CANCER LEADERSHIP COUNCIL

A PATIENT-CENTERED FORUM OF NATIONAL ADVOCACY ORGANIZATIONS ADDRESSING PUBLIC POLICY ISSUES IN CANCER

September 21, 2018

Scott Gottlieb, MD
Commissioner
Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

Re: FDA-2018-N-2689, Facilitating Competition and Innovation in the Biologicals Products Marketplace; Request for Comments

Dear Dr. Gottlieb:

The undersigned cancer organizations are writing to comment on the Biosimilars Action Plan: Balancing Innovation and Competition and the proceedings of the public meeting on biosimilars held on September 4, 2018. We appreciate the opportunity to comment.

We commend the Food and Drug Administration (FDA) for the development of the Biosimilar Action Plan (BAP) articulating a strategy balancing innovation and competition. Biological products have provided significant benefits to cancer patients and are critical elements of cancer care for patients with a wide range of cancer diagnoses. As FDA noted in the BAP, these products have also come at significant expense to the health care system and to individual patients. Protecting access to the benefits of biological products and addressing the cost of these products to patients are important goals of the BAP and goals that, if realized, will benefit patients.

One of the four goals of the action plan is "developing effective communications to improve understanding of biosimilars among patients, clinicians, and payors." The action plan identifies deliverables related to this communications goal, including: 1) a Biosimilar Education and Outreach Campaign, including an updated FDA Biosimilars website; 2) a webinar providing an overview of the regulatory framework for approval of biosimilars; and 3) a Reddit Ask me Anything (AMA) forum to engage pharmacists on biosimilars. These initial efforts are solid, but we recommend that FDA turn its attention to communications efforts that will directly reach patients and their care teams.

CONTACT: 2446 39TH STREET NW · WASHINGTON, D.C. 20007
Phone: 202-333-4041 · www.cancerleadership.org

The cancer organizations below are dedicated to a system of cancer care that supports informed decision-making about cancer treatment and includes access to adequate and accurate information supporting patient-centered treatment decisions. For some patients, adequate data and appropriate diagnostic testing support the choice and delivery of targeted therapies. For others, information about their treatment regimen is critical to developing a plan for managing cancer as a chronic disease, including appropriate symptom management. Information about biosimilars that is accessible to the patient will support informed decision-making and long-term management of cancer and treatment side effects.

We note that biosimilar communications efforts to date have focused on overall understanding of biosimilars and their regulatory review. These are important efforts, but we recommend product-specific efforts that will inform patient decision-making. Such educational materials might address whether a product is a biosimilar or also an interchangeable product.

The issue of patient education about biosimilars was one of many areas of focus during the September 4, 2018, meeting. FDA officials asked some patients and patient advocates if information about biological reference products is also necessary for patients, if information about the approval of biosimilars is, in the eyes of patient advocates, critical to patients. In days after the meeting, trade press publications have reported that FDA officials have recommended that the agency produce patient educational materials about the analytical studies that are used to support biosimilar approvals. At the same time, those officials have suggested that patients may not be able to interpret materials about analytics.

We agree that the development of patient-centered materials that would include information about the analytical basis for biosimilar approvals will not be an easy task. We also agree that use of these materials by patients will be a challenge, but we anticipate that these materials would be utilized by patients with their cancer care team and that this collaborative approach would increase the usefulness of the materials. Despite the obstacles, we think that the effort deserves the attention of the agency, and we stand ready to bring our expertise in development of patient materials to a collaboration with the agency. This task is worth our attention and effort because it holds the promise of reassuring patients and the patient community about biosimilars and also providing information to inform treatment decision-making, as we describe above.

There has also been some suggestion that biosimilars should be the subject of post-marketing studies. We suggest that FDA evaluate whether biological reference products and biosimilars might be the subject of real world evidence data collection. Perhaps employing real world evidence efforts in connection with biological reference products and biosimilars used in cancer treatment would be a first step and pilot project for the

concept. We understand this is not a simple matter. However, the effort might yield important information for patients, providers, product developers, and the agency.

We appreciate the opportunity to comment on the BAP and look forward to collaborating with the agency on patient education materials.

Sincerely,

Cancer Leadership Council

American Society of Clinical Oncology
Cancer*Care*
Children's Cause for Cancer Advocacy
Fight Colorectal Cancer
Hematology/Oncology Pharmacy Association
International Myeloma Foundation
The Leukemia & Lymphoma Society
LIVE**STRONG**
Lymphoma Research Foundation
National Coalition for Cancer Survivorship
Ovarian Cancer Research Fund Alliance
Prevent Cancer Foundation
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