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A Quantitative Exploration of Challenges to the Sustainability of the United States Biosimilar Market

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Background

- Biosimilars are biologic medications that are highly similar to, and have no clinically meaningful differences from, existing approved biologics known as “reference products”.[1]
- Biosimilars have generated significant savings by increasing competition and driving down prices in the biologic product markets.
- These dynamics increase cost-savings in the short-term but may result in diminished incentives for manufacturers to enter and/or remain in the market.

Objective

We sought to explore the relationship between market concentration in the U.S. on the price of reference products and biosimilars

Conclusions

- Our findings suggest that higher market concentration (less competition) is associated with higher prices.
- Although no biosimilar manufacturers have exited the US market, an exit would increase market concentration and may lead to potential price increases.
- If current downward price trends continue, the cost-saving potential of biosimilars could be altered.

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Methods

- A total of 21 biosimilars were available in the US market as of July 2023.
- We used Centers for Medicare and Medicaid Services (CMS) data over 34 quarters beginning in 2015 to assess the relationship between market concentration quantified with the Herfindahl-Hirshman Index (HHI) and Average Sales Price (ASP) in eight biologic markets.
- ASP change was quantified as the ratio of the volume-weighted product market ASP over time to the ASP of the originator in the quarter prior to biosimilar competition.
- Using an instrumental variables approach, we evaluated the relationship between market concentration (HHI) and price (ASP ratio) using reference product fixed effects models.

$$ASP_{ratio_{it}} = \beta_0 + \beta_{it-2} IV + \varphi_i + e_{it}$$

- Where $ASP_{ratio_{it}}$ represents one of the two defined price ratios for reference product i in quarter t. IV represents quarters since reference product approval, the instrumental variable used for HHI (the the sum of each product market share squared, lagged by two quarters). φ_i is a reference product fixed effect and e_{it} is the error term.[2] β_{it-2} is the coefficient of interest.
- Calculation of HHI relationship to wASP: $\frac{115\% \times average\ HHI\ in\ quarter\ t \times \beta_{it-2}}{average\ wASP\ in\ quarter\ t+2}$.

Table 1. Product Groups

Bevacizumab
Epoetin Alfa
Filgrastim
Infliximab
Pegfilgrastim
Ranibizumab
Rituximab
Trastuzumab

Table 2. Definitions

Average Sales Price (ASP): weighted average of all manufacturer sales prices[3]
ASP Ratio: mean volume-weighted product market ASP in each quarter divided by the fixed reference product ASP in the quarter before competition
Biosimilar: a biological product that is highly similar with no clinically meaningful differences from a reference product[4]
Reference Product: an FDA-approved biologic (branded drug) to which biosimilars are compared[4]
Herfindahl-Hirshman Index (HHI): a measure of the competitiveness of an industry in terms of the market concentration of its participants, with the highest value being 10,000 (single firm).[5] High values indicate more concentration (less competition).

Results

$$\beta_{it-2} = 0.000883; \quad p < 0.01$$

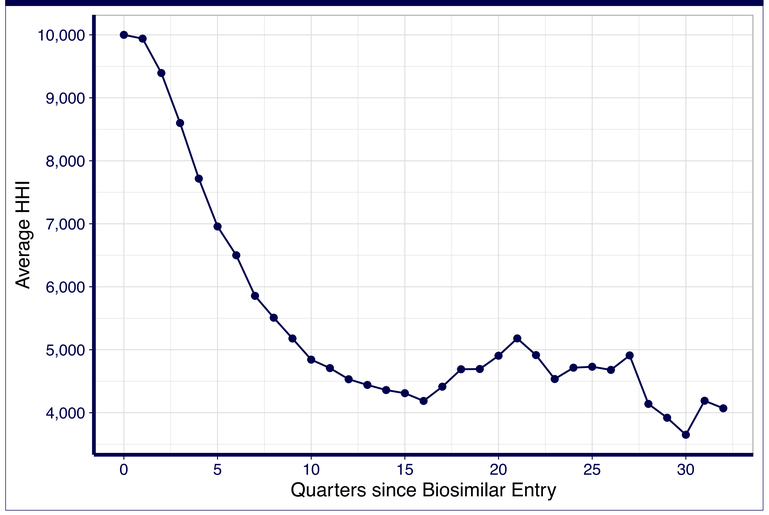
- The number of competitors in each market varied (range 2 to 7) and the pricing dynamics in each are unique. The mean HHI was 6,500, 4,843, and 4,360 at 4-, 8-, and 12-quarters after biosimilar entry across product markets.

Table 3. Results

Quarters after biosimilar entry	Mean HHI	Price ratio Δ related to 15% higher HHI
4	6,500	**10.8%**
8	4,843	**9.6%**
12	4,360	**10.7%**

In aggregate, we found that a 15% higher market concentration (HHI) was associated with an approximately 10% higher ASP price ratio at these three time points.

Figure 1. Average HHI by Quarter since Biosimilar Entry



Limitations

- Some biologics in our sample only had biosimilar data for a few quarters, due to recent biosimilar entry.
- Price, volume, and market share trends vary widely across individual drug markets, so while our estimates apply to biologics markets on average, estimates within each individual market may range significantly.
- Price dynamics may be influenced by other therapies that can serve as substitutes that are not included in this analysis.

Discussion

- Market concentration is a measure of competition and is related to price in the originator and biosimilars markets.
- Competition puts downward pressure on prices and generates savings, but threatened sustainability may decrease market entrants and increase the risk of market exits, both of which may lead to reduced competition and therefore savings.