

## Before The General Law Committee

March 8, 2016

### Testimony of CURE (Connecticut United for Research Excellence) “Support For”

#### S.B. No. 313 (RAISED) - AN ACT CONCERNING BIOLOGICAL PRODUCTS

Chairman Leone, Chairman Baram, Members of the General Law Committee, Ladies and Gentlemen:

My name is Dr. Anthony Sabatelli. I am a partner with the intellectual property law firm of Dilworth IP in Trumbull, Connecticut. I am testifying on behalf of CURE, Connecticut United for Research Excellence, where I chair CURE's Government Affairs Committee. CURE serves the bioscience cluster of Connecticut and is the State's affiliate of BIO, the Biotechnology Innovation Organization.

CURE thanks the General Law Committee for raising S.B. No. 313, AN ACT CONCERNING BIOLOGICAL PRODUCTS, and also for this opportunity to testify on the Bill.

CURE is fully aligned with and supports BIO and the coalition that has worked so hard with this Committee and the administration to get this important Bill raised. CURE now urges the Committee to move forward with this legislation, because it is in the best interest of patients, the State's thriving biotechnology and pharmaceutical industries, healthcare providers, pharmacists, and the public at large. This Bill is an important step to bring Connecticut in line with the nearly 20 states that have already enacted similar legislation and the 12 states in which such legislation is progressing.

CURE supports the Bill for the following reasons.

1. The Bill is a pharmacy practice act to address biological medicines and interchangeable versions of these medicines. Biological medicines are used to treat serious conditions such as cancer, rheumatoid arthritis, multiple sclerosis, heart disease, HIV/AIDS, Crohn's, and other complex diseases.
2. A new Federal pathway has now been created for the FDA to approve interchangeable versions of biological products. These interchangeable biological products would be available for substitution of the brand product. These interchangeable products are analogous to the familiar generic drug products which have been part of our healthcare system for many years. The first biosimilar was already approved in 2015, and the first interchangeable biological drug product is expected to enter the market in 2016.

Current Connecticut law has no clear pathway for substitution of interchangeable biological drug products. Therefore, State legislation is needed to update the State Pharmacy Practice Act to allow for substitution of these interchangeable products.

3. This legislation would ensure that physicians and patients have access to interchangeable biological products as a more cost effective treatment when it is in the best interest of the patient. Without enactment of this legislation, Connecticut retail pharmacies would not be permitted to substitute these interchangeable biological products.

4. The prescribing physician is in the best position to evaluate a patient's treatment history and options. Therefore, it is important for the prescribing physician to be able to designate exactly which product should be dispensed to the patient. This legislation would ensure patient safety and preserve the physician-patient relationship by addressing key protection guidelines for the substitution of interchangeable biological medicines.

5. This Bill would ensure greater communication, and I emphasize "communication", so both the patient and the healthcare provider would know exactly what product has been dispensed. Clear communication and a complete patient medical record help to reduce medical errors and threats to patient safety. The legislation would ensure that patients be informed of a substitution with an interchangeable biological medicine, in the same way they are currently informed when a generic equivalent drug product is substituted for a branded product. Under this legislation, only FDA approved interchangeable biological products may be substituted without prior prescriber consent. Physicians would still retain the authority to prescribe the branded biological drug.

6. Finally, a large coalition of pharmacies, branded and generic manufacturers and associations, providers, and patient groups agree on the language in this legislation.

### **Summary**

For the foregoing reasons, CURE urges this Committee to progress S.B. No. 313. It is in the best interest of patients, the State's biotechnology and pharmaceutical industries, and the public at large. The legislation will update Connecticut's Pharmacy Practice Act to establish a clear substitution process for FDA approved interchangeable biological medicines. Patients here in Connecticut will thereby be provided treatment options, which have already been addressed through legislation in many other states, which would otherwise not be available to them here in this State.

Thank you.

Anthony D. Sabatelli, PhD, JD  
Chair, Government Affairs Committee  
**CURE (Connecticut United for Research Excellence)**