



## Crohn's and Colitis Foundation of America Position Statement: Biosimilars

The Crohn's & Colitis Foundation of America (CCFA) advocates on behalf of the 1.6 million Americans who are affected by Crohn's disease and ulcerative colitis, which are collectively known as inflammatory bowel diseases. CCFA is also the professional organization for those physicians, nurses, scientists and other healthcare providers who care for patients with IBD. CCFA believes that treatment decisions should be shared between the healthcare provider and the patient. CCFA wants to ensure patient safety is paramount as the Food & Drug Administration (FDA) creates the approval standards for biosimilars. CCFA also advocates that the healthcare provider and patient relationship be deemed a priority in determining the most appropriate treatment options.

To enhance and to safeguard shared-decision making between the healthcare provider and patient, CCFA supports the principals below:

- **Safety and Effectiveness:**

CCFA encourages the FDA to ensure that all biologics and biosimilars undergo thorough human testing and meet the highest safety standards. Consideration should be given to the application of the biosimilar in pediatric patients.

CCFA urges that the FDA, when considering interchangeability with the biosimilar, provide reasonable proof that switching from the originator to the biosimilar would not incur immunogenicity or loss of response to the originator (and vice versa).

Risk of cross reactivity of anti-drug antibodies from the originator agent to the biosimilar must be clearly understood, defined, and listed on the label and prescribing information.

The risk of immunogenicity should be noted on the label and in prescribing information.

Each biosimilar should have a unique identification number, name or else use international non-proprietary names standards to eliminate patient and provider confusion.

Records of substitution should be tracked by the pharmacist and provided upon request to the provider.

- **Shared-Decision Making and Transparency:**

The prescribing provider should have the following rights:

- Be notified of a substitution of the originator agent with a biosimilar (or vice versa).
- Be able to prevent substitution by indicating "dispense as written" or "brand medically necessary."

When not otherwise specified in the prescription of these agents, patients, or their designated caregivers, as well as the treating providers, should be asked to provide approval for the substitution of an originator agent with a biosimilar.

We encourage the FDA and state legislatures to incorporate these policies.

Please direct any inquiries to Laura D. Wingate, Vice President Patient & Professional Services, at [lwingate@ccfa.org](mailto:lwingate@ccfa.org) or call 646-943-7447.

*Endorsed by the North American Society for Pediatric Gastroenterology, Hepatology, and Nutrition*

