

July 12, 2011

The Honorable Eli N. Avila, MD, JD, MPH, FCLM  
Secretary, Pennsylvania Department of Health  
Health and Welfare Building  
8<sup>th</sup> Floor West  
625 Forster Street  
Harrisburg, PA 17120

Dear Secretary Avila,

We are writing on behalf of the Pennsylvania Society of Oncology & Hematology (PSOH) and the Pennsylvania Rheumatology Society (PRS) to ask for clarification as to whether Pennsylvania law regarding pharmacists' ability to substitute generic drugs without physician permission applies to biosimilars. PSOH represents over three hundred physicians, nurses, and professionals in Pennsylvania, all dedicated to the treatment of cancer and PRS represents nearly a hundred rheumatologists in Pennsylvania.

Traditional drugs, including generics, are approved under the Food Drug and Cosmetic Act, whereas most biologics are approved under the Public Health Services Act (PHSA).

Biologics are large, complex molecules made from living cells. Because of their size and complexity, all biologics pose a unique potential to impact the body's immune system, potentially causing serious adverse reactions. They are difficult to characterize and produce, using complicated manufacturing processes. The FDA has acknowledged this.

As part of the federal health care reform law passed in 2010, Congress enacted the Biologics Price Competition and Innovation Act (<http://dpc.senate.gov/healthreformbill/healthbill70.pdf>), creating a new pathway for the approval of biosimilar medications under the PHSA. The new biosimilars law contains an approval standard for "interchangeability" and includes a definition of the term that references substitution.

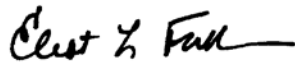
We believe that pharmacist substitution of biosimilars without prescriber consent is inappropriate. This is based on our concerns for patient safety and the fact that there are significant differences between biologics and traditional chemical drugs.

Pennsylvania law states that in order to be eligible for substitution, a drug must be “generically equivalent” (35 Pa. Stat. Ann. § 960.3(a)). The law further provides that a drug must be listed in the FDA’s “Orange Book” to be considered generically equivalent. Only products approved under the FDCA can be published in the FDA’s Orange Book. Therefore, we believe that because biosimilars approved under the new federal law will be approved under the PHSA, not the FDCA, pharmacist substitution of biosimilars should be prohibited in Pennsylvania.


The Pennsylvania Society of Oncology & Hematology and the Pennsylvania Rheumatology Society request the Department of Health’s opinion regarding this matter.

Thank you for your consideration.

Sincerely,



Eliot L. Friedman, MD  
President  
Pennsylvania Society of Oncology & Hematology



Donald S. Miller, MD  
President  
Pennsylvania Rheumatology Society

Cc: Michael Wolf, Executive Deputy Secretary, Pennsylvania Department of Health  
Neil Malady, Director, Legislative Affairs, Pennsylvania Department of Health