



Bill Summary

PROMOTING INNOVATION AND ACCESS TO LIFE-SAVING MEDICINE ACT

PATHWAY

- **FDA authority.** The bill authorizes the Food and Drug Administration to approve abbreviated applications for “biosimilar” and “biogeneric” (interchangeable) biological products.
- **Approval of “biosimilars.”** An application for a biosimilar version of a biological drug must demonstrate to FDA that there are no clinically meaningful differences between the two products. The application must also show that the two products are highly similar in molecular structure and share the same mechanism(s) of action, if known.
- **Approval of “biogeneric” or “interchangeable” products.** An applicant for a biosimilar may also try to establish that the product is “biogeneric,” i.e., “interchangeable” with the original product. A product found by FDA to be interchangeable can be safely substituted for the original product, if state law permits. The bill grants 6 months of exclusive marketing to the first applicant to demonstrate interchangeability to FDA.
- **Clinical studies.** The FDA has full scientific discretion to determine what studies are necessary to establish that (a) a biosimilar is as safe and effective as the original product, and (b) a biogeneric is interchangeable with the original product. FDA can require the applicant to conduct clinical studies in both instances.
- **Modified products.** An applicant may submit an abbreviated application for a product that differs from, or incorporates a change to, the original product, if the application contains sufficient information to show that the new product is safe, pure, and potent (safe and effective).
- **Post-market studies.** The FDA has full discretion to require post-market safety studies for biosimilars and biogenics.
- **User fees.** A company that files an application for a biosimilar biological product must pay a user fee to FDA just as companies for innovative products do.

EXCLUSIVITY

- **Initial exclusivity.** Consistent with Hatch-Waxman exclusivity periods, an original product with a novel molecular structure is entitled to 5 years of exclusive marketing. A modification of a previously approved product is entitled to 3 years of exclusive marketing in some instances.
- **Extensions.** These periods can be extended by up to 1 year if the applicant establishes that the product can be used for a new disease indication or conducts pediatric studies.

PATENT DISPUTES

- The bill establishes a procedure for resolution of patent disputes before a biosimilar is approved, and establishes penalties for failure to litigate patents in a timely fashion.