Whereas, Safe and effective treatments should be available to patients at the lowest possible cost; and

Whereas, Biosimilars are medicines that could be cost-saving alternatives for specialty drugs called biologics, which are large, complex therapeutic agents typically given by an injection or infusion. The relationship between biosimilars and biologics, at the regulatory but not biochemical level, is akin to the relationship between generic and brand name medicine, though biosimilars are not generic copies of their reference drugs; and

Whereas, The size, complexity, and heterogeneity of biologics, and thus biosimilars, necessitate a greater degree of scrutiny in their analytical evaluation than what is required for small molecule generics. Due to the complexity of biologics, separate regulatory approval and dispensing pathways were created to ensure effectiveness and protect patient safety; and

Whereas, In addition to adequate pharmacokinetic and pharmacodynamics studies, clinical data are necessary to ensure the safety and efficacy of biosimilars, and to provide the necessary level of confidence for their use by patients and providers; and

Whereas, Congress authorized the FDA to provide two pathways for biosimilar approval: 1) biosimilar agents that have equivalent safety, purity, and potency as original biologics; and 2) a higher level of interchangeable biosimilars in which alternating or switching between an original biologic and biosimilar would not be predicted to cause any changes in efficacy or safety; and

Whereas, Most state legislatures have passed laws that will allow substitution of an interchangeable biosimilar for a reference product, with the necessary notification of the prescriber to ensure patients receive drugs consistent with their provider's treatment plan; and

Whereas, The FDA must ensure that regular and interchangeable biosimilars are safe and effective. In January 2017 the FDA released draft guidance outlining requirements for manufacturers to use robust switching studies to determine whether alternating between a biosimilar and its reference product impacts the safety or efficacy of the drug; and

Whereas, The requirement for multiple-switch studies to demonstrate the safety of interchangeability is particularly vital to proper enforcement of the law, which requires studying "alternating" or repeatedly switching; therefore be it
RESOLVED, That our American Medical Association strongly support the rigorous pathway for demonstrating biosimilar interchangeability that was proposed in draft guidance by the FDA in 2017, including requiring manufacturers to use studies to determine whether alternating between a reference product and the proposed interchangeable biosimilar multiple times impacts the safety or efficacy of the drug (New HOD Policy); and be it further RESOLVED, That our AMA issue a request to the FDA that the agency finalize the biosimilars interchangeability pathway outlined in its draft guidance “Considerations in Demonstrating Interchangeability With a Reference Product” with all due haste, so as to allow development and designation of interchangeable biosimilars to proceed, allowing transition to an era of less expensive biologics that provide safe, effective, and accessible treatment options for patients. (Directive to Take Action)

Fiscal Note: Not yet determined

Received: 05/25/18

RELEVANT AMA POLICY

Biosimilar Product Naming and Labeling D-125.987
Our AMA urges the FDA to finalize Guidance on the naming and labeling conventions to be used for biosimilar products, including those that are deemed interchangeable. Any change in current nomenclature rules or standards should be informed by a better and more complete understanding of how such changes, including requiring a unique identifier for biologic USANs would impact prescriber attitudes and patient access, and affect post marketing surveillance. Actions that solely enhance product identification during surveillance but act as barriers to clinical uptake are counterproductive. However, because of unique product attributes, a relatively simple way to identify and track which biosimilar products have been dispensed to individual patients must be established. If unique identifiers for biosimilar USANs are required to support pharmacovigilance, they should be simple and the resulting names should reinforce similarities by using the same root name following standards for nonproprietary names established by the USAN Council.
CSAPH Rep. 4, A-14

Substitution of Biosimilar Medicines and Related Medical Products D-125.989
Our AMA urges that State Pharmacy Practice Acts and substitution practices for biosimilars in the outpatient arena: (1) preserve physician autonomy to designate which biologic or biosimilar product is dispensed to their patients; (2) allow substitution when physicians expressly authorize substitution of an interchangeable product; (3) limit the authority of pharmacists to automatically substitute only those biosimilar products that are deemed interchangeable by the FDA.
Citation: (Res. 918, I-08; Modified: CSAPH Rep. 1, I-11; Modified: CSAPH Rep. 4, A-14)

Abbreviated Pathway for Biosimilar Approval H-125.980
Our AMA supports FDA implementation of the Biologics Price Competition and Innovation Act of 2009 in a manner that 1) places appropriate emphasis on promoting patient access, protecting patient safety, and preserving market competition and innovation; 2) includes planning by the FDA and the allocation of sufficient resources to ensure that physicians understand the distinctions between biosimilar products that are considered highly similar, and those that are deemed interchangeable. Focused educational activities must precede and accompany the entry of biosimilars into the U.S. market, both for physicians and patients; and 3) includes compiling and maintaining an official compendium of biosimilar products, biologic reference products, and their related interchangeable biosimilars as they are developed and approved for marketing by the FDA.
Citation: (Res. 220, A-09; Reaffirmation A-11; Modified: CSAPH Rep. 1, I-11; Modified: CSAPH Rep. 4, A-14)