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Indiana Senate Health and Provider Services Committee  

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RE: Concerns with HB 1315

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 writes with concerns about HB 1315, Biosimilar biological products, as written and suggests amendments that will provide for greater patient protection.

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. 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 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.

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.

Again, IDF is very 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 does not occur until after the treatment has been dispensed.** In Virginia, the General Assembly has passed a similar bill to this one; however, it allows the patient to insist on the reference biologic and refuse the biosimilar. The bill in Virginia, that will soon be law, also requires the patient to be informed of the proposed substitution before the drug is dispensed. At the least both of those provisions should be a part of this bill, too. A similar provision was part of HB 1315 as introduced, but it has since been amended to remove the provision that would have required the patient’s consent for substitution.

IDF has concerns with HB 1315 as written. We recommend that the bill be amended to:

1. Exempt plasma products from the automatic substitution because of their complex nature and risk for adverse events
2. Require notifications of a decision to substitute a biosimilar prior to dispensing of the drug
3. Allow the patient for whom a biologic is prescribed to receive the prescribed product at the patient’s request