Testimony of Jonathan A. Harris
Commissioner of Consumer Protection
General Law Committee
Public Hearing, March 2, 2017

S.B. 867 "AN ACT CONCERNING REQUIREMENTS FOR HOME HEALTH CARE REGISTRIES"

S.B. 869 "AN ACT REQUIRING CRIMINAL BACKGROUND CHECKS FOR DOOR-TO-DOOR SALESPERSONS"

H.B. 7108 "AN ACT CONCERNING COMMUNITY ASSOCIATION MANAGERS"

H.B. 7118 "AN ACT CONCERNING BIOLOGICAL PRODUCTS"

Senator Leone, Senator Witkos, Representative Baram, Representative Smith and Honorable Members of the General Law Committee, thank you for the opportunity to offer testimony about multiple bills on today's agenda.

S.B. 867 "AN ACT CONCERNING NOTICE REQUIREMENTS FOR HOME HEALTH CARE REGISTRIES"

The Department of Consumer Protection supports this proposed legislation. Under current law, consumers may not realize the obligations they will incur by employing an aide referred to them by a registry until the consumer has already begun receiving services. This bill would simply require that consumers be notified about those liabilities prior to the commencement of services. By supporting this bill the Department is not, in any way, indicating that it favors agencies whose employees provide homemaker and companion services over registries . who provide these services by referring independent contractors. We support the furnishing of information to consumers so they can best understand the differences between the two models and make fully informed decisions.

S.B. 869 "AN ACT REQUIRING CRIMINAL BACKGROUND CHECKS FOR DOOR-TO-DOOR SALESPERSONS"

While we appreciate that the intent of this proposal is to protect the safety of the public, the Department does not currently register all people or entities that sell goods or services door-to-door Additionally, as drafted, it is unclear what form of background checks would be required or what DCP is expected to do with the results. If the intent of this proposed legislation is to require the Department to register door-to-door salespeople and maintain the results of their background checks, whatever the type, it could not be done without additional staffing resources. We would be happy to further discuss this with the proponent.

H.B. 7108 "AN ACT CONCERNING COMMUNITY ASSOCIATION MANAGERS"

Thank you for raising this bill for the Department. Currently, DCP registers community association managers, which are property managers for condominium associations, before they complete a nationally recognized course and pass a certain exam. C.G.S. § 20-453 requires that both be accomplished within a year of receiving their first certificate of registration. This bill requires these educational requirements to be completed before applying for a registration. This proposal ensures that applicants receive sufficient education before engaging in the condominium management busienss, which is consistent with the timeline of most credentials that require an educational component. It would also decrease the number of times the Department has to interact with applicants since the educational review would be done at the time of application review thereby helping DCP conserve resources.

The Department has begun discussions with CAI-CT, the association that represents community association managers, to address their concerns about this bill and discuss some other potential changes to this regulatory model. We will report these discussions to this committee and provide any suggested language upon which there may be an agreement.

H.B. 7118 "AN ACT CONCERNING BIOLOGICAL PRODUCTS"

This bill would allow pharmacists to substitute brand name biological products with other biological drugs. The Department appreciates and supports the overall goal of this proposal; however, we have significant concerns with the current language and its potential effect on public health and safety.

On January 18th of this year, the Food and Drug Administration (FDA) released draft guidelines for pharmaceutical companies seeking to designate a biological drug as interchangeable with another biological drug. This draft guidance largely focused on recommendations about the data and information needed for the FDA to support interchangeability. However, the FDA also made it clear that its requirements will vary based on the product submitted and that, "There is no single data package that will work for all proposed interchangeable products." [1] This is important to note because it reinforces the FDA's recognition that this newer form of drug, made with biological organisms, is more complicated than the way the FDA regulates traditional, chemically composed drugs.

The proposed legislation would broadly define an interchangeable in terms beyond the scope of what the FDA is recommending for biologic interchangeables. Subsection (a)(4)(C) of this proposal would allow for the substitution of a biologic with an interchangeable that is "therapeutically equivalent." Therapeutic equivalency standards are used as guidelines for substitution of traditional generic drugs, and have not been suggested as a reliable standard of substitution for biologics. In fact, in our own statutes with respect to generic substitution, therapeutic equivalent is defined as a drug product that is approved under the FDA and that will provide *"essentially"* the same efficacy and toxicity when administered to an individual. Due to the complexity of the molecules and increased potential for batch to batch variations in the molecules, the Department wants to ensure that interchangeable biologic drugs are being held to the highest standard of interchangeability. This proposal does not accomplish that goal.

DCP is also concerned that Subsection (d) in this draft does not require that the pharmacist alert the physician or the patient prior to filling an alternate biologic product in lieu of

[1] Mezher, Michael. "FDA Issues Long-Awaited Biosimilar Interchangeability" Regulatory Affairs Professionals Society. January 2017

the prescribed biologic. Prior notification to the physician will help to ensure that any possible negative health outcomes are addressed prior to the administration of the medication. In addition, if a substitution is made by a pharmacist, and the prescriber does not agree, it may negatively impact on the ability of the patient to get the biologic covered by insurance.

We are continuing to work with the proponents of this bill to ensure that these potential patient safety issues are addressed but, until we resolve these issues, we cannot support this proposed legislation.

Thank you again for the opportunity to provide testimony. Please contact Leslie O'Brien, the Department's Legislative Director, if you have any questions.