



## DATA EXCLUSIVITY AND BIOTECH COMPETITION

### Separating Fact From Fiction

Myths abound regarding data exclusivity and the ability of an innovator to extend the period of data exclusivity as provided in the health care reform bill passed by the U.S. House of Representatives and legislation currently under consideration in the Senate.

It's time to set the record straight.

**MYTH:** The health care reform legislation which passed in the House of Representatives (the Affordable Health Care for America Act/H.R. 3962) and the Senate (the Patient Protection and Affordable Care Act/ H.R. 3590) would allow manufacturers of innovative biologics to get 12 years of data exclusivity plus additional 12-year periods for making minor tweaks to existing biologics.

**FACT:** **Neither the House bill nor Senate bill would permit that scenario.** Currently, innovator biologic manufacturers have infinite control over their data so Congressional proposals would not be “giving” 12 years of data exclusivity, but instead would be taking away all but 12 years. The innovator biologic would have 12 years of data exclusivity preserved during which another company could not rely on the innovator’s safety and efficacy data to get the approval of a competing product. (The competitor could, however, create its own unique product and submit its own application with its own clinical trial data to bring a competing product to market.) The only allowable extension to this 12-year period on the original product would be a 6-month extension for conducting pediatric studies specifically requested by the Food and Drug Administration (FDA). In no case could a biologic product have more than 12.5 years of data exclusivity.

According to the plain language of the bill, there can be no extension of data protection – no new 12-year period and no other extension– for a new indication, a new dosage form or dosing schedule, a new delivery system, new delivery device, a new route of administration, or a different strength. And certainly no additional time for a “tweak” to the product.

If, however, the manufacturer makes a change in the structure of the product such that it is considered by FDA to be a new product, the manufacturer must conduct new clinical studies to demonstrate safety and efficacy to obtain a new and separate FDA approval for an entirely new product. This new product would receive its own, separate 12-year period of exclusivity if the change in the structure of the product results in changes in the safety, purity or potency of the medicine. Even in such a case, this period of data exclusivity would apply only to the new product, not to the original product, thus leaving the original product open to biosimilar competition after the expiration of its own 12-year period of data protection.

**MYTH:** Brand name biologics can get an infinite number of 12-year periods of data exclusivity to continue their monopolies indefinitely.

**FACT: Monopoly is a term that applies to a market.** The 12-year period of data protection is *not* 12 years of exclusive and protected marketing. A competitor which creates its own unique product and submits its own application with its own clinical trial data will not be barred from getting to market because of a 12-year period of data exclusivity. Hence, there could be multiple biologics in the same class (as is currently the case for human growth hormones, insulins, erythropoiesis-stimulating agents, beta-interferons, etc.) which would provide competition and offer a choice of treatment options to patients.

The 12-year period would protect the innovator's data – not its product – from competitors seeking approval of a product based not solely on their own data, but based, in some meaningful part, on the data of the innovator.

BIO believes that **data exclusivity** must be included in the pathway for biologics and has NOT sought **market exclusivity** for biologic therapies in a pathway for biosimilars.

**MYTH:** There is no value in allowing companies to receive a period of data exclusivity for next generation biologics.

**FACT: It is important to preserve incentives necessary to attract the investment that is essential to conduct expensive clinical trials on uniquely new products and those which are significant improvements over previous medicines.** This is especially important to the biotechnology industry which is composed largely of small companies, many of which have one or no products on the market and are not yet profitable.

Next generation products can be of enormous value to patients because new discoveries can make existing medications safer or more effective through changes to the structure of a molecule. When significant changes are made to the original medication, the FDA requires the manufacturer to conduct new clinical trials and submit a new drug application for approval and considers it an entirely new product.

Patient advocacy organizations (such as the Colon Cancer Alliance, Easter Seals and National Kidney Foundation) and medical specialty groups (such as the Alliance of Specialty Medicine and Association of Black Cardiologists) recognize the importance of providing incentives for manufacturers to conduct clinical trials and seek a separate approval by the FDA for next generation products.

Statements from patient and medical specialty groups which support incentives for next generation products are available thru the following links:

[http://bio.org/healthcare/followonbkg/Patient\\_Letter\\_Evergreening.pdf](http://bio.org/healthcare/followonbkg/Patient_Letter_Evergreening.pdf)

[http://bio.org/healthcare/followonbkg/Alliance\\_of\\_Specialty\\_Medicine\\_Evergreening.pdf](http://bio.org/healthcare/followonbkg/Alliance_of_Specialty_Medicine_Evergreening.pdf)

[http://bio.org/healthcare/followonbkg/National\\_Health\\_Council\\_Evergreening.pdf](http://bio.org/healthcare/followonbkg/National_Health_Council_Evergreening.pdf)

Additionally, this bill follows the European system, wherein minor changes to existing products do not result in new periods of data exclusivity, but improvements that result in new products of value to patients are entitled to their own separate data exclusivity period.