WHAT TO KNOW ABOUT THE INFLATION REDUCTION ACT'S DRUG PROVISIONS

What is the Inflation Reduction Act (IRA)?

The IRA, signed into law on August 16, 2022, will impose price caps on 100 medicines in the Medicare program by 2031. These government price controls will hurt innovators -- particularly small biotechs -- and patients desperate for new treatments.

Nonetheless, the IRA does include separate reforms that aim to help Medicare enrollees with out-of-pocket expenses. The law also contains promising measures on agricultural biotechnology and environmental sustainability -- including historic investments of $369 billion for clean energy and climate change initiatives and $20 billion for targeted conservation programs.

Is it really fair to describe the IRA's "negotiations" as price controls?

Yes. IRA proponents say the legislation merely allows the government to "negotiate" the price of drugs. But the legislative text makes clear that these negotiations are just government price controls by another name.

The law requires the government to set a "maximum fair price," which is based on a statutory formula and other factors. Given the outsized penalties in the law, companies are essentially forced to accept this price.

Will the IRA impact R&D?

Unquestionably yes. Health consulting firm Avalere estimates that the IRA will cost biotech companies $450 billion over the next decade. Such a staggering reduction in revenue will obviously lead to cuts in R&D spending.

- According to recent estimates by University of Chicago economist Tomas J. Philipson, the IRA's price controls could result in 135 fewer new drug approvals for patients and the consequent loss of 331 million life years by 2039.
- Small biotechs that drive innovation -- and account for the majority of new medicines -- will be disproportionately impacted by the law. The venture capital investments that fuel their pursuit of promising treatments will decrease (as investors look to other sectors) and, unlike large companies, they lack cash reserves to turn to. We're already seeing biotechs forgoing planned clinical trials because of price controls.
- R&D cutbacks could result in roughly 600,000 lost biotech jobs in the United States by 2031, per estimates from health consultants Vital Transformation.

How does the IRA impact other parts of the distribution chain?

Unfortunately, the IRA is largely a missed opportunity to address other parts of the distribution system that have provided warped incentives, such as PBM rebate reform. There aren't any

mandates placed on PBMs and plans to ensure that formulary structure and benefit design are not then utilized to further restrict patient access or steer them toward high-rebate drugs.

Does the IRA include a carve out for small biotechs?

Yes, but one that's likely to help a limited number of companies.

The IRA exempts a drug from price controls if the medicine in question accounts for more than 80% of a small biotech's Medicare business yet less than 1% of Medicare Part B or Part D spending.

However, for qualifying products, the exception expires in 2029, and you can only qualify if you meet the conditions in 2021 mentioned above in 2021.

While that provision will help some small biotechs, it is unlikely to significantly offset the overall damage done under price controls.

- Biotech companies generally focus on early- and mid-stage research, and they typically lack the resources to conduct late-stage, hugely expensive clinical trials or build out a worldwide sales and distribution network. That's why they often sell themselves to, or partner with, larger companies that have more production and distribution experience.
- Vital Transformation recently analyzed a cohort of 363 new medicines approved by the FDA between 2011 and 2020 and found that 55 percent were developed by small firms with less than $500 million in annual revenue. But it was large companies who managed post-FDA approval development, marketing, and scale for many of these medicines.
    - A recent example of this dynamic, for instance, is when BioNTech successfully partnered with Pfizer after developing its breakthrough mRNA Covid-19 vaccine.
- The success of this diversified R&D ecosystem has led to a 152 percent increase in U.S. external R&D partnerships and investments since 2011, per Vital Transformations estimates.

The IRA effectively penalizes such partnerships and perversely incentivizes small biotechs to spend their limited capital -- that's best allocated to R&D -- on boosting manufacturing and distribution capabilities to avoid the price controls. The implicit penalty for partnering with bigger companies will lower biotech valuations and make it harder for small firms to raise the venture capital they need to hire scientists and conduct research.

As Small Business & Entrepreneurship Council president Karen Kerrigan notes, the price controls will hinder small biotechs' ability to innovate.

Does the IRA include any exemptions for rare disease or orphan drugs?

Yes, but again the limited scope of the IRA fail to match drug development and actually risk disincentivizing orphan drug R&D. Orphan drugs designated for *only one* disease or condition and approved for only that one disease or condition are exempt. Any subsequent designations- even for another orphan condition- would result in the elimination of the exemption for all conditions.

This has serious unintended consequences for follow-on R&D for existing orphan drug conditions and will naturally impact manufacturer decision making.

Are there any redeeming parts of the IRA when it comes to biotech?

The IRA does include important reforms to help Medicare enrollees by:

- capping beneficiaries' out-of-pocket drug spending at $2,000/year, starting in 2025.
- including a "smoothing" provision to allow beneficiaries to spread cost-sharing obligations out over the whole year.
- limiting insulin copays to $35/month, starting in 2023.
- capping future increases in Medicare Part D premiums at 6% per year from 2024 to 2030.

The IRA also contains positive measures and takeaways for biotechs working on agriculture and climate change solutions, including:

- an historic federal investment of $369 billion for energy and climate change.
- a significant tax credit for sellers of sustainable aviation fuels (SAFs) from 2003 to 2004.
- grants of $500 million for blender pumps and other biofuel infrastructure, $244.5 million to support production, transport, blending, or storage of SAFs, and $46.5 million for developing low-emission aviation technologies.
- the IRA's largest agriculture expenditure of $20 billion for conservation programs targeted to private landowners.
- the potential to reduce U.S. emissions approximately 40% below 2005 levels by 2030.