

August 23, 2018

The Honorable Scott Gottlieb
Commissioner
U.S. Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993

Dear Commissioner Gottlieb:

We appreciate the Food and Drug Administration's (FDA) recent actions regarding biosimilars – specifically the FDA's Biosimilars Action Plan. As you know, one of the most important ways the FDA can help increase marketplace competition is by finalizing its guidance, "Considerations in Demonstrating Interchangeability With a Reference Product" regarding the process a biosimilar manufacturer must follow to obtain an interchangeable designation. We appreciate that the FDA acknowledges that this guidance is needed to provide a clear and consistent pathway for demonstrating interchangeability, and ultimately achieving prescription drug cost savings in the biological product market, and we urge you to finalize the guidance as soon as possible.

When Congress passed the Biologics Price Competition and Innovation Act (BPCIA) in 2010, it was with the hope of providing an FDA approval pathway for more affordable biological products, similar to what exists for generic versions of small molecule drugs. In the small molecule market, the ability to substitute more affordable, but equally effective, generics for brand drugs has been extremely successful in reducing drug costs. However, keeping the current interchangeability guidance in draft form creates significant uncertainty in the biologics market that could discourage similar levels of substitution for the highest cost products. While small molecule generics are immediately recognized as eligible for pharmacy-level substitution in line with state pharmacy practices, the additional hurdle placed on biosimilar developers to demonstrate interchangeability makes the goal of lowering cost through substitution more difficult.

More than eight years after passage of the BPCIA, there is still a lack of final FDA guidance for the industry to follow. While the FDA has approved 12 biosimilar products to date, none have been deemed interchangeable, and therefore they cannot be substituted without the intervention of a health care provider. We are concerned that this continued dynamic will discourage further investment from biosimilar developers, and ultimately reduce the number of interchangeable biologics that reach the market. This loss of meaningful price competition also runs counter to the savings that were intended by the creation of a biosimilar approval pathway.

We believe finalizing the interchangeability guidance is a crucial part of achieving cost savings in the biological product market. This guidance will give the industry a clear, consistent framework to demonstrate interchangeability, which in turn will encourage manufacturers to invest in research and development of biosimilar products and to seek the designation of

interchangeability for their products. We are very hopeful that this guidance will increase access to affordable biological products and strongly urge the FDA to finalize it as soon as possible.

Thank you for your attention to this matter. We look forward to continuing to work with you to improve access to affordable medications.

Sincerely,

Alliance of Community Health Plans
America's Health Insurance Plans
American Hospital Association
ASHP (American Society of Health-System Pharmacists)
Blue Cross Blue Shield Association
Blue Cross Blue Shield of Michigan
Campaign for Sustainable Rx Pricing
CVS Health
Greater New York Hospital Association
Families USA
Federation of American Hospitals
Kaiser Permanente
Patients for Affordable Drugs
Pharmaceutical Care Management Association
Public Citizen
Prime Therapeutics
Vizient