



November 4, 2003

The Honorable Tom Perez
Montgomery County Council
Stella B. Werner Council Office Building
100 Maryland Avenue
Rockville, MD 20850

Dear Councilmember Perez:

On behalf of the Biotechnology Industry Organization (BIO) and the Tech Council of Maryland BioScience Alliance (BioAlliance) we are writing to express our concern regarding an initiative to purchase prescription drugs from Canada by county government agencies.

Individual local government or state-sponsored importation programs may subject Maryland residents to a potentially unsafe drug supply. Even a systematic importation program would pose great risk for 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 importation of biotechnology derived products poses even greater concern for the consuming public. Most biotech products are biologic agents and are therefore highly dependent – for both the effectiveness and safety – on the conditions and temperatures in which they are stored and on how they are handled both 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.

As you consider a Canadian importation program for county employees, we urge you to consider the potential human impact of a program created only to generate cost savings “at a time of tight budgets.” According to FDA Commissioner Mark McClellan, “the FDA has serious concerns about proposals

Canadian Importation Letter

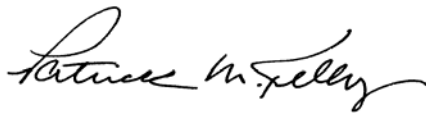
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that would open America's borders to a stream of imported prescription drugs for which FDA cannot assure safety, effectiveness or quality." Commissioner McClellan's concerns are echoed by the Secretaries of Health and Human Services in both the current and previous administrations, and eight former FDA Commissioners, all of whom have stated emphatically that the safety of prescription drug products being imported into the United States by other than FDA-regulated manufacturers cannot be guaranteed.

Maryland can take pride in the knowledge that it is the third largest biotech region in the world. In order to preserve such an elite status, careful deliberation of the ramifications importation may have on the future development of healthcare technologies and on Maryland's innovative biotechnology companies is of paramount importance.

Sincerely,



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



John W. Holaday
Chairman
Maryland BioScience Alliance

About BIO

BIO is the national trade association for the biotechnology industry, representing more than 1,000 member companies. Members include biotechnology companies, academic institutions and state biotechnology research centers. We represent 58 member companies and institutions in Maryland and work closely with the Maryland BioScience Alliance and the 295 life science companies they represent in the state.

About BioAlliance

The Maryland Bioscience Alliance, also known as the BioAlliance, is a division of the Technology Council of Maryland (TCM). The BioAlliance is a statewide, non-profit membership organization dedicated to serving the needs of Maryland's growing biotechnology community. As a state affiliate of the Biotechnology Industry Organization, the BioAlliance works synergistically with BIO to promote industry advocacy, facilitate group purchasing and provide critical networking.