



*Congress of the United States  
House of Representatives  
Washington, D. C. 20515*

*Anna G. Eshoo  
Fourteenth District  
California*

April 20, 2012

The Honorable Margaret Hamburg, M.D., Commissioner  
Food and Drug Administration  
15B-31 Parklawn Building  
5600 Fishers Lane  
Rockville, Maryland 20857-0001

Dear Dr. Hamburg,

As the House sponsor of the Pathway for Biosimilars Act, known as the Biologics Price Competition and Innovation Act (BPCIA) in the Senate and sponsored by the late Senator Edward Kennedy, I write to provide my comments regarding the Citizen Petition submitted to the Agency by the law firm Covington & Burling LLP on behalf of Abbott Laboratories (Abbott) on April 2, 2012.

Senator Kennedy and I introduced this legislation to create a new pathway for biosimilars because we understood how expensive biologics can be. With no generic options, these life-saving drugs were out of reach for too many patients across our country.

To establish a new pathway, it was critical to balance the need for patient access with incentives for innovation. The Kennedy-Eshoo legislation struck that balance by establishing 12 years of data exclusivity for innovator products. The BPCIA clearly states that this period of exclusivity applies to all biologics and the expiration clock is retroactive:

P.L. 111-148, Title VII, Sect. 7002 (7)(A) Approval of an application under this subsection may not be made effective by the Secretary until the date that is 12 years after the date on which the reference product was first licensed under subsection (a).

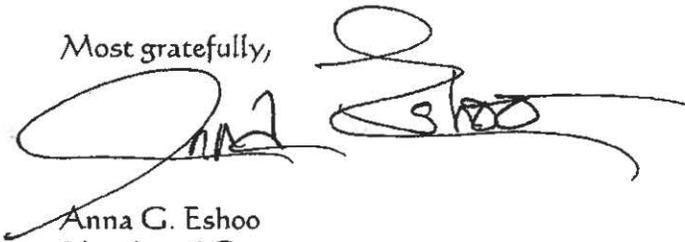
While Abbott's Citizen Petition argues that pre-BPCIA approved biologic products cannot be subject to the law, I want to state very emphatically that it was Congressional intent for the new pathway to apply to biologics approved before and after the passage of the Affordable Care Act. We specifically designed the legislation this way in order to allow for immediate and/or impending use of biosimilars by

patients at a lower cost, and to capture the large savings which could be gained from top-selling biologics losing their exclusivity around time of passage.

Abbott's actions undermine the very legislation it supported during Congressional debate on this issue. They were part of a broad coalition that supported the legislation and they never raised the issue throughout the legislative process. Retroactive application of the 12 years of exclusivity was a guiding principle of the many discussions about the legislation to which Abbott was a party to every step of the way.

In the name of patients, legislative integrity, and full Congressional intent, I urge the Agency to reject Abbott's Citizen Petition.

Most gratefully,

A handwritten signature in black ink, appearing to read 'Anna C. Eshoo', with a long horizontal flourish extending to the right.

Anna C. Eshoo  
Member of Congress