



BIOTECHNOLOGY
INDUSTRY
ORGANIZATION

Testimony from the Biotechnology Industry Organization

Senate Finance Committee Hearing on SB 167 Prescription Drugs – Canadian Mail Order Plan March 3, 2004

Please accept this testimony on behalf of the Biotechnology Industry Organization (BIO) regarding SB 167, legislation currently under consideration to create a Canadian mail order plan for prescription drugs.

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.

Over the past few years, a combination of political and budgetary forces has caused many states to explore policy changes related to prescription drug access and pricing. Although BIO acknowledges Maryland's fundamental need to exercise budgetary restraint in response to a serious public health issue, we are deeply concerned about the current pending initiative to lower prescription drug costs and the potential impact of this cost-containment legislation on the biotechnology industry.

We wholeheartedly support improving access to medicines for all patients, especially for those who suffer the most and are most in need. However, a Canadian importation program is currently illegal under federal law, poses a serious risk of financial liability for the state, exposes Maryland citizens to a potentially unsafe drug supply, and will have a disastrous impact on Maryland-based companies researching innovative new medicines.

The U.S. Food and Drug Administration (FDA) states in clear and unequivocal terms that the importation of prescription drugs from a foreign country is illegal under the federal Food, Drug and Cosmetic Act (FDCA). In a letter sent to California Deputy Attorney General Gregory Gonot dated Aug. 25, 2003, Associate Commissioner William Hubbard stated, "Any state law that would legalize imports in contravention of the FDCA would be preempted by federal law. Moreover, those importing drugs in violation of the FDCA would be subject to liability under the statute, regardless of whether the importation was otherwise sanctioned by the state."

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A state-run importation program will expose the state to serious liability issues related to the procurement of adulterated, misbranded, or counterfeit prescription drugs. The potential tort liability the state would face if even one patient is harmed by a product facilitated through the state-run program could negate any cost savings achieved through the program. Addressing the annual David A. Winston Lecture last year FDA Commissioner Mark McClellan stated, "Much as they would like to, state and local governments and private groups cannot provide reliable safety assurances when they purchase drugs from foreign sources. It's simply not enough to replace a comprehensive federal and state system for assuring drug safety by picking a company operation outside the U.S. that appears to be legitimate and hoping that their drugs turn out to be safe."

In addition to the FDA's strong warnings about safety and liability, Maryland Assistant Attorney General Kathryn Rowe in a letter dated Jan. 28, 2004 to Maryland House Majority Leader Kumar Barve stated, "I think it is safe to conclude that there are possible state or local programs, or possible fact situations, under which the state or a political subdivision could find itself liable for injuries caused by imported prescription drugs... Thus, while tort liability is a matter of some concern, federal criminal prohibition, in my view, presents a much more significant hurdle for such a program."

It cannot be emphasized enough that 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 FDA. Today, American citizens have absolutely the safest supply of medicines in the world. Maryland 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 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 if the products are to be safe and effective. Because biologics are typically injected into the bloodstream, the risk to patients from imported products that were improperly prepared or handled, is immediate and incalculable.

Biotechnology is one of the most research-intensive industries in the world. The U.S. biotech industry spent \$20.5 billion on research and development in 2002. Our bench scientists work an average of 7 to 10 years and can spend upwards of \$500 million to bring just one human therapeutic product to market. This does not include funds expended on failed projects or developing ideas for future products. It is an incredibly capital-intensive technology.

As capital drives research and development, any government action to reduce return on investment is perceived as a threat to the lifeblood of the biotech industry. The importation of Canadian pricing for American consumers is tantamount to an indirect price control imposed by the same state governments trying to grow the industry.

Maryland's enactment of a Canadian importation program will lead investors and the financial community to conclude that investment in medical research in Maryland is not worth the risk.

The biotech industry in Maryland is working to provide cures and treatments to millions of people suffering from disease and debilitating conditions. Any attempt to improve access to drugs should *encourage*, not discourage biotechnology research and development. Perceived price controls *discourage* investment in research. Biotech innovation is the key not only for improving health-care, but also for ultimately lowering health-care costs in the long run.

Thank you for the opportunity to submit testimony on this important subject matter. If you have any questions, please contact me at (202) 962-9200 or by e-mail at pkelly@bio.org.

Respectfully Submitted by
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