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July 16, 2009

Members of the 111th Congress
U.S. House of Representatives
Washington, D.C. 20515

Dear Representative,

FreedomWorks, a grassroots organization with more than 750,000 members nationwide, is actively engaged in the current debate over health care reform and has been a strong advocate of market-based reforms that would expand consumer choice and competition in the health care sector. Independent of the larger debate over the direction of health care reform in America, however, I would like to alert you to a potentially dangerous amendment that is being offered to H.R. 3200, American's Health Choices Act of 2009 by Rep. Eshoo that would severely restrict the emerging market for biogeneric drugs.

With the rising cost of pharmaceutical drugs and healthcare, it is increasingly important to encourage competition in the market for life saving therapies. Biologics show great promise and have been used to produce insulin, human growth hormone, and other important therapies. Globally, the market for these drugs has increased to more than $60 billion. To expand this market and increase access to these life-saving drugs, it is important that the Food and Drug Administration has a regulatory pathway to approve biogenerics, or biologic follow-ons. Much like generics, biogenerics hold the promise of new competiton and expanded consumer choice in new therapies to treat a variety of conditions, from AIDS to Alzheimer's, to several different cancers.

Currently, the FDA has limited authority to approve biogenerics. Many pharmaceutical companies claim that biologics are too complex to be produced as generics. This is not true; there are a number of pharmaceutical companies—brand name and generic—that have the capability and desire to enter the market for biologics with expiring patents. One biogeneric has already been approved by the FDA, and the agency has stated that it believes it is possible to establish an abbreviated approval process for these drugs that allows manufacturers to establish their bioequivalence. Already, the European Union and Australia have established procedures to approve biogenerics.

As an important component of health care reform, Congress should move forward with legislation to ensure all Americans enjoy access to the latest therapeutic drugs at the most affordable prices. Unfortunately, the Eshoo Amendment includes a 12-year exclusivity period that will do little to promote the competition necessary to expand consumer choice and check rising health care costs.

A market approach is the correct solution to getting less expensive therapies to patients, as it also encourages the development of new and desperately needed medicines. For these reasons, I urge you to vote "no" on the Eshoo Amendment. FreedomWorks will continue to follow the health care reform debate closely, advocating market-based reforms that expand patient choice and improve access to life-saving therapies.

Sincerely,

Matt Kibbe
President and CEO