

# **Principal Differences Between the “Promoting Innovation and Access to Life-Saving Medicine Act” and the “Access to Life-Saving Medicine Act” introduced in the 110th Congress**

## **A. New Exclusivity Provisions**

### **1. Original exclusivity.**

The amended bill adds the exclusivity periods that currently are available under Hatch-Waxman to provide incentives for innovation. Original biologic products would get 5 years of exclusivity and modifications of existing products (new uses, new dosage forms, and modifications in molecular structure) would get 3 years. The amended bill provides for extensions of the 3 and 5 year periods by up to 1 year:

(1) Provides a 3-6 month extension if the original applicant obtains approval of a medically important new use of the product no later than 1 year before the original period of exclusivity expires. The extension is for 6 months, unless the product has U.S. sales of more than \$1 billion per year, in which case the extension is for 3 months.

(2) Makes biologics eligible for 6 months of pediatric exclusivity.

### **2. Evergreening issues**

The biologics that are eligible for the 5-year exclusivity should be carefully defined to avoid “evergreening”: the possibility that a manufacturer could make a small modification to an existing products and gain a new 5-year periods. The 5-year exclusivity provision in Hatch-Waxman was limited to new chemical entities: innovative drugs identified by their novel molecular structures. Although the concept of a “new chemical entity” cannot be directly applied to biologics, the amended bill attempts to describe an analogous set of biologics by limiting the maximum period of exclusivity to biologics that are sufficiently different from other approved biologics in molecular structure to require a full new application. The bill also specifies certain types of minor changes in molecular structure that will not be eligible for 5 years of exclusivity (though they may be eligible for 3 years). The list is drawn from a current FDA regulation defining orphan drug exclusivity for large molecules.

## **B. Changes to Pathway**

### **1. The amended bill would permit FDA to consider, in making interchangeability determinations, safety issues resulting from substitution, including immunogenicity.**

**Reason for change:** FDA testified that switching back and forth between products could produce immunogenic (allergic) responses not produced by either product alone, and that the agency would need to assess this possibility before finding two products interchangeable.

**2. A proposed generic must be “highly similar” to the brand in molecular structure to be eligible for an abbreviated application. The new bill eliminates a provision that deemed certain categories of products to be “highly similar.”**

**Reason for change:** The original bill included examples of “highly similar” structures, taken from an existing FDA regulation on orphan drugs, to insulate FDA from disputes over whether a proposed drug was sufficiently similar to the brand. The provision was criticized for limiting FDA’s discretion to decide which structural differences were significant or not. The new bill gives FDA full discretion to determine which products are “highly similar” and which are not.

**3. The new bill gives FDA authority to disapprove an untested indication for a product with the same mechanism of action as the reference product if the Secretary finds that safety, purity, and potency of one or more uses sharing the same mechanism of action can only be demonstrated by data supporting that use.**

**Reason for change:** FDA should have discretion to determine whether additional data are needed even if several indications share the same mechanism of action.

**4. The new bill gives FDA full discretion to request post-marketing studies for generic biologics.**

**Reason for change:** The original bill restricted FDA’s authority to request post-marketing studies from generic applicants unless the same studies had been requested from the original manufacturer. Now that FDA has new authority to require post-market studies, under the Food and Drug Administration Amendments of 2007, follow-on applicants would be subject to the same post-market requirements as brand products.

### **C. Changes to Patent Provisions**

**1. The new bill adds a provision designed to help avoid collusive agreements between generic and brand companies. If a biosimilar applicant contacts a patent holder, the contact must be reported confidentially to the FTC.**

**2. The new bill clarifies that patent holders other than the brand manufacturer may be notified.**