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Hon William J. Lippert, Chair
House Committee on Health Care
State House, Room 45
115 State Street
Montpelier, Vermont 05633-5301

April 3, 2018

Dear Chairman Lippert:

The Office of Professional Regulation monitors pharmacy-related legislation for the Board of Pharmacy. This session, S.92 "proposes to direct pharmacists to fill prescriptions for biological products with an interchangeable biological product unless otherwise specified by the prescriber or purchaser." The bill represents a rational extension of existing State policy, in order to reach biological products in addition to conventional legend drugs.

We write to ensure that two technical issues have been considered by the Committee:

1. Sec. 1, at proposed 8 V.S.A. 4601(5), defines "interchangeable biological product" to include "a biological product that the U.S. Food and Drug Administration has ... determined to be therapeutically equivalent as set forth in the latest edition of or supplement to the U.S. Food and Drug Administration's Approved Drug Products with Therapeutic Equivalence Evaluations (the Orange Book)." *Id.* § 4601(5)(B) (underline added).

   The Orange Book is specific to generic drugs and does not include interchangeable biological products. The intended reference may be to "the Center for Biologic Evaluation and Research List of Licensed Biological Products with Reference Product Exclusivity and Biosimilarity or Interchangeability Evaluations to Date (the Purple Book)."

2. Sec. 2., at proposed 8 V.S.A. § 4605(e), mandates that a pharmacist dispensing an interchangeable biological product give direct notification of the substitution to the prescriber within five business days. No similar provision of law applies to the long-successful generic-substitution law codified at § 4605(a)-(d). Because substituted biosimilar drugs are certified by the FDA as clinically indistinct from corresponding reference products, the communication between pharmacist and prescriber may be unlikely to convey clinically relevant information.

Ms. Phillips is not a witness at today's hearing on S.92, but she will be present and available in case she may be of assistance in respect to the considerations described above.

Sincerely,

Gabriel M. Gilman
General Counsel

Carrie C. Phillips
Executive Officer for Pharmacy

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