
June 7, 2004

The Honorable Bill Frist, M.D.
United States Senate
Washington, D.C. 20510

Dear Majority Leader Frist:

We, the undersigned biotechnology executives, strongly oppose further efforts to legalize prescription drug importation. Importation will put patients at risk, chill investment in biotechnology and other pharmaceutical research and development, and threaten intellectual property protections.

First, legalizing importation will place patients at risk of obtaining products that do not meet the FDA standards that patients have relied upon for decades. Since biotechnology products are unique, many are particularly susceptible to adulteration, degradation and virtually undetectable counterfeiting. Many cannot be administered safely by the patient, but require intervention and/or supervision of a health care provider. BIO believes that the importation of non-biotechnology products could increase the availability of unsafe or ineffective biotechnology products.

Second, efforts to legalize importation (and to import foreign price controls) will have a negative impact on biotechnology investment. The cost and time to develop a new pharmaceutical product is generally agreed to be more than $800 million and 12-15 years; the costs and time to develop a new biotechnology product can be substantially greater. Since many biotechnology companies do not have the financial underpinning provided by multiple profitable products already on the market, they rely on maintaining a high rate of capital investment for long periods of time – investment that is made based on an expectation of a healthy return. National or local policy changes that affect the potential viability of the biotechnology market (via price controls or any other means) will affect the willingness of investors to take this risk.

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Third, prescription drug importation legislation will erode intellectual property rights. One bill would prevent U.S. manufacturers from enforcing their patents against foreign products that, if marketed in the U.S. under current law, would violate the patent on the U.S. product. Even though the foreign product is imported into the U.S. market in direct competition with the U.S. FDA-approved drug, the manufacturer would be denied recourse under U.S. patent laws. The impact on the biotechnology industry of such a change to patent rights would be enormous.

Finally, although efforts to legalize importation are intended as a mechanism to lower the price of prescription drugs, the Congressional Budget Office and numerous economists have challenged the assumptions of substantial cost savings, noting both the unique features of the world pharmaceutical marketplace and the substantial costs incurred by intermediaries in the proposed import/export scheme that certainly would be passed along to patients. Moreover, recently introduced bills would impose numerous requirements that were not even envisioned by the economists who looked at earlier legislation, so transaction costs under these proposals would be significantly higher. Additionally, examination by economists of European parallel imports shows that the expected significant savings for consumers have not materialized, although the traders have realized tidy profits. None of the bills recently introduced guarantee that the cost differential for the importer/exporter actually would be passed along to the consumer.

We urge you to oppose further importation legislation. Importation measures will harm the biotechnology industry and will, more importantly, harm the patients we are dedicated to help. Legalizing importation is not the answer to improving access to prescription drugs. Its promise is false and its dangers are real.

Sincerely

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