June 16, 2014

The Honorable Gail Haines
Chairwoman
Health Policy Committee
Michigan House of Representatives
Lansing, MI 48909-7514

RE: Opposition to HB 5598

Dear Chairwoman Haines,

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 HB 5598, a bill to amend 1978 PA 368, entitled "Public health code" by amending sections 17702, 17704, and 17755 (MCL 333.17702, 333.17704, and 333.17755), section 17702 as amended by 2012 PA 209.

IDF opposes this bill for a number of reasons outlined below. First and foremost though is that this legislation is extremely premature. After 4 years, the FDA has still not provided any guidance regarding the pathway for biosimilars including how biosimilars will be named. HB 5598 attempts, through current law to name biosimilars (Sec. 17702 (3)) before the FDA has even decided how biosimilars will be named. Its other provisions pose a serious and potentially deadly risk to patients with primary immunodeficiency diseases who require infusions of the biologic drug, immunoglobulin – a blood plasma product. Unlike generic drugs, biosimilars can never be identical copies of a reference product.

Primary immunodeficiency diseases occur in persons born with an immune system that is either absent or hampered in its ability to function. While some of the over 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.

Patients with PI may face additional risks from adverse reactions to biosimilars. Current medical 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 without any notification to the provider and does not make clear when the patient is notified about the substitution. No notification or notification after the fact puts patients with PI at risk. The bill makes no provision for informing the physician that a substitution has taken place. Physicians need to know the products their patients receive in order to make the most appropriate treatment decisions. Patients need to know what is put into their bodies.

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 need to be included.
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. IDF has requested that the FDA should exempt immunoglobulin therapies from the biosimilars pathway until the science advances significantly. This will be in keeping with the European Medicines Agency (EMEA), which opted to exclude immunoglobulin from its regulatory pathway for biosimilars.

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.

For patients with PI, immunoglobulin 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 a primary immunodeficiency disease, foregoing immunoglobulin therapy could result in infection that could easily lead to serious illness, disability or even death.

The labeling requirements of the bill do not reflect how specialty drugs such as immunoglobulin are routinely handled. There are no prescription labels to speak of: rather there are delivery tickets (see attached) and manufacturing labels.

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 HB 5598 as written. We recommend that the bill be defeated or amended to:

- Exempt immunoglobulin therapy 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
- Require that naming provisions be in accordance with FDA regulations

Sincerely,

Lawrence LaMotte
Vice President, Public Policy

CC: Committee Members