FACT SHEET: Bringing Lower-Cost Biosimilar Drugs to American Patients

Biosimilars are the equivalent of the "generic version" of expensive, FDA-approved biologic drugs, offering the same safety and effectiveness as brand-name biologics at significantly lower costs. These complex medications treat serious conditions including cancer, autoimmune diseases, and rare disorders that affect millions of Americans.

The Problem: Limited Access to Affordable Biologic Treatments

Patient Affordability Crisis

- Biologic drugs can cost patients tens of thousands and upwards of hundreds of thousands of dollars annually, creating insurmountable financial barriers for many Americans who need these life-saving treatments.
- Expensive biologic medications make up only 5% of prescriptions in the U.S. but account for 51% of total drug spending as of 2024.
- High prescription costs lead to treatment abandonment, with patients rationing doses, skipping treatments, or going without medication entirely, resulting in disease progression, hospitalizations, and worse health outcomes.
- Provider hesitancy and patient concerns about switching to biosimilars persist despite extensive safety data, often due to misconceptions about their equivalence to reference products.
- Insurance coverage gaps and high deductibles mean even insured patients face substantial out-of-pocket costs for biologics.
- Medicare and Medicaid face cost pressures from expensive biologics.

Insufficient Biosimilar Market Competition

- FDA-approved biosimilars are as safe and effective as the branded drugs, yet their market share remains below 20%.
- To date, FDA has approved 76 biosimilars, corresponding to a small fraction of approved biologics.
- By contrast, there are more than 30,000 approved generics, exceeding the number of approved brand drugs.
- In 2024, FDA approved 42 biosimilars compared to 110 by the European Medical Agency (EMA).
- Only 10% of branded biologics currently have biosimilars in development, despite biologics representing a significant and growing percentage of overall drug costs.

- 27% of high-value biologics (>$500M in sales) lack biosimilar development despite clear commercial opportunities and demonstrated patient need for affordable alternatives.

Barriers to Biosimilar Market Entry

- The high cost of biosimilar development, combined with uncertain market returns due to low adoption rates, creates a challenging business case that deters investment in biosimilar programs.
- FDA analysis found that comparative efficacy studies, usually requiring one to three years and costing $24 million on average, often add little scientific value compared with advanced analytical testing. The biosimilar industry was established 15 years ago under highly cautionary regulatory frameworks that are now outdated. For example, the first biosimilar, Zarxio, took 24 years to reach patients after its reference biologic Neupogen was first approved in 1991.

Cost Savings

- Biosimilars have generated $56 billion in healthcare savings since 2015, with $20 billion saved in 2024 alone, demonstrating their significant economic impact on the U.S. healthcare system.
- The sales price for biosimilars is on average 50% less than the reference brand biologic price was at the time of biosimilar launch, providing immediate cost relief to patients.

FDA's Solution

- *Eliminating unnecessary clinical trials* – Using improved analytical testing methods instead of requiring expensive human studies when the science shows they're not needed.
- *Facilitating pharmacy-level substitution* – Removing barriers by advancing interchangeability so pharmacists can substitute lower-cost biosimilars, just like they do with generic drugs.
- *Reducing red tape to lower the barriers to market entry* – Providing clearer guidance and more efficient processes to speed up approvals and reduce development uncertainty.