Biosimilars
FORUM

STATE BIOSIMILARS
SUBSTITUTION COMPROMISE

State law governs the substitution by pharmacists of generic drugs for their branded counterparts. These state pharmacy laws will need to be updated to allow for the substitution of biologic products only with FDA approved interchangeable biologics.

The leading companies developing and marketing biologic products, including biosimilars and interchangeable biologics, have been engaged in discussions on the various state legislative proposals. Through the legislative process, it has become clear that physicians, and patients, see value in transparent communication on all biologic medicines dispensed in order to maintain a consistent and complete medical record.

Such communication should rely on the growing adoption of interoperable electronic health records and electronic prescription records that allow a patient's health care team to communicate regarding a patient's medication history. In instances where such electronic records are not yet in place, pharmacist to prescriber communication will foster confidence in all biological medicines, including originator products, biosimilars, and interchangeable biologics.

The approval standards being developed by FDA require that the products be highly similar to and have an absence of clinically meaningful differences from the reference product. Overall, confidence in these medicines will be advanced by application of consistent standards to the dispensing and use of all biologic medicines.

Proposed Approach for Pharmacist-Prescriber Communication in 2015 Legislation:

- State pharmacy laws should be updated to enable pharmacy substitution of only interchangeable biologics, as approved by the FDA.
- Within a reasonable time following the dispensing of a biological product, the dispensing pharmacist or the pharmacist's designee shall communicate to the prescriber the specific product provided to the patient, including the name of the product and the manufacturer. The communication shall be conveyed by making an entry in an interoperable electronic medical records system or through an electronic prescribing technology or a pharmacy record that is electronically accessible by the prescriber. Otherwise, the pharmacist shall communicate the biologic product dispensed to the prescriber, using facsimile, telephone, electronic transmission, or other prevailing means, provided that communication shall not be required where:
    - There is no FDA-approved interchangeable biologic for the product prescribed; or
    - A refill prescription is not changed from the product dispensed on the prior filling of the prescription.
- Other provisions related to the dispensing of a biologic product shall generally replicate state law pertaining to small molecule products, including that the patient is aware of the medicine they receive, physicians retain dispense as written authority, and pharmacy records are retained.
- All biological products should be treated equally under state law, whether they are approved under the Public Health Service Act or the Food, Drug and Cosmetic Act.