



BIOTECHNOLOGY
INDUSTRY
ORGANIZATION

June 15, 2004

The Honorable Deborah Ortiz
California State Senate
Senate Committee on Health & Human Services
State Capitol
Room 2191
Sacramento, CA 95814

Re: Opposition to AB 1957

Dear Madam Chair:

On behalf of the Biotechnology Industry Organization (BIO), I am writing to express concern regarding Assembly Bill 1957 to authorize the establishment of a state-sponsored Web site to facilitate the purchase of prescription drugs from Canadian sources. While we understand the financial constraints that patients and the state's health benefit programs face, careful consideration must be given to the impact this legislation could have on access to safe drugs as well as on the state's biotechnology industry.

It is clear that individual state-sponsored importation programs may subject California residents to a potentially unsafe drug supply. Even a systematic importation program would pose great risk to consumers, as the purity, potency, and safety of such products can never be assured once they have left the control of the original manufacturer and the jurisdiction of the Food and Drug Administration (FDA). Today, American citizens have absolutely the safest supply of medicines in the world. We cannot afford to risk that safety.

The prospect of importing biotechnology-derived medicines is especially troubling. Most biotech products are biologic agents and are highly dependent – for both effectiveness and safety – on the conditions and temperatures in which

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they are stored, and on the way they are handled during distribution and after they reach their destination. Because biologics are typically injected into the bloodstream, the risk to patients from such imported products, prepared or handled incorrectly, is immediate and incalculable.

Because of the sensitivity of biological and biotechnology products, congressional importation proposals generally have exempted many biological products from provisions that would legalize the importation of prescription drugs. U.S. Senator Judd Gregg (R. – N.H.) recently introduced S. 2493, the “Safe Importation of Medical Products and Other Rx Therapies Act of 2004” (“Safe IMPORT Act”), which specifically exempts from importation drugs manufactured through one or more biotechnology processes, a drug required to be refrigerated, or a photoreactive drug. For the comprehensive definition of biological and biotechnology products, please refer to the exclusions language of the bill beginning on page 5, line 21.

Such biotech exemptions, however, do not set our minds at ease. One need only look at the astonishing numbers of prescription products entering the U.S. via mail and consignment carrier every day to know that illegality or exemptions are merely words on paper. For unscrupulous vendors and unwitting patients, the fact that it is illegal to import virtually all of these products and that importing some of them is especially dangerous seem to be no deterrent at all.

Recent FDA import “blitz” examinations have shown that adulterated, misbranded and counterfeit products continue to cross our borders even under the watchful eyes of the U.S. regulatory system. Although Canadian parcels represent the bulk of imported drugs coming into the country, these parcels often contain products that were passed through Canada from other foreign sources, such as Ecuador, Iran and Argentina. The supposition that the state’s public employees and most vulnerable patient populations will be safely importing drugs from another industrialized nation is neutralized when considering Canada’s trans-shipment of pharmaceutical imports.

For the record, we greatly appreciate your stalwart support of the biotechnology industry in California. We were honored to present you with BIO’s State Legislator of the Year award last year for your tireless advocacy on stem cell research. We now need your help to consider the implications of importing foreign

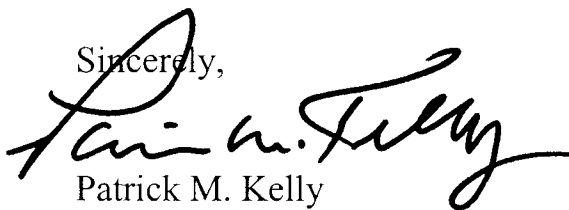
price controls and the potential impact it may have on California's biotechnology industry. We are very concerned that this initiative could have a serious effect on investment in biotechnology. Any decrease in investor confidence could result in a decrease in investment dollars, thereby placing critical research at risk.

In addition to eroding investor confidence, importing foreign price controls is not a solution that will benefit patients in the long run. It might create an initial savings for some drug expenditures. However, the long-term effect of price controls will be felt by all patients, both young and old, those with insurance and those without who are waiting for treatments and cures to the diseases that affect them today. These treatments are being researched and developed by California's vibrant biotechnology industry. Without continued investment in R&D, these treatments might never leave the laboratory.

California can take pride in the knowledge that it is the birthplace of the modern biotechnology industry and remains the largest biotech region in the world. In order to preserve the state's elite status as a world leader, careful deliberation of the ramifications importation may have on the future development of healthcare technologies and on California's innovative biotechnology companies is of paramount importance.

Thank you for your consideration. If you have any questions or need additional information, please feel free to contact me at (202) 962-9503 or by email at pkelly@bio.org.

Sincerely,



Patrick M. Kelly
Vice President,
State Government Relations
Biotechnology Industry Organization

cc: Matt Gardner, President, BayBio
Joseph Panetta, President & CEO, BIOCOM

Enclosure