



200,000 Physicians Strong

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The Honorable Anna Eshoo
U.S. House of Representatives
205 Cannon House Office Building
Washington, DC 20515

The Honorable Jay Inslee
U.S. House of Representatives
403 Cannon House Office Building
Washington, DC 20515

The Honorable Joe Barton
U.S. House of Representatives
2109 Rayburn House Office Building
Washington, DC 20515

Dear Representatives Eshoo, Inslee, and Barton:

The undersigned members of the Alliance of Specialty Medicine (Alliance) recognize your efforts to introduce legislation to establish a pathway for biosimilars/follow-on biologics (FOB).

The Alliance is a coalition of 12 national medical specialty societies representing more than 200,000 physicians dedicated to the development of sound federal health care policy that fosters patient access to the highest quality specialty care. Biotechnology has produced novel therapeutic agents that have markedly increased the ability to treat patients suffering from serious illnesses, and medical specialists increasingly rely on biologic medications to provide optimal care for patients.

As follow-on biologic pathways are considered in Congress, we urge you to ensure that any final legislation contains important safety provisions that will maximize the therapeutic benefits of these products, while minimizing their special risk factors. Our concerns focus on two areas directly related to patient safety:

1. Clinical Trials: No biosimilar should be approved before its safety and efficacy has been tested in humans.

Physicians rely on authoritative safety data when making prescribing decisions on behalf of patients. Any approval pathway for biosimilars should recognize the importance of clinical and non-clinical trials that establish the safety of biosimilars. We concur with the assertion made to Congress just six months ago by the FDA's Chief Scientist, Frank M. Torti, MD, MPH, now Acting Commissioner of Food and Drugs:

American Association of Neurological Surgeons • American Association of Orthopaedic Surgeons

American College of Emergency Physicians • American College of Obstetricians and Gynecologists

American Gastroenterological Association • American Society of Cataract & Refractive Surgery • American Urological Association

Coalition of State Rheumatology Organizations • Congress of Neurological Surgeons

Heart Rhythm Society • National Association of Spine Specialists • Society for Cardiovascular Angiography and Interventions

“Given the current level of understanding, at least some clinical information will be needed to assess the safety and efficacy of most FOBs. Legislation should require clinical trials, but FDA should be given discretion to determine through a transparent and public process what clinical trials are needed to support the licensure of an FOB.”

2. Interchangeability: We have stated in the past our belief that the approval pathway must not allow substitution or interchangeability of biosimilars for innovator products, because biosimilars can only be similar to, and are never identical to, an innovator product. They are not like generics, which are exact copies of innovator drugs. Interchanging biosimilar medications with original versions creates a complex risk-benefit assessment that can only be made appropriately by the patient’s physician.

Also, regulators in Europe and at the FDA, have recognized that one of the risks of switching patients between innovator and biosimilars (or vice-versa) is the potential for dangerous immune responses. We agree with the FDA’s Acting Commissioner Torti that:

“The FDA believes that patients should not be switched from the reference biological product to a follow-on biological product (or vice versa) unless directed to do so by their physician.”

The ultimate assessment of whether or not to interchange a brand-name biologic with a biosimilar version is a medical decision—one that is best made by a physician who has an in-depth knowledge of the patient’s medical history and potential risk factors.

The Alliance holds patient safety matters as the highest priority when considering provisions in biosimilar legislation. The Alliance of Specialty Medicine welcomes the opportunity to work with you on these important issues. Please contact Jeanie Kennedy at Kennedy@aaos.org for more on the Alliance positions on follow-on biologics.

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