BEN RAY LUJÁN
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Biosimilar Red Tape Elimination Act

Senators Lee and Lujan

Background

Biosimilars, which are "generic" alternatives to name-brand reference biologic drugs, have the potential to significantly reduce health care costs through increased competition. A recent RAND Corporation study estimates that biosimilars are on track to save Americans $38.4 billion over five years. While the future looks promising, major obstacles remain to biosimilars achieving their full cost-saving potential. The FDA's two-tiered system for approval has confused physicians, patients, and states about biosimilars' safety and efficacy.

First, to gain approval from the U.S. Food and Drug Administration (FDA) as a biosimilar, the drug sponsors must conduct clinical trials to establish that there are no clinically meaningful differences between the safety and efficacy profile of a reference biologic and the biosimilar. Second, to obtain an interchangeability designation from the FDA, the biosimilar sponsor must submit additional data from a switching study, in which patients switch back and forth between the biosimilar and its reference product.

These studies can be costly and time-consuming, especially if the reference manufacturer delays making its product available and have been shown to be unnecessary. Although the FDA has approved 41 biosimilars as of May 2023, it has granted interchangeability to only four. In addition, the U.S. is an outlier in the biosimilar market compared to Europe where once any biosimilar is approved it is considered interchangeable without switching studies. The European Medicines Agency (EMA) has been approving biosimilars since 2006.6 In 2022, EMA analyzed more than fifteen years of data and found that there is no evidence that switching between a biosimilar and its reference product increases the risk of immunogenicity.

Not having a therapeutic interchangeability designation is a major impediment to physician and patient confidence in biosimilars. The interchangeable designation has confused physicians, patients, and states by signaling that biosimilars are significantly different from their reference products. Some states have passed laws that disallow pharmacists from automatically substituting a biosimilar for its reference biologic unless they are deemed interchangeable by the FDA. Additionally, A recent AmerisourceBergen survey also shows that interchangeability is a major factor in U.S. payers' decisions about covering biosimilars.

To streamline the current regulatory pathway for biosimilar approval Senators Mike Lee and Ben Ray Lujan are introducing the **Biosimilar Red Tape Elimination Act**.

The Biosimilar Red Tape Elimination Act would:

- Deem that all biosimilars, upon FDA approval, shall be deemed interchangeable. The bill maintains the term "interchangeable" to preserve state law around interchangeability.
- Strike the current requirement for switching studies.
- Maintains the ability for the FDA to require a switching study if it deems necessary and requires reporting to House and Senate committees of jurisdiction on these studies.
- Preserves the ability for states to craft their own laws regarding biosimilar substitution.