Connecticut Department of Social Services
Making a Difference

Written Testimony before the General Law Committee
Department of Social Services
March 2, 2017

H.B. No. 7118 - AN ACT CONCERNING BIOLOGICAL PRODUCTS

As the single state entity in Connecticut responsible for the administration of the state's Medicaid Program, the Department of Social Services wishes to express our vigorous concern with Raised Bill 7118, An Act Concerning Biological Products.

Specifically, the Department has significant clinical reservations about the language that allows a pharmacist to substitute one biologic medication for a biosimilar ("the pharmacist shall inform the prescribing practitioner and the patient or representative of the patient at the earliest reasonable time of such interchangeable biological product…")

To begin, current standard of practice prohibits pharmacists from substituting between classes of products without prior authorization. Because each class of drug works in different ways, there are specific reasons why one medication was chosen by the practitioner over another. The Department does not believe biologics and biosimilars should be treated any differently.

Biologics are very complicated, large molecule medications that are too big and too complicated to be exactly copied. Therefore, medications following biologics are termed 'biosimilars' because they are similar in clinical effect and structure, but are <u>not</u> the same. Biosimilars are <u>not</u> generic forms of biologic drugs and should not be treated as such. For these reasons, the cost and the ramifications of unwise substitutions of biosimilar drugs are not the same as with generic medications.

Biologics and biosimilars are also not used the same way as small molecule medications (that are easily replicated). Where a small molecule drug may be prescribed on the same day as a visit for an acute illness, such as an antibiotic for an ear infection or an antihistamine for hay fever, biologics and biosimilars are used for chronic illnesses such as Crohn's disease, multiple sclerosis or rheumatoid arthritis. Biologics and biosimilars are also typically used after all other treatments with small molecule drugs have failed. Their mechanism of action is also very different from that of small molecule drugs in that biologics and biosimilars act (either entirely or in part) in place of a normal bodily mechanism to alter or mask the immune system.

Because of their effect on the immune system, biologics and biosimilars cannot be prescribed and started immediately without first determining that the patient does not have an underlying infection and other illnesses. It is therefore necessary that an extensive evaluation of the patient be performed before any biologic or biosimilar is prescribed and dispensed. If during this evaluation an infection or illness is detected, it must be treated before the biologic or biosimilar can be started.

This means there is ample time, from a pharmacist's perspective, to review and discuss possible biosimilar substitutions in advance of prescribing and dispensing such medications. The clinical practice mitigates any argument that a pharmacist does not have 'time' to discuss a substitution prior to release.

Furthermore, the Department has additional concerns with biosimilar substitutions without prior-discussions with practitioners and the patient.

Because biologics and biosimilars are large biologic products themselves, the body can develop antibodies against these medications so that they can no longer be used. This is important because most of these products do not cure the illnesses they treat, they suppress the illness, so if the biologic or biosimilar must be stopped because of antibodies, the illness very likely comes back or worsens unless there is an alternative – the biosimilar.

If a patient has been on only one form of the biologic, they develop antibodies to only that form of the biologic, not to the similar forms. So if antibodies are formed, a patient can switch to the biosimilar, often with minimal worsening of symptoms. But if a patient has been substituting back and forth between biosimilars, the likelihood is greater that the patient will develop antibodies to all the forms and will be left with dwindling options for treatment.

Take the case of a 14-year-old adolescent girl with Crohn's disease whose disease is resistant to treatment and starts a biologic with rapid improvement. The standard of care is often to start another immunosuppressive in addition to the biologic to delay her eventual development of antibodies to the biologic drug. Perhaps she will use that first biologic for a decade before antibodies develop and she must be switched to a biosimilar at age 26, and to yet another biosimilar at age 36. Alternatively, as this legislation would allow, the pharmacist could switch back and forth between biosimilars and, as a result, she could develop antibodies to all medications by age 28. We can hope that other biologics or other treatments will be discovered to treat her Crohn's disease, but what if they were not? The girl is left with no options for care.

For these reasons, it is imperative that a pharmacist discuss possible substitution with the prescribing practitioner and patient **in advance** of the substitution actually being prescribed and dispensed. Unfortunately, lines 59 through 63 of the bill only require notification upon dispensing: "Upon dispensing of an interchangeable biological product the pharmacist shall inform the prescribing practitioner and the patient or a representative of the patient at the earliest reasonable time of the substation of such interchangeable biological product for a prescribed biological product." This language has the potential to harm individuals in the long-term.

For the reasons noted above, the Department strongly opposes this bill.