The Unintended Consequences of the Inflation Reduction Act on Biosimilar Market Incentives and Medicare Savings

HPR38

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METHODS

- The Inflation Reduction Act (IRA) of 2022 authorized Medicare to negotiate prices for select high-expenditure drugs, with the first negotiated prices taking effect in January 2026.
- The IRA includes a 'special rule' that defers negotiation for biologics with "imminent" biosimilar competition.
- Because biosimilars play a key role in promoting competition and reducing spending, it is unclear whether this provision preserves market incentives for biosimilar development.
- This study examined how the IRA may interact with biosimilar competition.

BACKGROUND & OBJECTIVE

Data Sources

- Part B drugs: Average Sales Price data (2017-2025) from the Centers for Medicare and Medicaid Services quarterly payment files.
- Part D drugs: Net price estimates from SSR health.
- Market share: IQVIA Longitudinal and Adjudicated Data Set (2017–2024) from IQVIA

Analyses

We modeled Medicare savings under three policy scenarios to assess how IRA implementation may interact with biosimilar competition:

- ***Scenario 1 Biosimilar Competition***

We estimated historic price declines following biosimilar entry (2017-2024) and applied these trends to project future savings for negotiated biologics with imminent biosimilar entry, focusing on ustekinumab.

- ***Scenario 2 Current IRA Implementation***

We compared projected biosimilar-driven savings with expected IRA discounts (maximum fair price) for ustekinumab, assuming no biosimilar entry.

- ***Scenario 3 Modified IRA Implementation***

We modeled a scenario in which ustekinumab is excluded from negotiation due to biosimilar entry and replaced with palbociclib, a high-expenditure, single-source drug eligible under the IRA.

RESULTS

Figure 1: Market-weighted mean originator-biosimilar net prices since first biosimilar launch, part B & part D drugs

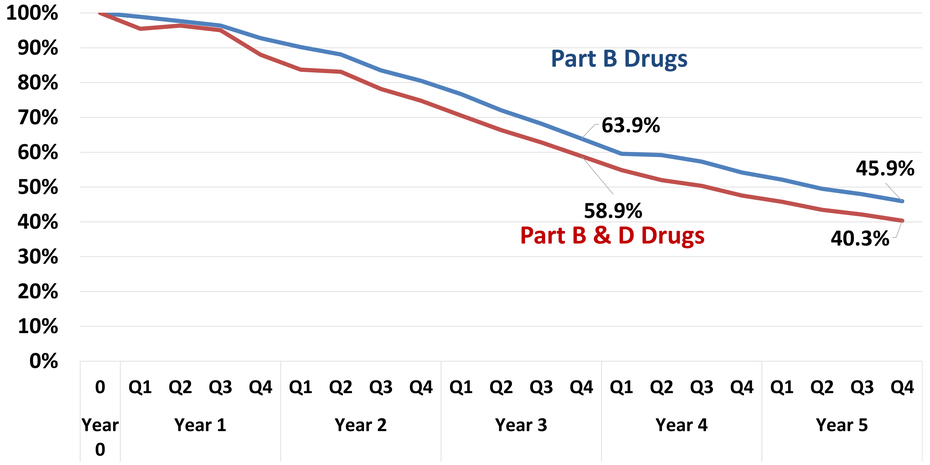
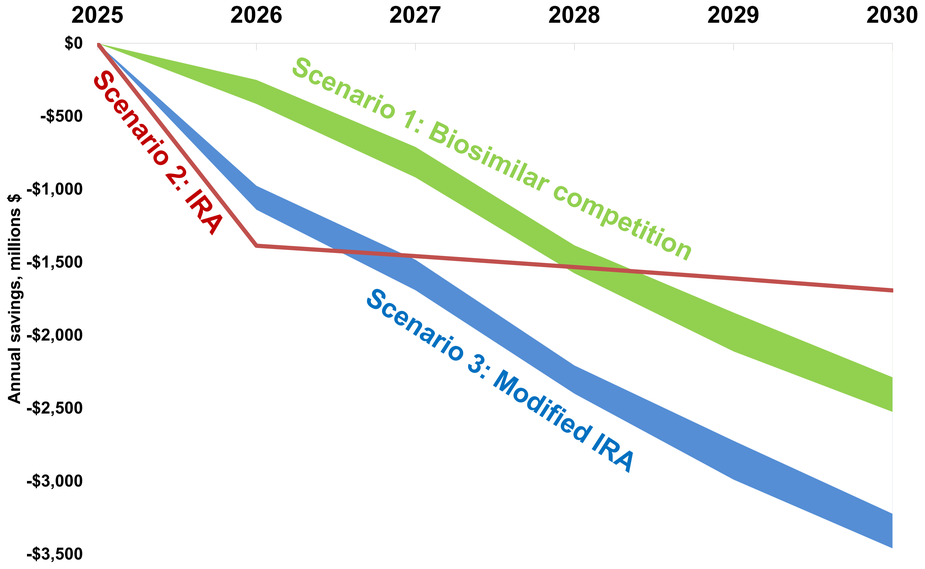


Figure 2: Estimated annual Medicare savings, by Scenario



Key Points

- Market-weighted biologic prices declined substantially after biosimilar entry, reaching 58.9% of pre-launch prices at 3 years and 40.3% at 5 years.(Figure 1)
- Scenario 1: Applying these trends to ustekinumab, we estimate that biosimilar competition would generate CMS savings of $251-$416 million in year 1 and $2.3 billion by year 5 (Figure 2).
- Scenario 2: We estimate IRA-driven savings for ustekinumab of approximately $1.4 billion in year 1 and $1.7 billion by year 5 (Figure 2).
- Scenario 3: Replacing ustekinumab with palbociclib on the negotiation list, while allowing ustekinumab to face biosimilar competition, yields estimated CMS savings of $976 million–$1.1 billion in year 1 and $3.2–$3.5 billion by year 5 (Figure 2).

CONCLUSION

- Biosimilar competition and the IRA both generate Medicare savings for, but at different rates and on different timelines.
- IRA price negotiation produces greater short-term savings, while biosimilar competition may yield larger cumulative savings by year 3 after market entry.
- Failing to balance short-term IRA savings with long-term biosimilar competition risks reducing both total savings and incentives for future biosimilar development.
- CMS should implement a "biosimilar readiness review" to assess whether credible biosimilar entry is likely within 1–2 years and clarify the definition of "imminent biosimilar entry."

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CONTACT

Not a SPEC Database project
For more information on the SPEC Database, contact James Chambers at james.chambers@tuftsmedicine.org