



BIOTECHNOLOGY
INDUSTRY
ORGANIZATION

June 3, 2004

The Honorable Rebecca Cohn
California State Assembly
Assembly Committee on Health
State Capitol
Room 6005
Sacramento, California 95814

Re: Opposition to SB 1144 & SB 1333

Dear Madame Chairperson:

On behalf of the Biotechnology Industry Organization (BIO) I am writing to express concern regarding the legislature's consideration of a pair of bills to authorize 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 potential harm which can result when proceeding with a plan that contravenes current legal standards and requirements. We are also concerned that this initiative could have far more broad implications on the biotechnology industry in the state. If anything, California should be at the forefront of considering ways to improve and expand markets for biotechnology products.

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 greater 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.

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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 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 – NH) recently introduced S. 2493 the Safe Importation of Medical Products and Other Rx Therapies Act of 2004 (“Safe IMPORT Act”) which specifically exempts drugs manufactured through one or more biotechnology processes, a drug required to be refrigerated, or a photoreactive drug from importation. 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 eye of the U.S. regulatory systems. 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.

Canadian Importation Letter

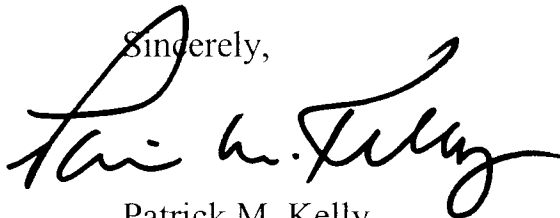
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California can take pride in the knowledge that it is the birthplace of the modern biotechnology industry and remains the largest biotech region in the world. In order to preserve California's elite status as a world leader, careful deliberation of 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,

A handwritten signature in black ink, appearing to read "Patrick M. Kelly". The signature is fluid and cursive, with a large initial "P" and "K".

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