IMMUNE DEFICIENCY FOUNDATION

The National Patient Organization Dedicated to Advocacy, Education and Research for Primary Immunodeficiency Diseases

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Oregon Senate Committee on Health Care and Human Services

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RE: Concerns with SB 460

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 SB 460, an act relating to 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 and inform the patient prior to dispensing. It is unclear exactly when the patient receives this information. For patients with primary immunodeficiency disease, immunoglobulin therapy is either sent to the patient's home via specialty pharmacy or administered in a clinical setting. This is not something that is picked up at the local pharmacy window. Would these patients not be informed about the change in product until the day of their infusion when the product is about to be administered? 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. The patient can of course refuse treatment. However, for a patient with primary immunodeficiency disease, not receiving their immunoglobulin therapy results in an inability to fight every germ at their lowest level and the risk of an infection that could cause them serious illness or even death.

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 for the patients is unclear and for physicians it does not occur until after the product has been dispensed.**

Several states have also enacted legislation similar to this that includes additional patient protections by allowing patients to insist on the reference product. In Virginia, the General Assembly has passed a bill that allows the patient to insist on receiving the reference biologic. Similarly, in North Dakota their bill signed into law includes a provision giving the patient the right to refuse the biosimilar product. The new law just signed in Utah gives the patient the right to request or consent to the substitution of an interchangeable biosimilar product before the product can be substituted. A similar provision should be included in any legislation approved by this committee.

IDF has concerns with SB 460 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. Include specific requirements for notifications of a decision to substitute a biosimilar prior to dispensing of the drug in a manner that will give patients ample time to decide on their best course of action
3. Allow the patient for whom a biologic is prescribed to receive the prescribed product at the patient's request