

## Reps. Eshoo, Inslee, and Barton Introduce Pathway for Biosimilars Act

Tuesday, March 17, 2009

Washington, D.C. - Representatives Anna G. Eshoo (D &ndash; CA), Jay Inslee (D &ndash; WA), and Joe Barton (R &ndash; TX) today introduced the Pathway for Biosimilars Act (H.R. 1548). The bill creates a process for approval of &ldquo;biosimilars&rdquo; or &ldquo;follow-on biologics&rdquo; while protecting patient health and safety, lowering health care costs, and providing adequate incentives for innovation. Representatives Eshoo and Inslee were the lead sponsors of two separate biosimilar bills during the 110th Congress, and now have one bill with Rep. Barton, ranking member of the Energy and Commerce Committee, to bring congressional stakeholders and interested parties to bipartisan consensus with this joint legislation.

In 1984 the highly successful Hatch-Waxman Act was enacted, establishing a new market for generic versions of pharmaceuticals. Today, patients can buy generic drugs that are safe and save them money compared with brand name drugs. The Pathway for Biosimilars Act will accomplish the same thing for biologics. Many of the most exciting developments in medical science are occurring in the field of biotechnology.

While ordinary pharmaceuticals primarily treat the symptoms of a disease or illness, the biotechnology industry has been developing biologics that can be manipulated to target the underlying mechanisms and pathways of a disease. The original patents on biologics are beginning to expire and Congress should act now to consider how the Food and Drug Administration (FDA) will consider and approve these groundbreaking treatments.

The pharmaceutical drug production process is easily replicated and a &ldquo;generic&rdquo; drug product is virtually identical to the original innovative compound. With biologics, the manufacturing process is unique to each biologic and is not generally disclosed as part of the published patent, making it impossible to &ldquo;duplicate&rdquo; the innovative biologic product. However, with sufficient safeguards for patient safety and incentives for innovation, the development of biosimilars has the potential to bring new competition, choices, and lower prices to the biotech industry.

&ldquo;Biotechnology can lead to cures for cancer, diabetes, and AIDS, and prevent the onset of deadly and debilitating diseases like Alzheimer&rsquo;s, heart disease, and Parkinson&rsquo;s,&rdquo; said Eshoo. &ldquo;But we need to preserve incentives to innovate and ensure that these therapies are safe and effective. Our bill accomplishes this.

&ldquo;This bill sets forth a straightforward, scientifically based process for expedited approval of new biologics based on innovative products already on the market. This new biosimilars approval pathway will promote innovation, competition, and lower prices, but also ensures that patients are given safe and effective treatments that have been subjected to thorough scrutiny and testing by the FDA.&rdquo;

&ldquo;With this legislation, we can create a pathway to lower-cost copies of biotech drugs without sacrificing safety or eliminating incentives to create breakthrough medicines,&rdquo; said Inslee, who serves on the House Energy and Commerce Committee and represents a Seattle-area district with a strong biotech sector. &ldquo;This is not an either-or

situation. We can deliver both safety and broader access to these life-saving medicines, while ensuring continued biotech innovation. And we must.&rdquo;

&ldquo;Congress needs to finally act on this issue. Our bill promotes competition through biosimilars in a way that puts patient safety first and also encourages new therapies and medical advancement,&rdquo; said Barton. &ldquo;I want the Energy and Commerce Committee to take up this issue soon, and I hope we can pass legislation this year.&rdquo; This legislation is supported by the academic and research community, patients, biotech companies, and the entrepreneurs who support the small start-up firms that form the basis of the biotechnology industry.

To see the bill, click here .

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