Opposition to SB 781

We at the Immune Deficiency Foundation appreciate the invitation to testify today on SB 781 which provides for automatic substitution of biosimilars by pharmacists. 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.

The legislature must take concrete steps to prohibit automatic substitution of a biosimilar with an original biologic. 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.

That is important for our patients because they are acutely vulnerable. The scientific literature and medical evidence is quite clear that when patients who are stabilized “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. That will not change with biosimilars.

As written, this bill will allow a pharmacist to substitute at his/her own discretion a biosimilar, dispense it and then tell the patient and physician later. What does this mean in real terms? It means that a patient who is at home waiting for their monthly infusion of antibodies finds out
when the nurse comes to their home that their drug has been changed. The patient can of course refuse treatment. However, at that moment the patient knows that their ability to fight every germ is at its their lowest level. The patient knows that to forego treatment at that moment they risk getting an infection which, literally, could be their last infection. What decision should they make? Have a treatment with a product that could produce serious adverse effects or risk an infection that could kill them? This scenario is the “rule” and not the “exception”.

Here is the “kicker”; such a scenario completely disregards the American Academy of Allergy, Asthma and Immunology medical standards of care for treatment of patients with primary immunodeficiency diseases. The standard of care is that when new drug is to be infused for the first time, it must be done under the supervision of a physician because of the greater probability of adverse reactions.

This bill is probably aimed at retail pharmacies. However, there is nothing in the bill that separates out retail pharmacies from specialty pharmacies which deal with specialized biologics like immunoglobulin (Ig).

While it is good that this bill calls for notification of the physician and patient, the problem is that such notification is after the fact. In Virginia, the General Assembly just passed a similar law. In that law, it is clear that a patient can insist on the reference biologic and refuse the biosimilar. The Virginia soon to be law also requires the patient to be informed before the drug is dispensed of the proposed substitution. At the least both of those provisions should be a part of the bill too.

This bill is premature. The FDA has not even issued regulations as to what the pathway for biosimilars should be. Even if there are some clinical trials going on, it will be years before the FDA’s regulations will be final and implemented. In Europe, a pharmacist is not allowed to substitute for a reference product. Also in Europe, plasma products like immunoglobulin for our patients and clotting factor for patients with hemophilia are exempted from their biosimilars pathway altogether.

In order for this bill to be remotely reasonable and safe for patients, we recommend that the bill be amended to:

1. Exempt Plasma products because of the need for the use of durable medical equipment and medical personnel required for infusion of the product into the patient
2. Require before the fact notification to physician and patient
3. Allow the patient to insist on the referenced product rather than the biosimilar

Finally, I don’t know if this flier was distributed to you by the Alliance for Safe Biologic Medicines or not. Please read this deceptive flier carefully. If you do, you will notice that the quotes of the patient organizations (including ours) reinforce my testimony today and DO NOT at all endorse “notification after substitution”. On the back page of the flier the statements about Europe also do not fit the “notification after substitution” scenario. The statements have been “repurposed” to fit the organization’s point of view without regard for the statements of patient statements and the footnotes cited.