

STATEMENT OF

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BEFORE THE

HOUSE GOVERNMENT REFORM

SUBCOMMITTEE ON HUMAN RIGHTS AND WELLNESS

ON

“CANADIAN PRESCRIPTION DRUG

RE-IMPORTATION: IS THERE A SAFETY ISSUE?”

THURSDAY, JUNE 12, 2003

**Testimony to the Sub-Committee on Human Rights and Wellness of the
Committee on Government Reform by David M. Brennan, Executive
Vice President, AstraZeneca, LP**

Mr. Chairman, Members of the Committee, my name is David Brennan. I am the executive vice president for North America of AstraZeneca LP, with responsibility for US and Canadian operations. AstraZeneca is one of the world's leading pharmaceutical companies. Backed by a strong research base and extensive manufacturing and commercial skills, the company provides a powerful range of products for seven important areas of healthcare - gastrointestinal, cardiovascular, cancer, respiratory, neuroscience, pain control and infection. Headquartered in the UK, with R&D headquarters in Sweden and a strong presence in the US market, AstraZeneca sells in more than 100 countries, employs 58,000 people worldwide and values the diversity of skills and abilities that they bring to the business. The company is recognized as having one of the best development pipelines in the industry working to maintain a flow of new medicines designed to meet patients' needs. AstraZeneca is committed to building on this success, using its leading position in many important areas of medicine to make a difference to the lives of patients and the healthcare professionals who treat them.

I am here today in response to your letter of June 3, 2003, to address the safety issues surrounding drug importation into the US, and to discuss the steps AstraZeneca Canada has recently taken to ensure the availability of our products for our Canadian patients. Let me start by saying we believe that the fundamental issue confronting millions of Americans is the lack of access to prescription drugs. Timely access to today's increasingly innovative medications improves health and saves lives, thereby reducing the health system costs of hospitalization, emergency care and long-term illness. A meaningful first step to solving this problem is the enactment of a Medicare Prescription Drug Benefit, not drug importation.

Congress must pass a responsible Medicare Prescription Drug Benefit this year.

In the meantime, AstraZeneca is doing its part to help individuals without drug coverage obtain the medicines they need. We are a founding member and active participant in Together Rx, an industry drug savings program, servicing more than 600,000 Americans. In 2002 alone, AstraZeneca gave more than one million Americans medicines worth over \$400 million through our patient assistance programs.

You asked me to testify today about the safety of pharmaceuticals imported into the United States. To answer this question, it's important to clarify what safety means in the pharmaceutical industry. When it comes to drugs, safety involves many factors—the patient, product, packaging, storage and handling, transportation, disclosures and labeling and shelf life.

There are provisions in place to help ensure the safety of our products being sold through AstraZeneca in Canada for use by patients in Canada. However, the safety of product that leaves Canada, outside of our distribution chain, cannot be assured. The truth is, there is little regulation of drugs exported from Canada. The Canadian government itself has stated that it cannot assure the safety of medications exported to the US.

That is why the FDA—including the agency's current leadership and ten former commissioners—two Secretaries of Health and Human Services, the US Customs Service and the Drug Enforcement Administration are on record as stating that importation of drugs from Canada or any foreign country would make it impossible to assure the safety of the American prescription drug supply.

As Secretary of Health and Human Services, Tommy Thompson said in 2002, "Opening our borders to reimported drugs potentially could increase the flow of counterfeit drugs, expired and contaminated drugs, and drugs stored under inappropriate and unsafe conditions....That's a risk we simply cannot take."

Dr. Mark McClellan, Commissioner of the FDA, testifying before the House Agriculture Appropriations Subcommittee said: "There is absolutely no guarantee that those drugs are up to the standard."

The opening of US borders to products from other countries including Canada would undoubtedly increase the risks of counterfeit and contaminated medications circulating through our system.

The head of Global Corporate Security for another pharmaceutical company has testified before a subcommittee of the House Energy and Commerce Committee. He described one instance in which millions of yellow tablets were discovered, indistinguishable from a genuine product, consisting of boric acid, floor wax and lead-based, yellow road paint. He showed video of machines that counterfeiters are using to mimic blister packs used by legitimate manufacturers. We believe that neither blister packaging nor any other "technology" solution will outwit the counterfeiters and protect the public safety.

It is in this context that AstraZeneca Canada has taken steps with respect to drug distribution in Canada: to uphold the laws of the United States that are in force to provide a very important protection for our citizens. Another element of this decision was to ensure that the company had sufficient inventory of our products for citizens of Canada. No Canadian supplier has been precluded from purchasing the products necessary to meet the needs of Canadian patients.

There are many people around the world, like those in Canada, who believe that governments should control prices and direct the allocation of healthcare, rather than individuals. Some in Congress advocate changing to such a system. Regardless of which view prevails, I hope you would agree that it would be a terrible disservice to the people of this country to hide the fact that the consequences of making such a system change would substantially erode the many benefits that our free market healthcare system in the US provides. We currently enjoy access to safe, effective and break-through medications for the American people, and we must continue to provide this access. Clearly, our

health care system is not perfect and there are many changes needed, such as a Medicare Prescription Drug Benefit. AstraZeneca is a company that is thinking through the policy issues and is willing to be part of the debate. We should not put at risk a system that broadly does what the American people want it to do – provide them with a continuing supply of innovative, effective and safe medications that often make dramatic improvements in the health and lives of people of all ages. Thank you.