



THE ALLIANCE FOR PATIENT ACCESS

March 25, 2009

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 Alliance for Patient Access, an organization of nearly 300 physician members, supports the Pathway for Biosimilars Act as it provides important safeguards benefiting patient safety and does not inappropriately deem biosimilars as interchangeable.

1. Follow-on Biologics need their own clinical trials before they can be judged safe.

The Pathway for Biosimilars Act recognizes a distinction between pharmaceuticals and biologics that makes a critical difference. With conventional drugs, the manufacturing process is relatively straightforward and generics are chemically identical to their brand-name counterparts. Additional clinical trials for safety and efficacy are often not indicated.

Producing biologics, on the other hand, is a far more complex science. Unlike pharmaceuticals that typically consist of small molecules, biologics are often much larger and more complex drugs. Manufacturing a biologic is a long and complicated process such that no two biological products are very unlikely to be identical. This is why there is technically no such thing as a "generic" biologic drugs. Follow-on biologics are, at best, rough copies of brand-name biologics and not exact duplicates.

2. Biologics are not interchangeable.

The Pathways for Biosimilars Act further protects patient safety by providing standards that must be satisfied before a biosimilar could be deemed interchangeable. In the more familiar world of chemically-based tablet drugs, some generics do provide an economic and clinically effective substitute for the original or "brand name" version. Due to the wide variation in dosage levels of biologics, though, pharmacies should not be permitted

to arbitrarily substitute a follow-on version for the one prescribed by a physician. Not only do safe and effective dosage levels for biologics differ from version to version, there are is often no conversion (dosage equivalents) to translate proper dosage between biologics.

For example, in one clinical setting the equivalent dosage ratio between biologic A and biologic B might be 4:1. In a different clinical situation the ratio could be significantly different between the same two biologics. Predicting the performance of one biologic on the basis of comparison with another is simply not possible without specific clinical testing. The variation in dosage levels among biologics makes a compelling case for clinical trials.

The Alliance for Patient Access thanks you for your leadership in proposing a safe and effective pathway by which patients will benefit from greater access to biosimilars.

Sincerely,

A handwritten signature in black ink that reads "D CHARLES MD". The signature is written in a cursive, slightly slanted style.

David Charles, M.D.  
Chairman