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Washington, D.C. – Today, Rep. Anna G. Eshoo (D-California) introduced the Pathway for Biosimilars Act, legislation to create a regulatory pathway for FDA approval of “biosimilars” or “follow-on” biologics with Rep. Joe Barton (R-Texas), Ranking Member of the House Energy & Commerce Committee.

“This legislation will establish a regulatory pathway for biosimilars that will promote competition and lower prices, and protect patient safety, drug efficacy and sound science,” said Rep. Eshoo. “The most exciting developments in modern medical science are occurring in the field of biotechnology, and this legislation will ensure that the amazing cures and treatments biotech delivers today will continue and more patients will have access to these revolutionary therapies.”

Many of the original patents in the biotechnology industry are beginning to expire and several patient groups, biotech companies, and healthcare providers have called on Congress to provide a regulatory pathway for follow-on biologics or biosimilars to be approved by the FDA. The Pathway for Biologics Act provides an abbreviated pathway for approval of biosimilars based in part on the safety and efficacy record of an innovative reference product.

The Pathway for Biologics Act permits the FDA to make a determination as to whether the biosimilar is interchangeable with the reference product, and gives the FDA the flexibility to determine what clinical testing – if any – is required for approval. To promote continued innovation in biotechnology, the legislation provides 12 years of data exclusivity to allow innovators to market their products and recoup their investments in research and development. Finally, to prevent uncertainty and delays over patent litigation, the bill establishes a process for resolution of patent disputes prior to the time biosimilar products are eligible to come onto the market.

“This legislation will protect patients, promote innovation, and prevent unnecessary litigation,” said Eshoo. “I’m pleased to have my colleague Rep. Joe Barton as a partner on this important bipartisan effort and we will work together to enact this legislation before the end of this Congress.”

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[Read Rep. Eshoo's introduction of the Pathway for Biosimilars Act here](#)

[Read a summary of H.R. 5629, the Pathway for Biosimilars Act here](#)

Read the text of the bill here