U.S. HOUSE OF REPRESENTATIVES
COMMITTEE ON ENERGY AND COMMERCE

February 2, 2015

TO: Members, Subcommittee on Health

FROM: Committee Majority Staff

RE: Hearing entitled "Examining Implementation of the Biologics Price Competition and Innovation Act"

I. INTRODUCTION

On Thursday, February 4, 2016, at 10:30 a.m. in 2123 Rayburn House Office Building, the Subcommittee on Health will hold a hearing entitled "Examining Implementation of the Biologics Price Competition and Innovation Act." The Biologics Price Competition and Innovation Act (BPCIA), enacted in 2010, established a new abbreviated licensure pathway at the Food and Drug Administration (FDA) for biological products determined to be "biosimilar to" or "interchangeable with" previously licensed biologics. In 2012, the Biosimilar User Fee Act (BsUFA) was enacted to support FDA's work related to the development and review of these products, the first of which was licensed in March 2015. In addition, the agency has issued several guidance documents and proposed regulations setting forth its current thinking on a number of closely watched policy determinations that will impact market entry and patient safety. Further, in preparation for additional biosimilar approvals, the Centers for Medicare and Medicaid Services (CMS) published final rules setting the stage for how the Medicare program will reimburse such products. This hearing will provide members an opportunity to hear from both agencies about implementation efforts to date as well as next steps.

II. WITNESSES

- Janet Woodcock, M.D., Director, Center for Drug Evaluation and Research, Food and Drug Administration; and

- Sean Cavanaugh, Deputy Administrator and Director, Center for Medicare, Centers for Medicare and Medicaid Services.

III. BACKGROUND

Many of the important therapies patients receive to prevent or treat a range of conditions and diseases are derived from living organisms and manufactured using biotechnology. Commonly referred to as "biologics," these medications consist of larger molecules and are generally more difficult to characterize and manufacture than chemically derived, smaller molecule drugs. Due in large part to the complexities involved in developing and testing these inherently unique products, they can be more expensive than their more conventional, chemical counterparts.

With this in mind, the BPCIA added section 351(k) to the Public Health Service Act,[1] authorizing FDA to approve a "biosimilar" if it is determined to be highly similar to a previously licensed product referenced in the application (reference product) and all remaining reference product patents and exclusivity periods have lapsed. Further, if an application shows that, in addition to meeting the biosimilarity standard, the medicine can be expected to produce the same clinical result in any given patient, FDA can approve it as being "interchangeable" with the reference product. To do so, the applicant must demonstrate that the risks to a patient with switching between the two products is no greater than if the patient were prescribed or administered only the reference product. Based on their medical judgment, in consultation with the patient, a health care provider will be able to explicitly prescribe a biosimilar in place of the reference product. Depending on State law, in a manner akin to conventional generic drugs, an interchangeable product may be automatically substituted for the reference product by a pharmacist even if the provider prescribed the reference product. Overall, "biosimilars" should provide patients with more options, and increased competition should produce savings for the health system.

This nascent market has garnered significant interest and generated robust policy discussions. On the FDA side, with patient safety and access in mind, a range of opinions have been expressed on the data necessary to show biosimilarity versus interchangeability; how biosimilars should be named in relation to their reference product; and whether biosimilars should have the same physician labeling as the reference product or whether there should be differences based on the data submitted and for which patient indications. FDA has opined on some of these issues in the form of guidance documents and regulations. In addition, the agency licensed the first biosimilar in March 2015, though the extent to which that can be cited as precedent on any or all of these policy issues is an open discussion.

Further, in November 2015, CMS published final rules for the Medicare Hospital Outpatient Prospective Payment (HOPPS), as well as the Medicare Part B Outpatient Physician Fee Schedule (OPPS) for calendar year 2016. Within these rules CMS issued regulations setting the stage for how the Medicare program will reimburse for biosimilar products. Questions have been raised about CMS' interpretations of several statutory provisions guiding reimbursement that could seemingly conflict with and potentially undermine FDA decisions on various matters. For example, CMS would group all biosimilars that share the same reference product under the same Healthcare Common Procedure Coding System (HCPCS) J code and each product would be reimbursed under the same code, regardless of whether FDA makes an interchangeability determination or if the biosimilar shares the same indications as the reference product.

IV. STAFF CONTACTS

If you have any questions regarding this hearing, please contact John Stone, Carly McWilliams, JP Paluskiewicz, or Adrianna Simonelli of the Committee staff at (202) 225-2927.

[1] While biological products are subject to regulation as drugs under the Food, Drug and Cosmetic Act (FDCA), they are actually licensed pursuant to section 351 of the Public Health Service Act (PHSA).