February 20, 2017

Senator Claire Ayer
Chair
Senate Committee on Health and Welfare
115 State Street
Montpelier, VT 05602

Representative Bill Lippert
Chair
House Committee on Health Care
115 State Street
Montpelier, VT 05602

Re: Support for an Act Relating to Interchangeable Biological Products

Dear Chairwoman Ayer and Chairman Lippert:

The Alliance for Patient Access (AfPA) would like to express support for legislation that would allow for the substitution of biological medicines when certain conditions are met. When introduced, this legislation should contain the patient safety principles that AfPA member physicians have identified as critical for safe access to biosimilar medications, notably physician communication of substitution.

AfPA is a national network of more than 800 physicians with the shared mission of ensuring patient access to approved therapies including prescription pharmaceuticals, biologics, and medical devices. Since 2011, AfPA has convened the National Physicians Biologics Working Group (NPBWG) as a home for physicians interested in policy issues relating to access to biologic therapies.

NPBWG members identified key principles that biosimilar substitution must meet to ensure patient safety and promote prescriber confidence. They are as follows:

1. FDA designation of a product as interchangeable before it may be substituted for a prescribed biologic.
2. Pharmacist communication to the prescribing physician and patient any substitution within a reasonable timeframe.
3. Physician ability to specify "no substitution" or "dispense as written."

AfPA urges you to include in your pending legislation each of these safety provisions, most importantly the physician communication requirement. This provision helps ensure a complete medical record and facilitates the best medical response to a patient's adverse event.

The Food and Drug Administration has already approved four biosimilars and may soon approve interchangeable biosimilar medicines. AfPA supports making potentially less costly medicines available to patients and physicians, but all efforts must be made to create policies that balance access, safety, and cost. The pending legislation provides a quality pathway for biosimilar medicines by maintaining communication safeguards. As such, AfPA urges you to support such legislation upon its introduction.

Sincerely,

Brian Kennedy
Executive Director

Cc: Members, Senate Health and Human Services Committee
Members, House Health Committee

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