United States Senate
WASHINGTON, DC 20510

January 7, 2011

Dr. Margaret Hamburg
Commissioner
Food and Drug Administration
10903 New Hampshire Ave
Silver Spring, MD 20993

Dear Commissioner Hamburg,

We are writing to provide some clarification to one of the questions posed by the Food and Drug Administration (FDA) in its notice of public hearing and request for comments regarding the *Biologics Price Competition and Innovation Act (the Act)*, which was enacted as part of PL 111-148.

In the FDA's public hearing notice, the agency requested input regarding exclusivity provisions in the legislation, namely "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?"

The Act does not provide market exclusivity for innovator products. It provides data exclusivity, which prohibits FDA from allowing another manufacturer of a highly similar biologic to rely on the Agency's prior finding of safety, purity and potency for the innovator product, for a limited period of time. It does not prohibit or prevent another manufacturer from developing its own data to justify FDA approval of a full biologics license application rather than an abbreviated application that relies on the prior approval of a reference product.

The Act also contains a provision on first licensure to prohibit any product from being granted more than one period of data exclusivity. The Act explicitly precludes any period of data exclusivity for the following:

- a supplement to a BLA; or
- a subsequent BLA (from the same company) for a non-structural change that results in a new indication, route of administration, dosing schedule, dosage form, delivery system, delivery device, or strength; or
- a subsequent BLA (from the same company) for a structural change that does not result in a change in safety, purity, or potency.

These restrictions are intended to prevent a sponsor from obtaining a separate 12-year term of data exclusivity for the same product or for a product that is structurally modified without a concomitant change in safety, purity, or potency.

At the same time, the Act provides incentives for innovators to research and develop new treatments for patients. If a manufacturer modifies an approved product to produce a change in safety, purity or potency, the modified product is rightly considered a new product. It will be protected by the data exclusivity provisions afforded new products. Exclusivity on the first generation product will expire as scheduled.

We look forward to working closely with you as you implement the Act.

Sincerely,

Senator Kay R. Hagan

Senator Orrin Hatch

Senator Michael Enzi

Senator John F. Kerry