

January 26, 2007

The Honorable Thomas K. Norment, Jr.
Chair, Senate Rules Committee
Senate of Virginia
Corner of Ninth and Broad Streets
Room 427
Richmond, Virginia 23218

Re: Senate Joint Resolution No. 397

Dear Senator Norment:

On behalf of the Biotechnology Industry Organization (BIO), I am writing to express our concern with SJR 397, a resolution that calls for the collection of data on current costs of insulin and human growth hormone in the Commonwealth, and requests the U.S. Food and Drug Administration (FDA) to issue guidelines to facilitate the production of "generic biologics" to treat diabetes and other diseases.

BIO is the national trade association for the biotechnology industry, representing 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. We work closely with the Virginia Biotechnology Association and the industry and educational members they represent.

Our primary concern with follow-on biotechnology products is centered on patient safety. Approval of follow-on biotechnology products must be based on the same rigorous standards applied by the FDA for the approval of pioneer biotechnology products. Patients should not have to accept greater risks or uncertainties in using a follow-on product than when they use an innovator's product. A clinical trial remains a fundamental

principle for evaluating the safety and effectiveness of a follow-on biotechnology product.

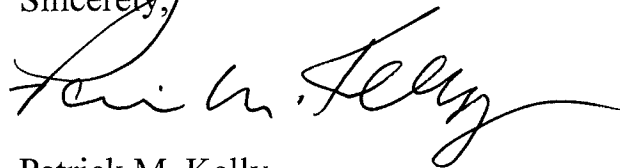
A biologic (biological product or biotechnology product) is derived from living organisms – human, plant, animal or microorganism. Most biologics are very large, complex molecules or mixtures of molecules. Many are produced using recombinant DNA technology. It is difficult, and sometimes impossible, to characterize a complex biological product by testing methods available in the laboratory.

Protein products are the most complex biologic medicines, and even slight changes in their manufacture can cause unpredictable changes in their effectiveness and side effects in patients. Unlike chemical drugs, such as pill products, both the process and the materials are significant determinants of the protein product. Changes to either the materials or the process can increase the risk of changing the product in a way that may harm patients. It is crucial to remember when considering follow-on biologics or follow-on protein products (FOPPs), that protein products cannot be copied or made into generics the way that chemical drugs can.

We strongly encourage the Senate Committee on Rules to consider the position of the biotechnology industry before implementing this resolution. Biological products are very different from chemical (pill) drugs. Patient safety requires that standards for approval of biologics remain high. To protect patients, all biological products must be tested in clinical trials.

Thank you for your consideration. If you have any questions, please feel free to contact me at (202) 962-9200.

Sincerely,



Patrick M. Kelly

Vice President

State Government Relations

Biotechnology Industry Organization