May 28, 2014

New Jersey
Senate Committee
Health, Human Services, and Senior Citizens
Room 50
State House Annex
Trenton, NJ 08625-0068

RE: Opposition to SB 1705

Dear Chairman Vitale and Vice-Chairman Madden,

The Immune Deficiency Foundation (IDF) is the national patient organization, founded in 1980, dedicated to improving the diagnosis, treatment and quality of life of persons with primary immunodeficiency diseases (PI) through advocacy, education and research. IDF opposes SB 1705, an act concerning the dispensing of certain biological products and revising various parts of the statutory law, and supplementing chapter 6 of Title 24 of the Revised Statutes.

Primary immunodeficiency diseases occur in persons born with an immune system that is either absent or hampered in its ability to function. While not contagious, these diseases are caused by hereditary or genetic defects and can affect anyone, regardless of age or sex. The World Health Organization recognizes more than 200 primary immunodeficiency diseases, which are a group of rare disorders. Some affect a single cell within the immune system; others may affect one or more components of the system. While some of the nearly 200 primary immunodeficiency diseases still resist effective treatment, biologic medications are extremely important long-term therapeutic agents for many of these life-threatening disorders, now and into the future.

The number of Americans now living with a primary immunodeficiency disease is estimated to be about 250,000, many of whom rely on immunoglobulin (Ig) therapy to replace the antibodies their bodies do not naturally produce. With lifelong Ig therapy, patients with primary immunodeficiency disease are able to live normal, healthy and productive lives.

Ig therapies are complex biologics made up of polyclonal antibodies, available in intravenous (IVIG) and subcutaneous (SCIG) modes of administration. These medicines are derived from human blood plasma sourced from over thousands of donors. Manufacturing changes the composition of donor pools, and final formulations can impact our patients’ tolerability, the infusion rate, and potential efficacy and safety of the product.

Unlike generic drugs, biosimilars can never be identical copies of a reference product. The choice of product should not be determined by a pharmacist, regulator, or insurer, but by a physician in consultation with his/her patient. We appreciate the inclusion of a provision that will allow the prescriber to indicate that the prescription should be dispensed as written, but still additional patient protections should be included.

Patients with PI face additional risks from adverse reactions to biosimilars that have not been adequately tested for safety and efficacy. Current scientific evidence proves that for patients who are stabilized and switch
to a new Ig product, the risk is greater that they will suffer an adverse reaction ranging from relatively mild headaches to anaphylaxis shock, stroke and even death. That will not change with biosimilars. Patients should not be changed to a biosimilar immunoglobulin product, which they may not tolerate as well as their current product, without consultation from their provider – before any substitution is made and before an infusion takes place. As written, this bill will allow a pharmacist to substitute the biosimilar and inform the patient in writing after a biosimilar has been dispensed; Notification after the fact puts patients with PI at risk.

For patients with PI, immunoglobulin therapy is either sent to the patient’s home via specialty pharmacy or administered in a clinical setting. This is not a prescription filled at the local pharmacy window. To receive no forewarning of a change in physician-prescribed treatment is not only a risk to patient safety but may also disregard the American Academy of Allergy, Asthma and Immunology’s standards of care for treatment of patients with PI, which indicates that a change in Ig therapy administration should receive the supervision of a physician due to a greater probability of adverse reactions. The patient can of course opt out of treatment. However, for a patient with primary immunodeficiency disease, self-rationing immunoglobulin therapy could result in infection that could easily lead to serious illness, disability or even death.

IDF is pleased that this bill allows the physician to indicate when substitution is not appropriate. We also agree that physicians and patients should receive notification of the decision to substitute a biosimilar product for the prescribed product. However, the issue is that notification for the patients is unclear and for physicians it does not occur until after the product has been dispensed.

Several states have enacted legislation providing additional patient protections by allowing patients to insist on the reference product. Last year laws in Virginia, North Dakota and Utah, were enacted that give the patient the right to insist on receiving the product they were prescribed by their physician. A similar provision should be included in any legislation approved by this committee.

IDF opposes SB 1705 as written. We recommend that the bill be defeated or amended to:

- Exempt plasma products from the automatic substitution because of their complex nature and risk for adverse events
- Require that prior to dispensing a biosimilar, the pharmacist must notify both the provider and patient at least 5 days before a substitution may occur
- Allow the patient for whom a biologic is prescribed to receive the prescribed product at the patient’s request

Sincerely,

Lawrence LaMotte
Vice President, Public Policy