

## Biologics and Biosimilars: An Overview of Current Legislation

Biologic drugs play an important role in the care of patients with kidney disease. In particular, a biologic pharmaceutical version of the hormone erythropoietin is commonly used to treat anemia in patients with advanced chronic kidney disease (CKD) or on dialysis. At present, no standard process exists for approval of generic biologics, also known as follow-ons or biosimilars.

In March 2009, two competing bills with the purpose “to establish a pathway for the licensure of biosimilar biological products” were introduced in the House of Representatives. H.R. 1427, introduced by Rep. Henry Waxman (D-CA) and H.R. 1548, introduced by Rep. Anna Eshoo (D-CA) share the goal of providing the FDA an avenue by which to review and license generic biologic drugs, but each takes a markedly different approach to the task.

In August 2009, the House Committee on Energy and Commerce amended H.R. 3200, America’s Affordable Health Choices Act” to include the provisions in Eshoo’s bill, H.R. 1548. Given the Obama administration’s emphasis on reducing prescription drug costs, and the potential impact of regulations governing the biologic follow-on approval process on pharmaceutical and biotechnology industries, as well as on patients and providers, the issue will likely remain at the forefront of health reform debates this fall.

ASN has been actively tracking this issue, including attending briefings with Congressional representatives and discussing potential outcomes with other medical professional societies. ASN will continue to follow the debate, providing guidance and recommendations to elected officials as necessary as well as updating ASN members on this important issue. Please contact ASN’s Policy Associate, Rachel Shaffer, at [rshaffer@asn-online.org](mailto:rshaffer@asn-online.org) or by phone at (202) 416-0660 for further assistance or more information on this topic.

The following chart provides a brief overview of the key provisions and differences between the two bills.

### H.R. 1426 & H.R. 1548: Comparison of Key Issues

Issue	H.R. 1427: Waxman Bill	H.R. 1548: Eshoo Bill
<b>Exclusivity<sup>1</sup></b>	<b>New Biologic:</b> 5 years <b>New Indication:</b> 3 years <b>Demonstrated Pediatric Benefit:</b> Additional 6 months exclusivity	<b>New Biologic:</b> 12 years <b>New Indication:</b> 14 years <sup>3</sup> <b>Demonstrated Pediatric Benefit:</b> Additional 6 months exclusivity
<b>First-to-File Exclusivity<sup>2</sup></b>	1 year	2 years
<b>New Clinical Trials Required for FDA Approval?</b>	No; relies on the safety and efficacy data used in approval of the reference drug	Yes; mandates trials comparing the biosimilar and the reference products
<b>Interchangeable With Reference Product?</b>	Yes, unless a physician specifies “no substitution” for the reference drug	No, except in a small number of cases
<b>Name Regulations?</b>	Biosimilars may have same official name as reference product	Biosimilars must have different official name than reference product
<b>Patent Notification</b>	Applicants for FDA approval of a follow-on biologic may request any pertinent patent information regarding the biologic from the reference drug manufacturer, who then has 60 days to supply it. Applicants may notify the reference drug manufacturer at any time, and must certify that the product will not infringe on a valid patent. The original patent holder has 45 days to sue the new applicant for infringement.	The FDA would notify the reference drug manufacturer of an application for approval of a follow-on biologic; that manufacturer would then be responsible to share patent information for that biologic and later to explain why a follow-on biologic would violate their patent(s).

<sup>1</sup>The time after initial licensing of a new (reference) biologic pharmaceutical, a new indication for its use, or a new formulation that includes it, that the FDA cannot approve a follow-on biologic

<sup>2</sup>The period granted to the first applicant to receive approval for a follow-on biologic, during which the FDA from may not approve for any other follow-ons to the reference drug

<sup>3</sup>If during the 8 years following initial approval the drug receives approval for a new indication, exclusivity for the drug may be extended up to a maximum of 14 years.