We at the Immune Deficiency Foundation appreciate the invitation to testify today on HB 1015 which places limitations on “step therapy” or “fail first” protocols used by health insurers to limit access to care. The Immune Deficiency Foundation is the national patient organization dedicated to improving the diagnosis, treatment and quality of life of persons with primary immunodeficiency diseases through advocacy, education and research.

Our patients are born with a malfunctioning or non-existent immune system. You may recall the “boy in the bubble” who had virtually no immune system - the severest form of a primary immunodeficiency disease. Patients with a primary immunodeficiency disease are unable to fight off viruses, bacteria or fungi. Most do not produce antibodies necessary to fight disease. They are susceptible to every germ and unable to protect themselves. That is the bad news. The good news is that for many of our patients there is a treatment that when taken for the rest of their life, they can live normal, healthy and productive lives! That treatment is Immunoglobulin (Ig) replacement therapy which consists of a blood plasma product from pooled plasma donations. When Ig is infused on a routine basis, either monthly or weekly depending on the route of administration, the antibodies in the donated plasma in essence act as the immune system for our patients. The treatment is life-long.

There are 12 different Ig products. The FDA recognizes that all are different and not interchangeable or clinically equivalent. They are not generic. Let me repeat that: they are neither interchangeable nor clinically equivalent! They are not generic.

Step therapy or fail first policies definitely put our patients at risk. The assumption at the heart of step therapy and fail first is that there are generic or interchangeable products. That is not the case with our patients. The scientific literature and medical evidence is quite clear that when there are policies in place that require our patients who are stabilized to “switch” their therapies to a new product, a number of those patients will suffer an adverse reaction ranging from relatively mild headaches to anaphylaxis shock, stroke and even death. It is not a question of “if” but a question of who and how severe.

For our patients, failing first endangers them. Step therapy or fail first treatment could be their last treatment.

We recognize that such policies are promoted to save payer costs. We do not have a problem at all with payers being efficient – as long as it does not endanger patients. However, one size does not fit all.
HB 1015 is a step in the right direction in providing patients protections from insurers practicing medicine. It allows physicians with their patients to make treatment decisions based upon medical standards of care rather than insurer business and administrative policies.

In the past few years, our patients have had to contend with insurers who have placed restrictions on their access to care. Highmark BCBS (PA, DE and WV) instituted a restrictive formulary policy consisting of only one brand of Ig. In their special bulletin announcing the change, they stated, “Commercially available products within the immune globulin (Ig) therapeutic drug class are considered by most physicians to be clinically equivalent and interchangeable.” The only problem is that the FDA says otherwise. After months of dialogue with medical specialists, IDF and a public media campaign, Highmark changed its Ig policy. It also “grandfathered” patients who are stabilized on a product not to have to switch products.

More recently, Coventry Health Care, a national insurer headquartered in Montgomery County, carried this idea even further. They not only restricted our patients to one Ig product, they also restricted reimbursement for only one site of care (home) and restricted the mode of administration to only Intravenous immunoglobulin (IVIG) and excluded sub-cutaneous immunoglobulin (SCIG). Their policy also did not allow for medically necessary exceptions.

As said before, each Ig product is different even though they treat similar conditions. However each product may contain different stabilizers used in the manufacture of the Ig product. For example, some use sucrose and others use sodium. It is dangerous to administer an Ig product with sucrose to a patient with diabetes or a product with sodium to a patient with high blood pressure. Step therapy and fail first policies, by definition, do not take into consideration the needs of each individual patient. Our patients without a functioning immune system are extremely vulnerable and need protection. HB 1015 will give physicians the ability to override any fail-first protocol if they think the preferred product is likely to cause an adverse reaction to the patient. Let the doctor decide what’s best for the patient rather than an insurance bureaucrat.

My testimony today has been endorsed by the American Plasma Users Coalition whose members include: Alpha-1 Foundation, Alpha-1 Association, Committee of Ten Thousand, GBS-CIDP Foundation International (Guillain-Barré syndrome and Chronic Inflammatory Demyelinating Polyneuropathy), Hemophilia Federation of America, National Hemophilia Foundation, Platelet Disorder Support Association, PSI Inc., World Federation of Hemophilia.

Please give HB 1015 a favorable report.