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

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Fourteenth District
California

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Division of Dockets Management (HFA-305)
Food and Drug Administration
5630 Fishers Lane
Room 1061
Rockville, MD 20852

Docket No. FDA-2010-N-0477

We thank the FDA for the time and attention it has dedicated to implementation of the *Biologics Price Competition and Innovation Act* (PL 111-148). As the principal authors of this legislation in the House, we appreciate the FDA recognizing the significant impact this legislation will have on medical innovation and patient care.

It is on this note that we write to clarify the Congressional intent behind our legislation, specifically in response to questions posed by the FDA in its notice of public hearing and request for comments.

First, we feel compelled to address what appears to be an error in the following question posed by the FDA.

> *"What factors should the agency consider in determining whether a modification to the structure of the licensed reference biological product results in a change in safety, purity, or potency, such that a subsequent Biologic License Application (BLA) may be eligible for a second 12-year period of marketing exclusivity?"*

To be clear, PL 111-148 does not provide "market exclusivity" for innovator products. Rather, it provides data exclusivity for 12 years from the date of FDA approval (Title VII, Sec.7002(7)(A)). There are significant and critical differences between the two types of exclusivity. Data exclusivity only prohibits the FDA from allowing another manufacturer to rely on the data of an innovator to support approval of another product. Importantly, it does not prohibit or prevent another manufacturer from developing its own data to justify FDA approval of a similar of competitive product.

Second, we want to clarify our intent on granting additional data exclusivity for modifications to an innovator product, known as "evergreening." As authors of the legislation, we took very seriously the concerns about "evergreening" and the legislation is clear that no product, under any circumstances, can be granted "bonus" years of data exclusivity for mere improvements on a product.

We want to be clear that if a "next generation" product is approved by the FDA as a new product (significant changes in safety, purity, or potency) then that new biologic will receive its *own* 12-year period of data exclusivity. This should not be confused with an additional period of data exclusivity for the original product. The letter and intent of the law is clear: 12-years of data exclusivity per new product.

As Members who care deeply about patient access to biologics, we also care about the advancement of science and our ability to treat the most complex diseases. Any proposal to limit the definition of a "new" product, and thus one which is entitled to its own period of data exclusivity has the potential to stifle innovation and negatively impact patient care.

We recognize that innovation can be incremental and patients frequently rely on next generation products to improve the treatment of their disease. Building on previous efforts and accomplishments is the definition of progress. We must encourage companies to further the evolution of life-saving drugs.

Thank you for your attention to these important matters and we look forward to the full implementation of the *Biologics Price Competition and Innovation Act.*

Sincerely,

Rep. Anna G. Eshoo Rep. Jay Inslee Rep. Joe Barton

cc: Margaret Hamburg, Commissioner, FDA
Karen Mithun, Director, Center for Biologics Evaluation and Research