Biotechnology Industry Organization (BIO) Testimony

Vermont State Senate

Committee on Health and Welfare

Language Concerning Substitution of Interchangeable Biologics

February 21, 2017

Good Morning:

Chairwoman Ayer and members of the committee, thank you for the opportunity to present before you today on language concerning the substitution of interchangeable biologic medicines.

My name is Patrick Plues and I am Vice President, State Government Affairs at the Biotechnology Industry Organization (BIO). We represent more than 1,100 biosciences companies across the United States.

Our companies are developing biologic medicines with the goal of curing many of the most complex and life threatening diseases -- including cancer, HIV, Alzheimer's and many rare diseases and disorders.

BIO urges the Vermont legislature to approve the proposed language, because without these statutory changes, Vermont patients would have difficulty accessing interchangeable biological products. We support this legislative language as it includes provisions that recognize

the special nature of biologics, provides patient-focused guidelines for the substitution of interchangeable biologics, and recognizes the critical importance of transparency necessary to dispense these special medications.

Over the past several years, BIO and our member companies have engaged in an iterative process internally and with other interested stakeholders as this legislation has advanced in states across the country. As of today, 26 states have passed statutory language to allow patients to access interchangeable biologic products. The principles for biosimilar substitution that BIO adopted in 2012, which are contained in the proposed language, set forth a common-sense approach for the substitution of innovator products when a biosimilar has been deemed interchangeable by the FDA, provided that the prescribing physician has not indicated that there shall be no substitution. The language also provides for the appropriate communication to the patient and prescriber of what product was dispensed, and requires that the pharmacy keep a record of the substitution.

BIO and our member companies know that these new types of biologic medicines approved by the FDA will be as safe and as effective as the innovator products currently on the market since the FDA will require that these products demonstrate a high standard of safety and efficacy. But as biologic medicines are different than small molecule drugs in the way they interact in the body, there is a heightened risk of adverse immune reactions, and sometimes these occur after a patient has been on the product for a long time. While infrequent, the body may also build up an immune response to the biologic medicine that impacts the efficacy of the medicine. For this reason, BIO believes that transparency is important across all types of biologics. And let me be clear that we in no way are advocating for patient/ physician consent for a switch of an interchangeable biologic, but rather only to require open communication between the physician and the pharmacist so the physician and patient know which product was dispensed.

In addition, we know Vermont has often taken the lead in discussions regarding prescription drug pricing, and we believe the proposed legislative language could lead to a reduction in prescription drug costs. RAND Corporation predicts biosimilars will lead to a $44.2 billion reduction in spending on biologic drugs from 2014 to 2024, while the Congressional Budget Office (CBO) projects savings from biosimilars to be $25 billion from 2009 to 2018. The Centers for Medicare and Medicaid Services (CMS) has not released savings estimates, but notes that "state Medicaid programs should view the launch of biosimilar biological products as a unique opportunity to achieve measurable cost savings and greater beneficiary access to expensive therapeutic treatments for chronic conditions." We've included these and other state cost savings estimates in a separate handout, which accompanies my testimony.

In closing, this language closely follows the Principles that BIO established for the substitution of biologic products and we would ask for your support in passing this important legislative language.

I am happy to answer any questions.