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Despite Achievements, Barriers That Discourage Biosimilar Use Remain

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EXECUTIVE SUMMARY

- **The Inflation Reduction Act's price controls discourage biosimilar development.**
- **Payment system inefficiencies, such as the buy-and-bill payment system and rebate walls, disincentivize the use of lower cost biosimilars.**

Despite the savings biosimilars have already enabled, there are barriers to further progress. First, the price controls from the Inflation Reduction Act (IRA) disincentivize biosimilar development. Second, the convoluted pricing system discourages greater use of lower cost alternatives. How the payment system disincentivizes their use varies depending on whether the medicine is administered in a clinical setting or taken at home by patients. While not addressed here, there are also psychological concerns and insufficient professional education regarding the safety and efficacy of biosimilars as documented in a 2024 JAMA study that also need to be addressed.[1]

1 Mroczek DK, Hauner K, Greene GJ, Kaiser K, Peipert JD, Golf M, Kircher S, Shaunfield S, Lylerohr M, Cella D. "Obstacles to Biosimilar Acceptance and Uptake in Oncology: A Review" JAMA Oncol. 2024 Jul 1;10(7):966-972. doi: 10.1001/jamaoncol.2024.1447. PMID: 38814582.

THE INFLATION REDUCTION ACT'S NEGATIVE IMPACT ON BIOSIMILAR DEVELOPMENT

The Inflation Reduction Act (IRA) effectively imposed price controls on the pharmaceutical market that, by design, will expand every year. The IRA's price controls create a substantial risk that investors will be unable to recoup their capital costs if they invest in the expensive process of developing biosimilars. This disincentive exists even though the IRA contains a provision that delays the price negotiations for an innovator drug if there is a biosimilar in development and about to launch due to concerns that this rule is not being interpreted correctly. As a result, alternative investment opportunities look relatively more attractive compared to investing in continued biosimilar innovation.

This disincentive reduces the resources available to fund future biosimilar research. The result will be less biosimilar innovation, decreased competitive pressures, and ultimately higher prices. These additional costs will reduce future realized savings.

BUY-AND-BILL INCENTIVIZES THE USE OF HIGHER COST INFUSION BIOLOGICS

Clinics, doctors' offices, and hospitals (hereafter clinics) typically purchase the medicines used in a clinical setting first and are then reimbursed once the drugs have been administered, known as buy-and-bill. The reimbursement is supposed to cover the clinic's estimated cost of the drug plus a percentage markup over the drug's average sales price (ASP) to cover the storage and administration expenses. ASP is calculated based on the sales and revenue data manufacturers report to the government from the previous 6 months. Several inefficiencies in this payment method create biases against lower cost biosimilars.

Clinics' administration costs do not vary depending on whether a higher cost medicine or a lower cost biosimilar is used. Administering higher cost medicines provides greater revenues, however. Consequently, clinics have an incentive to use more expensive products – the higher the cost of the drug, the higher the margin that the clinic earns. In response to this disincentive, Medicare Part B currently reimburses biosimilars based on the sum of the biosimilar's ASP plus a fixed percentage of the reference product's price.

Clinics also face financial risks because their reimbursement can be based on the ASP that prevailed months after their purchase. If the ASP fell in the intervening months, the lag may cause the reimbursement to be less than their acquisition costs, causing them to lose money from administering the drug.

REBATES KEEP PRICES HIGH FOR SELF-ADMINISTERED BIOLOGICS

The rebate system also creates disincentives that can discourage the use of lower cost biosimilars. Paramount among these is the current opaque pricing system that creates anti-competitive obstacles. The practice referred to as a "rebate wall" exemplifies the problem.[2]

2 Winegarden W "Tear Down This Wall: Documenting the patient costs created by anti-competitive rebate walls" Pacific Research Institute Issue Brief, December 2020, https://www.pacificresearch.org/wp-content/uploads/2020/12/RebateWall_F_web.pdf.

Rebate walls occur when rebates are tied to specified volume or market share targets.[3] When the dollar sales of a drug are large enough, which often occurs when a drug treats multiple indications, losing these dollar rebates causes insurers and pharmacy benefit managers (PBM) to lose money. To avoid this penalty, payers will, essentially, block patient access to lower-priced medicines.

While the originators, PBMs, and payers may benefit, overall healthcare costs are inflated. Since rebate walls stifle competition, they cause prices to remain excessively high over time, imposing large costs on patients as well by forcing them to pay higher out-of-pocket costs (e.g., coinsurance obligations) on expensive medicines while not benefiting from the rebates. As a result, successful rebate walls worsen the drug affordability problem by denying patients access to drugs that would be just as efficacious but cost less.

Illustrating that these concerns exist in practice, Drug Channels noted with respect to Humira that, "few of the PBMs' plan sponsor clients—employers, health insurance plan, labor union, governments, and other third-party payers—initially adopted low-list-price products."[4] Further, "while plans often complain about PBMs, most plan sponsors seemed to remain addicted to the rebates that PBMs pass along to them. PBMs have their own incentives for preferring higher drug list prices over lower ones."

THE BOTTOM LINE

Whether for drugs administered in a clinical setting or taken at home by patients, the payment system incentivizes the use of medicines with higher list prices over lower-priced biosimilars. The adverse impacts include higher healthcare costs that have an outsized impact on patients through greater out-of-pocket spending. In addition to these barriers, the IRA's price controls are a major disincentive for future biosimilar development. With less biosimilar development, potential future savings will be lost.

3 Arad N, Staton E, Hamilton Lopez M, Goriola S, Higgins A, McClellan M, Richman B "Realizing the Benefits of Biosimilars: Overcoming Rebate Walls" Duke Margolis Center for Health Policy, https://healthpolicy.duke.edu/sites/default/files/2022-03/Biosimilars%20-%20Overcoming%20.

4 "Humira Biosimilar Price War Update: Should We Be Glad that CVS Health and Express Scripts Are Using Private Label Products to Pop the Gross-to-Net Bubble?" Drug Channels, Wednesday, September 04, 2024, https://www.drugchannels.net/2024/09/humira-biosimilar-price-war-update.html.