S. 1954, Biosimilar Red Tape Elimination Act

Section 1. Short Title

This Act may be cited as the "Biosimilar Red Tape Elimination Act."

Section 2. Biosimilar Biological Products

- Subsection (a) – Amends Section 351(k) of the Public Health Service Act to automatically deem all biological products licensed under this subsection as biosimilars to be interchangeable with the applicable reference product, removing the need for a separate interchangeability determination by the FDA. This section also establishes a transition period of 60 days after the date of enactment and deems interchangeability either at the end of the transition period for already licensed biosimilars, upon licensure for products licensed after the transition period, or upon the expiration of a first interchangeable exclusivity in cases where such an exclusivity is already in effect.
- Subsection (b) – Outlines conforming amendments, including the removal of distinctions between biosimilars and interchangeability in Public Health Service Act and the Federal Food, Drug, and Cosmetic Act. This section also clarifies what shall be considered a new active ingredient for biological products.
- Subsection (c) – Establishes that the Secretary shall issue, update, and revise final guidance on the review and approval of biosimilar products to conform with the amendments of this Act no later than 18 months after the date of enactment.