



May 11, 2009

The Honorable Anna Eshoo
205 Cannon House Office Building
Washington, DC 20515

The Honorable Jay Inslee
403 Cannon House Office Building
Washington, DC 20515

Dear Representatives Eshoo and Inslee:

Third Way is pleased to endorse the Pathway for Biosimilars Act (H.R. 1548). We first and foremost support the creation of a regulatory pathway for biologic medicines that will offer patients access to lower-cost medications. Health care costs have skyrocketed for many Americans and efforts like yours to help them gain greater access to more affordable medications and should be applauded.

While any legislation addressing this topic must consider potential cost savings, patient safety issues unique to biologics, and fair incentives for continued innovation must also be front and center. Unlike generic versions of traditional drugs, biologic medicines are more complex in that they are made from living cells and no two biologics made by different manufacturers will be identical. One minor change in the manufacturing process can alter the way the medicine reacts in patients. Your bill recognizes the inherent difference between biosimilars and generic drugs and establishes the necessary safeguards for patients by giving the FDA discretion to require any necessary non-clinical studies, clinical trials and post-marketing follow-up studies. Additionally, your bill appropriately recognizes that the FDA should only make determinations of interchangeability when the science has evolved to support such a determination. Furthermore, we hope that your legislation will be expanded to include all compounds from a biologic origin.

Your bill does an excellent job balancing the concerns of patients with the need to ensure that the United States remains the leader in the development of new biologics. In this vein, we applaud your provisions that provide for a fair period of data protection (otherwise known as "exclusivity") of 12-14 years and balanced procedures for both innovators and generics for the timely resolution of patent disputes. We share your belief that we need to do all we can to provide Americans with less costly medications while still encouraging the discovery of new and better medications.

We thank you for your balanced leadership on this issue.

Sincerely,

A handwritten signature in blue ink that reads "Rob Keast". The signature is fluid and cursive, with the first letters of the first and last names being capitalized and prominent.

Rob Keast
Director of Outreach