Automatic Substitution within the “Biologics Price Competition and Innovation Act of 2009”

As part of the “Patient Protection and Affordable Care Act,” Congress established a process under which the Secretary of Health and Human Services is required to license a biological product that is shown to be biosimilar to or interchangeable with an already licensed biological product (“reference product”) by incorporating the “Biologics Price Competition and Innovation Act of 2009.” This paper will examine the implications for automatic substitution within this new public law.

Key elements to automatic substitution
The determination of pharmaceutical substitution without physician approval is a combination of two key provisions within any biosimilars legislation -- interchangeability and naming. Interchangeability is when two or more biologics have characteristics making them clinically equivalent so that they are fully substitutable. Generally, FDA must make that determination. To further denote that interchangeability among generic drugs, FDA assigns the two products the same International Nonproprietary Name (INN).

Currently, all State laws allow the pharmacist to substitute a less expensive generic product for the brand name product. In some states, like Pennsylvania, unless the prescriber signs or initials “brand necessary” or “brand medically necessary,” the pharmacist is required by law to provide the generic form, unless the patient demands a brand name drug.

Interchangeability. Interchangeability requires that the products be “highly similar... notwithstanding minor differences in clinically inactive products,” same “safety, purity, and potency” for one or more condition, “same mechanism or mechanisms of action”, same “route of administration, dosage form, and... strength.” There language also references to required clinical and animal studies to assert those claims, but those requirements may be waived at the discretion of the Secretary. In addition, to be interchangeable, the biologic “can be expected to produce the same clinical result... in any given patient.” Further, if the biological product is to be used more than once, then there can be no greater risk “in terms of safety or diminished efficacy.”

Naming. There is no naming provision. Therefore, FDA must decide how to determine the appropriate nomenclature.