



BIO Statement of Opposition to S. 6210-A (Diaz)/A. 9207-A (Crespo)

Senate Finance Committee

June 7, 2010

Senate Finance Committee Member:

On behalf of the Biotechnology Industry Organization (BIO) I am writing to state our opposition to Senate Bill 6210-A/Assembly Bill 9207-A, an initiative to permit the purchase of certain prescription medications from Canadian mail order pharmacies by New York civil service employees and retirees. BIO believes that, at bottom, even a narrowly-tailored importation program with reasonable oversight cannot adequately ensure the safety and efficacy of all of the products available to residents from these pharmacies. In consequence, BIO believes that the proposed importation initiative could unnecessarily expose New York residents to unsafe prescription medications, thereby jeopardizing their health and well-being.

BIO represents more than 1,200 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. In New York, we work closely with the New York Biotechnology Association, which itself represents over 250 New York-based biotechnology and research institutions.

In short, while New York may think a state-sponsored importation program is the best solution to decrease drug costs for its residents, the unintended consequences of such a program are immeasurable. Most importantly, a state-sponsored importation program may subject New York 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 the Legislature deliberates this importation initiative, we urge you to consider the potential human impact of a program created only to generate cost savings. According to former FDA Commissioner Mark McClellan, “the FDA has serious concerns about proposals 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 have been echoed by the Secretaries of Health and Human Services in several previous Administrations, as well as 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. In fact, current FDA Commissioner Hamburg – as recently as this past December – has reinforced FDA’s concern that drugs imported from Canada cannot be guaranteed safe and effective.

Although BIO acknowledges New York’s fundamental need to provide its residents with drugs at affordable prices, we believe that drugs should be guaranteed to be safe, of high quality, and efficacious by the FDA. It is for this reason that we oppose the importation initiative currently under consideration. Thank you for your consideration of our concerns. If you have any questions, please feel free to contact me at (202) 962-9514.

Sincerely,



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