



BIOTECHNOLOGY
INDUSTRY
ORGANIZATION

February 5, 2004

The Honorable Roman Prezioso, Jr.
Chairman, Senate Health and Human Resources
Room 439 M, Building 1
1900 Kanawha Boulevard
E. Charleston, West Virginia 25305

Re: Opposition to House Bill 4084

Dear Mr. Chairman:

On behalf of the Biotechnology Industry Organization (BIO), I am writing to express our concerns regarding recently introduced legislation to create the West Virginia Pharmaceutical Commission. The Commission would be tasked with negotiating the purchase of prescription drugs from Canada and mandating price controls for pharmaceuticals purchased for state programs such as Medicaid, the State Children's Health Insurance Program (SCHIP) and the Public Employee Insurance Agency (PEIA). We believe that the enactment of price control laws and the importation of Canadian drugs will create an atmosphere that discourages research investment in the biotech industry in the state.

BIO wholeheartedly supports the rights of all patients, including recipients of government funded health plans, to have full access to all medically necessary FDA approved therapies and medications. However, we cannot support an approach to providing drugs to patients that is driven by direct price controls or the illegal importation of drugs from a foreign country.

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Price controls will wreak havoc on the biotech industry's ability to raise private capital for innovative drug development. Although maximum manufacturer prices will not immediately impact biotechnology companies that do not have products on the market, they will have a profound effect on future biotech innovation and investment in the state. Responsible public policy for successful biomedical development in West Virginia must take this into account.

As you are aware, it takes a great deal of time and significant financial investment to bring biotech products to the market. It will be very difficult to raise investment capital in an atmosphere where the government determines how much return on investment a company should be allowed or which drugs are the most cost effective. Laws that restrict access to new technologies based solely on price, not only reduce the quality of care for individual patients, but also could discourage investment in potentially lifesaving research.

The proposed state-sponsored importation program may subject West Virginia 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 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.

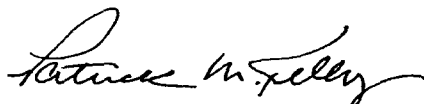
According to FDA Commissioner Mark McClellan, “the FDA has serious concerns about proposals that would open America's borders to a stream of imported prescription drugs for which FDA cannot assure safety,

effectiveness or quality.” Commissioner McClellan’s concerns 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.

Although BIO acknowledges West Virginia’s fundamental need to exercise budgetary restraint, we are deeply concerned about these initiatives to control prescription drug costs. Any attempt to improve access to drugs should encourage, not discourage research and development. Medical innovation is the key not only for improving our health, but also for ultimately lowering health care costs.

Thank you for your consideration of our concerns. If you have any questions, please feel free to contact me at (202) 962-9200.

Sincerely,



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

About BIO

BIO represents more than 1,000 biotechnology companies, academic institutions, state biotechnology centers and related organizations in all 50 U.S. states and 33 other nations. BIO members are involved in the research and development of health-care, agricultural, industrial and environmental biotechnology products.

cc: Chaed Smith, Senior Technology Officer, Governor’s Office of Technology