Date: February 21, 2017

To: Senate Health & Welfare Committee

From: Paul Harrington, VMS Executive Vice President &
Jessa Barnard, VMS Vice President for Policy

Re: Substitution Practices for Biosimilar Products

The Vermont Medical Society appreciates the invitation to testify before you today regarding substitution practices for biosimilar products. The VMS is the state's largest physician membership organization, representing over 2000 physicians, medical residents and medical students across specialties and geographic and practice location.

In general, VMS neither supports nor opposes the overall concept of substituting interchangeable biosimilar products at the pharmacy level. Rather, the VMS requests that any proposal evaluated by the Committee meet the following principles on substitution of biosimilar products adopted by the American Medical Association in 2014:

AMA Policy D-125.989, Substitution of Biosimilar Medicines and Related Medical Products

Our AMA urges that State Pharmacy Practice Acts and substitution practices for biosimilars in the outpatient arena:

> *(1) preserve physician autonomy to designate which biologic or biosimilar product is dispensed to their patients;*
> *(2) allow substitution when physicians expressly authorize substitution of an interchangeable product;*
> *(3) limit the authority of pharmacists to automatically substitute only those biosimilar products that are deemed interchangeable by the FDA.*

In addition, VMS members strongly believe that the prescribing clinician should be informed when a substitution is made. Proponents of allowing automatic substitution in Vermont have shared with VMS a recent draft of legislation that appears to meet the policy outlined above as it would be limited to substitution of only those products deemed interchangeable by the FDA and would inform the prescriber of the substitution within 5 business days. However, VMS does a have a specific concern with the latest draft reviewed. That draft would deem entry of the substitution into an electronic record (such as an interoperable electronic medical record, pharmacy benefit management system or pharmacy record) as notice to the prescriber. If the pharmacist does not have access to an electronic system, the pharmacist would be allowed to provide notice via other prevailing means such as telephone, fax or electronic transmission. VMS requests that any legislation not deem recording of notice in an electronic database as notice to the prescriber and should state that if a pharmacist or prescriber does not have access to the electronic systems outlined that notice must be provided by other prevailing means.

Thank you for considering VMS's views and we are happy to answer questions you may have.