March 7, 2013

Dear Chairwoman Bledsoe, Vice Chairman Bookout and Members of the Senate Committee on Public Health, Welfare and Labor:

RE: Testimony on SB 149

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 (PIDD) through advocacy, education and research. IDF supports SB 149, to regulate the substitution of biosimilar biological products for certain prescribed products, if amended to require notification of a decision to substitute a biosimilar prior to dispensing of the drug.

Primary immunodeficiency diseases are a constellation of disorders disrupting the immune system resulting in a spectrum of illnesses. In some cases, the body fails to produce any or enough antibodies to fight infection. In other cases, the cellular defenses against infection fail to work properly. There are more than 185 different primary immunodeficiency diseases currently recognized by the World Health Organization. The number of Americans now living with primary immunodeficiency diseases 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.

Immunoglobulin replacement 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 product, or plasma, sourced from over a thousand 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.

Currently, the FDA recognizes each immunoglobulin brand as unique and requires each drug to develop and complete an individual clinical trial protocol to receive licensure, even if it is from the same manufacturer. This reflects the many processing steps involved in plasma fractionation, purification, stabilization and virus inactivation or removal that yields products that are distinct from one to another. Unlike small-molecule drugs, plasma therapies such as Ig are natural proteins of the human body and can differ in terms of processing and end composition.

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.

Patients with primary immunodeficiency diseases face additional risks from adverse reactions to biosimilars that have not been adequately tested for safety and efficacy. Scientific literature and medical evidence shows that for patients who are stabilized and switch their therapies to a new product, a number 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 the product on which they are already stabilized, without consultation from their provider. Current science cannot demonstrate that two different products will provide the exact same clinical result in a large cohort of patients or that switching patients from one product to another will pose no additional risks.
For these reasons, IDF greatly appreciates the inclusion of the provisions that will allow the prescriber to indicate that the prescription should be dispensed as written and that allow the individual for whom the reference product is prescribed to indicate that the prescription shall be dispensed as written. 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 does not occur until after the treatment has been dispensed.**

As written, this bill will allow a pharmacist to substitute the biosimilar when appropriate, dispense it and then tell the patient and physician. This means that a patient will not learn until the time of treatment that the Ig product has been changed. The patient can of course refuse treatment. However, with their inability to fight every germ at their lowest level, they risk an infection which could cause them serious illness or even death. Patients with primary immunodeficiency diseases can receive infusions in a physician’s office, in the hospital outpatient setting or in their home. Such a scenario is not only a risk to patient safety but, in the case of patients who receive their products in the home, may also disregard the standards of care for treatment of patients with primary immunodeficiency diseases which says that when an Ig therapy is changed, the new product must be infused under the supervision of a physician because of the greater probability of adverse reactions.

IDF has concerns with SB 149 as written. We recommend that the bill be amended to require notifications of a decision to substitute a biosimilar prior to dispensing of the drug.