New Legislations on Generics and Biosimilars Brewing in Congress

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March was a busy month for makers of generics and biologics, with several bills being introduced in the 111th Congress proposing new legislations on generics and biosimilars. While these bills are making the rounds in committee reviews, responses from industry stakeholders run the gamut from bipartisan support to partisan rejection, with few surprises.

H.R. 1706, Protecting Access to Generic Drugs Act of 2009, was introduced by Rep. Bobby Rush (D-IL) on March 25, 2009. This act proposes to “prohibit brand-name drug companies from compensating generic drug companies to delay the entry of a generic drug into the market.” This practice is perceived by supporters of the bill as hurting consumers by postponing access to cheaper medications. In this economic climate, compounded by the ever-growing rates of chronic diseases, reports of Americans forgoing medications because of cost issues are common, adding fuel to the fire.

The flip side is, says Rep. Joe Barton (R-TX), the ranking Republican on the House Energy and Commerce Committee (where the bill is being reviewed), that this legislation “could eliminate the motivation for drug makers to settle drug-patent challenges, causing lengthy litigation that ultimately ‘erodes any benefit to the consumer.’” This sentiment is echoed by others in the industry, who suggest that this bill may stunt drug innovation, or that “fewer generic drugs may be developed because of this.”

Responding to critics, Rep. Rush says “the bill is opposed by both PhRMA and most generic companies. The fact that both innovator and generic companies oppose the bill is striking, because brand-name and generic companies are not supposed to agree on anything.” Furthermore, the bill “does not ban all settlements in drug patent cases,” and it “will save taxpayers, businesses, and consumers tens of billions of dollars.”

In contrast, H.R. 1427, Promoting Innovation and Access to Life-Saving Medicine Act—which aims “to provide the licensing of biosimilar and biogenetic biological products”—was reintroduced to the new Congress by Rep. Henry Waxman (D-CA) on March 11, 2009—was met by bipartisan support in Congress. It does not offer an extended protection period, which likely led Jim Greenwood, president of the Biotechnology Industry Organization, to say, “the bill seeks to cut prices but instead cuts corners,” adding that “this proposal leads us off the map as we seek an effective, fair, and safe pathway to a biosimilar market.”

A variation on the Waxman bill—H.R. 1548, Pathway for Biosimilars Act—was reintroduced on March 17, 2009, by Rep. Anna Eshoo (D-CA). Eli Lilly offered strong support, saying this pathway “carefully weighs the needs of patients and stakeholder companies. This balance…would assure patients and payers the benefits that come from greater competition, preserve incentives for biotechnology innovation and foster investments that will produce more high-paying jobs in the life sciences.” Unlike H.R. 1427, this bill offers a 14-year “data protection period.”

This legislative focus reflects the push toward healthcare reform, cost-reduction, and increased access promoted by the new administration. Stay tuned.

And while this drama has been playing in the halls of Congress, the US Food and Drug Administration has been, quietly, approving a slew of new generics since the start of 2009.

References