Evaluation of the Relative Impact of Factors Influencing Originator U.S. Market Share Following Biosimilar Launch

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OBJECTIVES

Biosimilar products, which are derived from an originator biological molecule, have had a significant impact on various therapeutic areas. With rapidly emerging therapies, examining the impact of biosimilar pricing and access is critical for understanding the complexities of the healthcare system.

Biosimilars are often available at a lower cost to their reference product, seeking to gain preferred access on health plan formularies to drive market share. However, originator manufacturers typically engage in contracting to provide discounts and rebates in an effort to defend market share from biosimilar competition. Given the value of understanding the implications of biosimilar approvals, we reassessed a predictive model developed in 2023 to evaluate the relative impact of factors influencing originator US market share.

METHODS

To reexamine the impact of predictor variables on the impact on originator market share, we utilized a multivariate regression model developed in 2022. The analysis included 10 originators with 26 approved biosimilars. Variables included aggregate biosimilar market share relative to each originator, number of biosimilars, duration of biosimilar competition, originator orphan designation, WAC differentials between originator and biosimilar(s), and payer management. An analysis of 15 health plans' formulary documents as of 12/1/23 was conducted to identify step therapy requirements for each originator. Market share and model inputs were captured from FDA, NORD, IQVIA Biosimilar Report, Drugs.com, and other publicly available sources. The significance level was α=0.05.

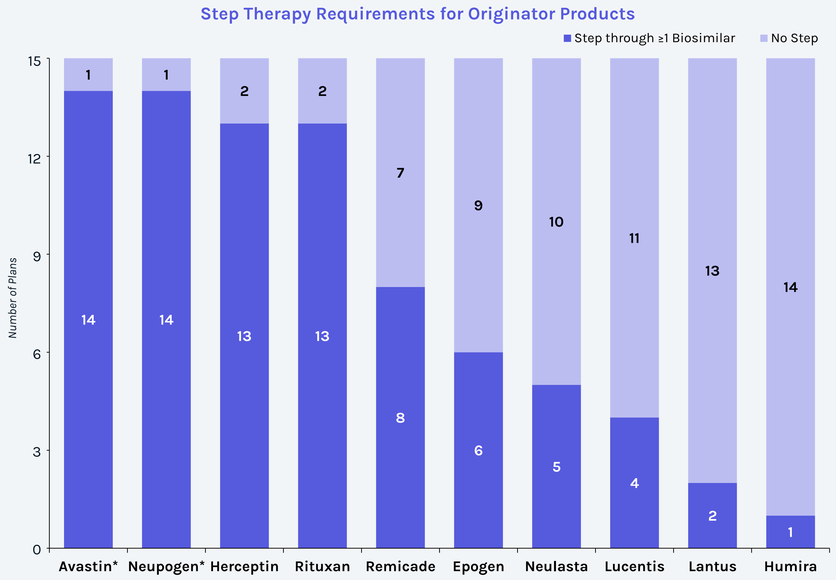

Figure 1. Step therapy requirements across 15 that require ≥1 step through a biosimilar product

RESULTS

The 6-variable model, including all 10 originators, resulted in an R^2 of 0.589 (p=0.269). After an exhaustive analysis, the only predictor variable to achieve statistical significance was payer management (βmanagement=0.717, p=0.024) and achieved significance only when assessed independently from the other variables. Upon excluding the orphan originators, the R^2 increased to 0.931 (p=0.133). Number of biosimilar competitors achieved significance independently (p=0.041), when combined with payer management (p=0.041), and various other combination of predictor variables. Furthermore, the adjusted-R^2 values for both the regression models in 2022 and 2023 remained relatively consistent. The 2024 model exhibited a marginally lower R^2 and adjusted-R^2, alongside a higher p-value, potentially attributed to the modest expansion in sample size.

Output of ISPOR 2022 Model				
Model Type	**N**	**P-Value**	**R^2**	**Adjusted-R^2**
Model Including Orphan Originators	**8**	**0.508**	**0.581**	**0.020**
Model Excluding Orphan Originators	**6**	**0.293**	**0.961**	**0.804**

Table 1. Statistical output of a multivariable regression model from 2022

Output of ISPOR 2023 Model				
Model Type	**N**	**P-Value**	**R^2**	**Adjusted-R^2**
Model Including Orphan Originators	**10**	**0.269**	**0.589**	**0.259**
Model Excluding Orphan Originators	**8**	**0.133**	**0.931**	**0.794**

Table 2. Statistical output of a multivariable regression model from 2023

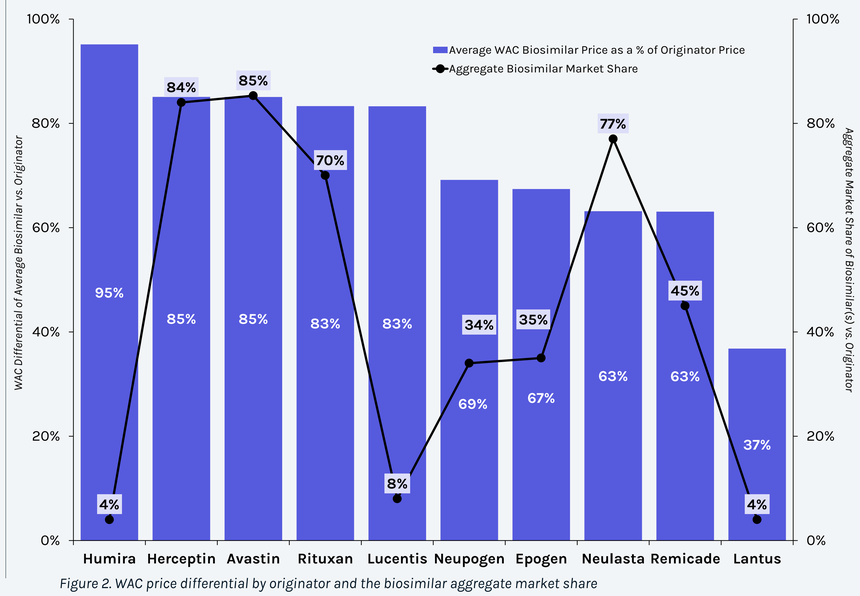

Figure 2. WAC price differential by originator and the biosimilar aggregate market share

Output of ISPOR 2023 Model				
Model Type	**Regressions**	**P-Value**	**R^2**	**Adjusted-R^2**
Model Excluding Orphan Originators	**Number of Biosimilar(s)**	**0.041**	**0.598**	**0.518**
	Number of Biosimilar(s) & Payer Management	**0.018**	**0.866**	**0.799**
	Number of Biosimilar(s), WAC Differentials Between Originator and Biosimilar(s) & Payer Management	**0.0378**	**0.920**	**0.839**
	Number of Biosimilar(s), WAC Differentials Between Originator and Biosimilar(s) & Payer Management	**0.133**	**0.931**	**0.794**

Table 3. Statistical output of a simple linear regression model from 2023

CONCLUSIONS

Although both adjusted-R^2 and R^2 values increased upon excluding the orphan originators, the results continue to be limited by a relatively low sample size. These outcomes align with last year's analysis, showing relatively similar R^2 but an increased p-value. This suggests the current model is a more accurate representation of the factors influencing originator market share. The primary difference with last year's model is the emergence of payer management as the sole significant predictor of biosimilar market share, but only when assessed in a simple linear regression. In contrast, the previous model highlighted WAC differential as the primary statistically significant predictor. This shift is likely because payer management, which is often guided by confidential contractual agreements (e.g., price discounts or rebates), was more influential on market share predictions. Although the duration of biosimilar competition and the number of competitors did not attain statistical significance, they likely exert an indirect influence on payer management. Specifically, the prolonged presence of biosimilar competition may foster increase downward pricing pressure, prompting more payer management strategies.

FUTURE IMPLICATIONS

As more biosimilar products are commercialized, understanding the factors that influence aggregate market share is crucial for creating strategies to optimize commercial opportunities for a product expected to lose exclusivity. Given the typically lower cost of biosimilars, payers may seek to further limit originator use in favor of biosimilar alternatives. It will be important to monitor how biosimilar aggregate market share changes due to suspected price erosion following the originator's loss of exclusivity.

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α = Alpha
β = Parameter Estimates