Interchangeable Biosimilars Offer Great Promise for Affordable Life-Saving Drugs

Drug prices are out of control, putting life-saving medications out of reach for too many American families. The problem is the price, set by brand-name drug manufacturers based on what they think the market will pay.

Generics and biosimilars provide much-needed competition to drive those drug prices down. But uptake of biosimilars has been limited because previously, none have been approved by the Food and Drug Administration (FDA) as *interchangeable*.

Getting to interchangeability for biosimilar drugs is hard – because of the chemistry. Biologic drugs are derived from living cells, like blood, proteins, viruses or other living organisms. Biosimilars are highly similar to their biologic reference product, and have no clinically meaningful difference in terms of safety and effectiveness. They even have the same active ingredient, but they are made differently from the originator biologic. Still, biosimilars can never be *identical* to the originator biologic drug because of the complexity of their chemical make-up, with living cells as their key elements.

While a doctor may prescribe a biosimilar, they must specifically identify it in their script. A pharmacist cannot make a simple substitution for a much less expensive biosimilar at the pharmacy counter the way they currently do with generic drugs, unless the biosimilar has "interchangeable" status that can be granted only by the FDA.

That's what makes the recent FDA approval of Semglee as the first interchangeable biosimilar so exciting. Semglee is a biosimilar insulin product for adults and children with Type 1 diabetes. FDA's approval means Semglee is now interchangeable for Lantus, which is prescribed to millions of Americans each year. Now, pharmacists can offer Semglee to their customers who are prescribed Lantus, without a need for a doctor's intervention where permitted by state law – making Semglee much more readily available to millions of patients.

Biologics and biosimilars are important medical advancements that are being used to manage many chronic conditions, as well as to prevent, treat, and even cure diseases. They represent the future of prescription drugs. But an innovative new drug doesn't do any good if no one can afford it.

That's why AHIP is encouraging Congress and the Administration to take steps to:

- **Speed up the approval process for interchangeability** for biosimilar drugs to the extent possible without compromising patient safety.
- **Shorten the patent exclusivity period for biologics.** By reducing the exclusivity period from 12 years to 7 years, Congress could promote greater price competition and help alleviate cost pressure for payers, patients, and consumers.
- **Prohibit anti-competitive "pay-for-delay" settlements that hinder competition.** The Federal Trade Commission (FTC) indicates that these pay-for-delay shenanigans cost Americans $3.5 billion in higher drug costs each year.
- **Stop the evergreening of patent protections.** Ending the patent gaming will thwart Big Pharma's attempts to artificially prolong the exclusivity period for high-priced drugs.
- **Limit product hopping that does not benefit patients.** Patients should not be held captive to a higher-cost drug, when an equally effective biosimilar is available.

Every American deserves to get the medications they need at a cost they can afford. We should not need to choose between innovation and affordability. With the right solutions, and genuine collaboration, we can have both.

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