



## **The Patient Protection and Affordable Care Act**

### **Biologics Price Competition and Innovation Act**

The Biologics Price Competition and Innovation Act, which is included in the Patient Protection and Affordable Care Act, creates an approval pathway for biosimilar and interchangeable biological products while preserving the incentives that have fueled the development of these medicines.

#### **Approval Process**

- ✓ The Patient Protection and Affordable Care Act amends section 351 of the Public Health Service Act to allow the submission of a biological license application (BLA) for a biosimilar or interchangeable biological.
- ✓ A biosimilar applicant must demonstrate that there are no clinically meaningful differences in safety, purity, and potency between a biosimilar product and the brand or product. A demonstration of biosimilarity requires analytical data, animal testing and clinical studies, unless a requirement is determined by the Secretary to be unnecessary.
- ✓ A biosimilar product may be approved as interchangeable either at the time of initial approval or after a supplemental approval. An interchangeable product is a biosimilar product that can be substituted for the brand product without the intervention of the health care provider who prescribed the product. A demonstration of interchangeability requires evidence that the biosimilar product will produce the same clinical result as the brand product in any given patient and that it presents no additional risk if a patient is switched between products.

#### **Guidance Documents**

- ✓ The Patient Protection and Affordable Care Act allows the Secretary acting through the Food and Drug Administration (FDA) to issue guidance documents that will aid in disseminating the standards and criteria that FDA will use in approving biosimilar and interchangeable biological products.
- ✓ The FDA, following a public process, can issue guidance related to the approval of biosimilar and interchangeable biological products. The absence of a guidance document does not prevent the approval of a biosimilar or interchangeable biological product. Such guidance can be modified or reversed as the FDA deems appropriate.

#### **Patent Resolution**

- ✓ The Patient Protection and Affordable Care Act creates a process that accelerates the litigation of patents while preserving the innovators' patent protection.
- ✓ The biosimilar applicant must provide information about its manufacturing process to the brand company. A series of informational exchanges then occur in which the biosimilar applicant and the brand company identify patents that each believes to be valid, invalid, infringed or noninfringed.
- ✓ At the end of this process a list of patents that are in question is identified. The validity of the claims of infringement can then be adjudicated.

#### **Exclusivity**

- ✓ The Patient Protection and Affordable Care Act provides incentives to ensure that the innovation and development of new life-saving medicines by universities and companies continues, as well as incentives to encourage the development of interchangeable biological products.
- ✓ Brand manufacturers and innovators are awarded 12 years of data exclusivity from the approval date of the product. The first biosimilar applicant to demonstrate interchangeability receives a full year of exclusivity.

### **Pediatrics**

- ✓ The Act provides the application of certain provisions of the section 505A of the Food, Drug and Cosmetic Act to biological products.
- ✓ Specifically, this provision provides an additional six months to the period of exclusivity otherwise applicable to the biological product but only if the applicant agrees to and completes pediatric studies of such products as request by the FDA and makes applicable labeling changes.
- ✓ Similar to the existing authority under section 505A of the Food, Drug and Cosmetic Act, this provision sunsets after five years.