United Spinal Association

Expanding Opportunities for Veterans and All Paralyzed Americans

Protect Consumer Safety, Access and Choice of Biologic Medicines

The Affordable Care Act (ACA), signed into law in 2010, established new regulatory authority for the Food and Drug Administration (FDA) to review and approve biosimilar versions of FDA approved biologic medicines (biosimilar products are similar but not identical to the original biologic product). The ACA lays out basic standards that must be met including that the biosimilar is "highly similar" to an already-approved biological product. The law also gives FDA authority to find a biosimilar to be "interchangeable" which requires a significantly higher standard confirming that it will achieve the same clinical result in any given patient. The law left many important details about biosimilar approval standards to the FDA to develop.

United Spinal Association endorses Biotechnology Industry Organization's biosimilar principles which designate that substitions of biosimilar products can only occur when the FDA has designated a biosimilar product as interchangeable; the prescribing physician should be able to prevent substitution in light of the patient's medical treatment and history; the prescribing physician should be notified of the substitution – even though interchangeable biologics will be "expected" to produce the same clinical result, patients could react very differently to an interchangeable product. The patient, or the patient's authorized representative, should, at a minimum, be notified of the substitution. The pharmacist and the physician should keep records of the substitution - many biologic medicines are used to treat chronic conditions that can change over time so it is important for a patient's treatment team to have records that document how and when a patient was treated with biologic therapies.

The ACA permits manufacturers of biosimilars to rely on clinical trial data from the original biologic as long as several conditions are met (such as if the FDA deems the biosimilar product to be similar in structure with no clinically meaningful differences to the innovator product). However:

- **biologic medicines are unique and complex proteins that are made from highly specialized and purified living cells.**
- **biosimilars <u>are not</u> identical "generic" versions of the innovator biologic medicines** they seek to copy because they are made from different cell lines and different manufacturing processes.
- **biosimilars may provoke immune responses that differ from biologic medicines** that can only be understood with adequate human clinical trials.

REQUEST TO POLICYMAKERS

- The FDA is expected to publish proposed guidance for public comment this year related to key aspects of implementation of the biosimilars law. The Federal Trade Commission (FTC) may also issue a report with advisory recommendations regarding the naming and marketing of biosimilars, but the FTC has no direct jurisdiction. Please hold oversight hearings on this important process and urge the FDA to release guidance as soon as possible that ensure patient safety, patient access to the right biologic medicines, patient choice and full transparency.
- Choice should be at the center of any decision to substitute or switch therapies and should only be decided by the patient and provider. Patient choice needs to be preserved and regulatory decisions must be based on sound science.
- Biosimilar regulations must put patient safety first. Policymakers and regulators must address appropriate patient safety and efficacy concerns as they relate to decisions around interchangeability, clinical indications, labeling, naming and substitution.
    - Particular attention must be given to assure that rigorous clinical testing proves that a biosimilar works safely in each and every condition or disease for which it is approved to be prescribed, as well as in each distinct group of patients with that disease.