The Biosimilar Red Tape Elimination Act Provides a New Profit Source for PBMs

The act would help PBMs shift patients to their own profit-making medicines.

The Biosimilar Red Tape Elimination Act[i] would deem all biosimilars interchangeable with their reference products without the U.S. Food and Drug Administration (FDA) needing to make any additional determination. The bill would do away with important scientific standards while failing to address the broader misaligned incentives in the marketplace allowing pharmacy benefit managers (PBMs) to block biosimilar competition and profit off medicines at the expense of patients.

Today, there are over 40 biosimilars launched in the U.S.[viii]

What is an interchangeable biosimilar?

For a biosimilar to be deemed as interchangeable, FDA must additionally determine:

The biosimilar can be expected to produce the same clinical result as the reference product in any given patient.

There is no greater risk in terms of safety or diminished efficacy if a biosimilar patient is switched or alternated between the biosimilar and the reference product.

Under the Biologics Price Competition and Innovation Act the FDA has existing ample authority to take a case-by-case approach to data requirements for interchangeability determinations and to decide whether switching studies (clinical trials) are needed to approve a specific proposed interchangeable biosimilar product.[ii]

What would the Biosimilar Red Tape Elimination Act change?

Under federal law, interchangeability is defined to mean that a biosimilar may be substituted without the intervention of the patient's prescriber. By deeming all biosimilars interchangeable, the bill would tie FDA's hands as it would only be able to approve a biosimilar if the agency determined it could be automatically substituted.

As science continues to evolve in the years ahead, the bill may leave FDA with no choice but to refuse to approve biosimilar products for more complex biologics, thereby limiting competition in the years ahead. This is because as it could limit FDA from requiring the studies needed to determine the risk **of switching or alternating between the reference product and biosimilar.**

The bill also does not address anticompetitive PBM behavior, but rather would further enable them to manipulate the biosimilar market to their own advantage.

- PBMs often exclude biosimilars from coverage which blocks patient access.
- A biosimilar, whether interchangeable or not, may not be automatically substituted at the pharmacy counter if PBMs exclude them from coverage in the first place. This reality will remain true if the bill is enacted.
- The three largest PBMs, which control 80% of the marketplace, have blocked patient access to biosimilars for years, even though biosimilars have lower list prices than their brand counterparts and could lower out-of-pocket costs for many patients. Large PBMs are often compensated based on list price-based rebates and fees, which incentivizes them to prefer medicines with higher list prices and large rebates.[iii]

Following the launch of the first FDA-approved interchangeable insulin biosimilar, **not one of the three largest PBMs included the low list price version of the product as a preferred option on their standard commercial formulary** in 2022, 2023, or 2024.[vi]

- All three large PBMs have recently launched or announced plans to commercialize biosimilars produced through their own affiliates. Among those that have launched, reports indicate PBMs are providing preferential coverage for these biosimilars while excluding reference products and non-PBM-affiliated biosimilars from formularies.[v, vi, vii]
- If the Act were enacted, an automatic interchangeable designation would enable PBMs to more easily exclude non-PBM affiliated competitors' products from formularies and entirely shift patients to their affiliates' products, regardless of provider and patient preferences or whether the PBM's biosimilar was the lowest cost option for patients, employers, or plan sponsors.

The bottom line:

The Biosimilar Red Tape Elimination Act is a giant giveaway to vertically integrated entities who have for many years manipulated the biosimilar market for their own profits. Rather than boosting competition and reducing drug costs, it will only create more opportunities for greedy middlemen to increase their profits and decrease treatment options for patients.

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v David Wainer. "Coming to a CVS Near You: A Store Brand Monoclonal Antibody," Wall Street Journal. April 29, 2024. https://www.wsj.com/health/pharma/cvs-biosimilar-drugs-production-08227182.
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vii AJ Fein. Drug Channels News Roundup, June 2024: Cordavis Humira Update, OptumRx's New Biosim Biz, Generic Drugs' Wild Ride, IRA Predictions, and Dr. G on Med School. June 2024.
viii http://www.amerisourcebergen.com/-/media/assets/cencora-biosimilars-usmarketlandscape-11mar24/cencora-biosimilars-usmarketlandscape-