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BIOTECHNOLOGY INDUSTRY ORGANIZATION
STATEMENT IN SUPPORT OF VIRGINIA H.B. 1422

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The Biotechnology Industry Organization (BIO) is the world's largest biotechnology trade association. BIO represents more than 1,100 biotechnology companies, academic institutions, state biotechnology centers, and related organizations across the United States and 31 other nations. BIO members are involved in the research and development of healthcare, agricultural, industrial, and environmental biotechnology products. One of BIO's core missions is the promotion of a safe, innovative, and competitive market for biologics in the United States. To that end, BIO's member companies have approved five principles related to substitution of biologic medicines. The policies outlined in House Bill 1422 align with all five of BIO's principles on biologic substitution and we therefore support its passage.

Biologics are very complex medicines. Unlike traditional "small molecule" drugs, biologics are not chemically synthesized but, rather, are manufactured from living cells and tissues using a highly controlled and optimized process. Each resulting biologic therapy is complex and unique, and in many cases cannot be fully characterized by current analytical tools. As a result, even minor differences in manufacturing processes can cause variations in the end product. Consequently, two biologics made using different cell lines and differing manufacturing processes will rarely, if ever, be exactly the same.

Biosimilars are biologic products manufactured with the goal of closely mirroring the composition and treatment profile of an innovator product but are produced without access to the innovator's proprietary manufacturing processes. The production of biosimilar products, therefore, will invariably lead to differences in composition compared to the original innovator product.

Currently, the Federal Food and Drug Administration (the "FDA") is developing guidance regarding the regulatory pathway for the approval of biosimilar and interchangeable biologic products. This approval pathway was established by federal law, and distinguishes clearly between biologic products that are "biosimilar" to an innovator biologic – meaning they are "highly similar" to an innovator product – and biologic products that meet a heightened standard to be deemed "interchangeable."

While FDA's role in the approval of biologic and biosimilar medicines includes the designation of an interchangeable status, the policy on whether one biologic product may be substituted by dispensers when a different biologic product was prescribed is governed by state law. In recognition of this state-level authority over biosimilar and interchangeable biologic medicines, BIO has developed a set of core Principles[1] that we believe should be considered by all states evaluating biologic substitution legislation. We believe that our Principles, if followed, strike the appropriate balance of preserving the physician-patient relationship, protecting patients, maintaining incentives for innovation, and promoting a competitive market for biologic therapies. As drafted, House Bill 1422 is in-line with BIO's own Principles and we therefore support its passage.

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[1] *See Attached:* BIO Principles on Patient Safety in the Substitution of Biologic Products

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