THE INFLATION REDUCTION ACT EXCLUSION EFFECT: AN ANALYSIS OF INFLATION REDUCTION ACT MINIMUM-DISCOUNT NEGOTIATION RULES

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SUMMARY

- The 2022 Inflation Reduction Act (IRA) introduced mandated price discount/negotiations
- However, there are exemptions from this mandate excluding therapies such as those with less than $200M in annual Medicare spending, biosimilar or generic entrants available, only a single orphan indication, and those that are vaccines or plasma-derived
- This research seeks to assess how much these exemptions may impact the law's ability to contain Medicare spending
- Results showed that 228 therapies exceeded the IRA annual spending threshold, 33% of which were exempt from negotiation, majority with generics and biosimilars available

INTRODUCTION

- The 2022 Inflation Reduction Act (IRA) was introduced to contain Medicare spending
- A key feature of the Act was the introduction of mandated price discount / negotiations of at least 25% for selected therapies that have been on the market at least 9-13 years
- However, the IRA includes several exemptions excluding therapies from these discounts / negotiations e.g., therapies with less than $200M in annual Medicare spending, biosimilar or generic entrants available, only a single orphan indication, and those that are vaccines or plasma-derived

IRA MINIMUM-DISCOUNT NEGOTIATIONS' IMPACT

- Through the creation of a mandated minimum-discount negotiation program, the IRA seeks to obtain significant savings for Medicare by capping the current free pricing period that pharmaceuticals have historically enjoyed indefinitely with Medicare
- With established minimum-discount thresholds starting at 25%, a key uncertainty regarding the impact of the IRA will be determined by the level of discounts the Secretary of Health and Human Services applies to the initial negotiations beginning in 2026
- In addition to the IRA's impact on Medicare spending the long-term price pressure introduced by the IRA's minimum-discount negotiations will likely lead to increases in launch pricing
- Manufacturers will likely update their lifecycle management strategy and launch sequencing to prioritize faster revenue growth prior to negotiation eligibility as opposed to historic strategies of launching in a proof-of-concept indication

OBJECTIVES

- The present research seeks to assess how much the mandated minimum-discount negotiation exemptions may impact the law's ability to contain Medicare spending, and, thus, fulfill the law's overall goal
- The research also seeks to understand what IRA exemption categories will be most impactful based on 2020 Medicare spending trends

METHODS

- 2020 Medicare expenditure data were examined to assess the fraction of eligible therapies and drug spend, that exempt therapies represent, and in particular exempt therapies without biosimilar or generic competition (since cost containment opportunities should already be captured through the price competition that generics and biosimilars introduce)
- All therapies that did not meet the IRA $200M spending threshold were removed. Next, the remaining therapies were cross checked for the remaining exemption classifications. The research also qualitatively considered indirect effects of the IRA on exempt therapies (i.e., impact of discounted competitors)

RESULTS

- 228 therapies exceeded the IRA annual Medicare spending threshold. Of these, 33% (N=77) would be exempt from negotiation
- Exempt therapies ranged between chronic and acute conditions, oncology and non-oncology, as well as across manufacturers
- Furthermore, we found that 67 exempt therapies had a biosimilar or generic competitor available, but there were also several vaccines (N=5) and plasma-derived therapies (N=5)
- Medicare spent $30.7B on exempt therapies in 2020, accounting for 4% of total spending
- Options for exempt therapies without existing biosimilar / generic competition (i.e., vaccines and plasma derived therapies) only accounted for 0.5% ($4.5B) of 2020 Medicare spending

Figure 1 | IRA Negotiation Eligibility Based on 2020 Medicare Spending

Key Finding: Approximately one third of the therapies above the spending threshold are ineligible for negotiations

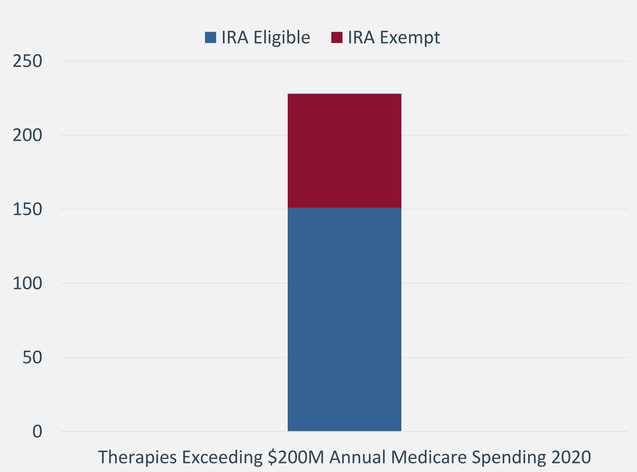
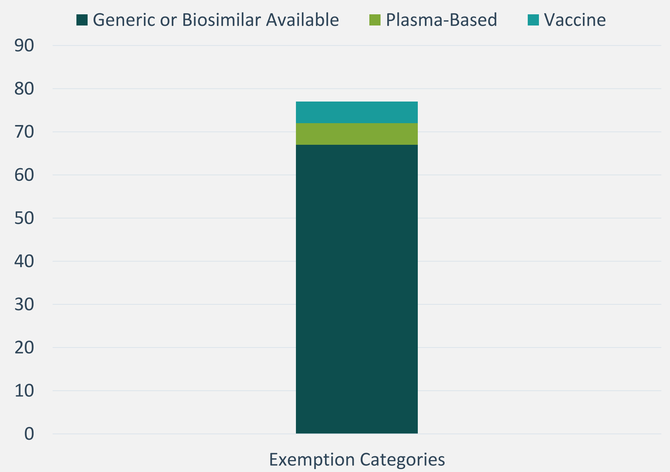


Figure 2 | Exemption Category Distribution Based on 2020 Medicare Spending

Key Finding: Most ineligible therapies have generic or biosimilar competitors available



SMALL BIOTECH EXEMPTION IMPACT

- In addition to the exemptions analyzed in this research, the IRA also includes a temporary exemption for negotiation eligibility for small biotech firms
- To meet the small biotech exemption criteria, manufacturers must have a qualifying single source drug that was at least 80% of all Part B or D Expenditures in 2021 for the company and equal to or less than 1% of all Part B or D total expenditures
- While a significant portion of therapies are eligible for this exemption, the rule is only in effect for negotiation selection in 2026-2028
- Therefore, the small biotech rule is not expected to be impactful to the overall cost-saving effect of the IRA as only 40 negotiation selections will occur by this time

CONCLUSION

POLICY IMPACT

- Since genericization is the main driver of IRA negotiation exemptions, these exemptions will likely have a minimal impact on the IRA's effect on cost containment
- Therapies with generic and biosimilar competitors will remain exempt from negotiations but still experience long-term price pressure

PHARMA IMPACT

- Although biopharma stakeholders will likely pursue exemptions, due to the narrow exemption criteria, it is likely there will be limited opportunities to remain exempt from IRA price negotiations without a generic competitor
- Ultimately, exemptions will not enable long-term exclusivity or post-exclusivity profits for most therapies

INVESTMENT IMPACT

- Manufacturers may prioritize investing in exempt therapy categories (e.g., vaccines, plasma-based therapies) due to their long-term protection from mandatory discounts

REFERENCES

1. Medicare Drug Price Negotiation Program: Initial Memorandum, Implementation of Sections 1191 – 1198 of the Social Security Act for Initial Price Applicability Year 2026, and Solicitation of Comments.

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Disclosures: All the authors are employees of Trinity Life Sciences (Waltham, MA), and CF holds equity in Trinity Life Sciences.