



BIOTECHNOLOGY
INDUSTRY
ORGANIZATION

May 19, 2004

The Honorable Chuck Smith
Orange County Board of Supervisors
Hall of Administration
10 Civic Center Plaza
Santa Ana, California 92701

Dear Supervisor Smith:

On behalf of the Biotechnology Industry Organization (BIO) I am writing to express concern regarding the county's exploration of a Canadian importation program. While we understand the financial constraints that patients and the county's health benefit program 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 county. If anything, Orange County should be at the forefront of considering ways to improve markets for biotechnology products.

It is clear that individual local government or 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.

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

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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. Such 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 county’s public employees will be safely importing drugs from another industrialized nation is neutralized when considering Canada’s trans-shipment of pharmaceutical imports.

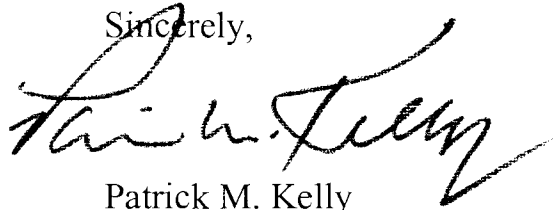
Please find attached a copy of BIO’s Drug Importation Resource Guide. I hope that you will find this guide useful as the county evaluates the issues of safety, legality, and liability related to a foreign import program. The guide materials clearly articulate the Food and Drug Administration’s (FDA) position on the issue and the ramifications for states and municipalities that choose to pursue such a program. Specifically, I would draw your attention to the letter featured under Tab 2 of the guide. This recent letter from the FDA to Caldwell County, North Carolina, addresses the agency’s concerns surrounding Canadian drug importation programs for county employees and dependents.

We greatly appreciate all you have done in support of the county’s vibrant and growing biotechnology industry. We welcome the opportunity to discuss our concerns with you and the rest of the board of supervisors as you consider potential resolutions to this important issue. The biotech industry is committed to working

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with Orange County to find an equitable way to benefit patients and preserve the growth of our vital biotechnology industry.

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

Enclosure