct or indirect remunerations, for covered part D drugs, and include any dispensing fees for such drugs."

[7]CMS

[8]Congressional Budget Office

[9]Committee for a Responsible Federal Budget

[10]Average of 2014 to 2021 worldwide branded pharmaceutical revenue growth for 11 of the top 15 biopharma companies as of 2021. BMS, AbbVie and Takeda excluded due to transformative acquisitions in the years between 2014 and 2021. Eli Lilly excluded due to lack of segment-specific revenue reporting in 2014.

[11]U.S. Health and Human Services

[12]CBO

[13]Pharmaceutical Research and Manufacturers of America (PhRMA)

[14]No Patient Left Behind, July 25, 2022

[15]Americas Society for Clinical Pharmacology & Therapeutics

[16]For drugs with new generic competition between 2012 and 2018

[17]CDC Data, December 2021

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