Statement of the  
Crohn’s and Colitis Foundation of America  
Before the FDA Arthritis Advisory Committee  
February 9, 2016  
RE: Biologics License Application 125544

Thank you for your efforts to facilitate a robust market for medications and to ensure that they are safe and effective. We write on behalf of the Crohn’s and Colitis Foundation of America (CCFA) to express our views and concerns for biologics and biosimilars as you consider the application for CT-P13. Biosimilars pose both an opportunity to lower health care costs and a risk to patient safety if not properly utilized. We urge you to support access to lower-cost biosimilars while also ensuring that optimal patient care - as determined by the patient and their doctor - comes first.

CCFA advocates on behalf of the 1.6 million Americans who are affected by Crohn’s disease and ulcerative colitis, collectively known as Inflammatory Bowel Diseases (IBD). IBD are chronic disorders of the gastrointestinal tract which cause abdominal pain, fever, and intestinal bleeding. Many IBD patients rely on biological therapies to treat their disease. Current anti-TNF (biologic) therapies for IBD include infliximab, approved in 1999, adalimumab in 2007, certolizumab pegol in 2008, and golimumab in 2013. A new class of biologic drugs, anti-integrins, have emerged and include natalizumab, approved in May 2008, and vedolizumab, approved in May 2014.

Indication Extrapolation  
CCFA has refrained from advocating for extra IBD-specific evidence when a proof for another condition has been deemed sufficient by FDA. We are willing to accept FDA approval of therapies indicated for Crohn’s disease and ulcerative colitis by extrapolation based on studies in other conditions, especially rheumatoid arthritis. We do have other specific concerns, listed below.

Interchangeability  
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). This is of particular importance, given the risk of loss of response to therapy and the risk of infusion or injection reactions that may occur due to immunogenicity or allergic reactions.

Patient and Provider Education  
FDA should partner with stakeholder organizations to educate patients and providers about biosimilars. CCFA is concerned about the lack of awareness and understanding about
biosimilars among both of these groups. Misunderstanding could lead to slow uptake of biosimilars, misuse, and in the worst circumstances, malpractice.

**Highlights from the CCFA Biosimilar Position Statement**
Attached is the CCFA position statement on biosimilars, crafted by the CCFA National Scientific Advisory Committee, Government & Industry Affairs Subcommittee. Below are other key points from the statement that have not been mentioned above:

**Immunogenicity and patient safety**

- 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.

  *Explanation: Note that the CCFA recommendation does not require that unique studies of biosimilar agent efficacy be performed in CD and UC patients. We are willing to accept the FDA approval of therapies for biosimilarity and interchangeability based on studies in other conditions, especially rheumatoid arthritis. We do have other specific concerns, listed below.*

- 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.

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

  *Explanation: We feel strongly that providers should know exactly which agent their patient is receiving. We are opposed to indiscriminant switching of therapies by pharmacies or payers.*

**Transparency in prescribing**

- The prescribing provider should have the following rights:
  - Be notified of any 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”

Please consider CCFA as a resource for you as you examine applications for biosimilars. The membership of CCFA includes world experts on the evaluation and management of IBD patients, and we would be pleased to arrange a call or meeting to discuss further. For additional information, please contact the CCFA office.

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information, contact the CCFA Director of Advocacy, Sarah Buchanan, at sbuchanan@ccfa.org. Thank you for your consideration of the above issues concerning patient safety, transparency in prescribing, and access to biologics and biosimilars.

Sincerely,

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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 reactvity 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 or call 646-943-7447.