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Statement of Senator Craig Thomas, Chairman
Subcommittee on International Trade
Senate Finance Committee

"International Trade and Pharmaceuticals"

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The United States has embarked upon an aggressive trade strategy to open world markets to U.S. goods. To be successful, the United States needs to negotiate agreements that eliminate barriers, create transparency and level the playing field for domestic companies doing business abroad. Whether it is an automobile manufacturer, an agriculture producer, or a soda ash processor, opening up the world for U.S. business must remain a top priority for our trade negotiators.

We will hear testimony from two outstanding panels regarding international trade and the impact on the U.S. pharmaceutical industry. I believe this is one of the first such hearings in the Senate, but doubt it will be the last. The topic has broad implications for nearly every American and I'm pleased that we are taking a look at the issue today.

It is no secret we pay the highest prices for name brand prescription drugs in the world. There is also wide acknowledgement that the U.S. industry faces significant trade barriers around the globe that inhibit their ability to operate in an open and fair market. Many countries have erected trade barriers through the use of government-set price controls, volume restrictions, reference pricing, and decision-making processes that are often non-transparent. In addition, lax enforcement of intellectual property rights contributes to the trade difficulties the industry encounters. These practices limit market access and artificially reduce the number of consumers in the marketplace.

There are a variety of explanations for the current state of affairs. Virtually every other developed country has some form of socialized medicine where the government establishes drug prices and controls the market. Regulations rarely allow a price to be set that reflects the actual cost of production and generally prohibits the recovery of a company's research and development investment. This framework developed over time and has remained virtually unchecked for decades.

With passage of the Trade Act of 2002, however, the situation changed. Through this legislation, Congress established as one of its primary trade objectives tighter regulatory practices to ensure that 1) government regulations and practices achieve increased transparency; 2) proposed regulations be based on objective evidence; 3) consultative mechanisms are established to promote transparent rule-making processes; and 4) government measures such as price controls and reference pricing which deny full market access for products from the United States are eliminated.

As we know, the issue of regulatory practices related to pharmaceuticals was one of the last items to be resolved in the recently completed Australia Free Trade Agreement negotiations. It is a sensitive issue for the folks in Australia and I respect their concerns. But it is an issue that deserved to be on the table and one that needs to be raised in future negotiations.

I look forward to hearing more regarding the Australia negotiations and how the Administration will address the Trade Act of 2002 objective on regulatory practices in the future. In addition, I welcome witness comments on how negotiations on this issue down the road will impact the drug industry and consumers around the world, including in the United States. Identifying the objective is easy. Achieving the objective is the challenge.

While the focus of today's hearing is on international trade policy, I do want to say a few things about a prescription drug issue that has been talked about a lot recently – importation. I understand the political urgency behind the recent introduction of importation legislation. It is frustrating to listen to the struggles of constituents who cannot afford their medications and not be able to offer a lot of solutions. However, the Senate is supposed to be a deliberative and

thoughtful body and I am concerned in our hurry to address the situation we have not evaluated all the implications of legalizing prescription drug importation.

As mandated by the Medicare Modernization Act, Secretary Thompson appointed a task force to examine the issue and make recommendations by December 2004 on how to safely import drugs. The task force has already held several public meetings that have highlighted an issue often overlooked -- the generic drug industry.

Today FDA-approved generics account for more than 51 percent of all prescriptions filled in the United States. Generics depend on a competitive market place and innovation for their business. The generic industry has testified before the task force and has submitted written testimony for today's hearing sharing their concerns that a nationwide drug importation program could adversely affect them. Consumers would have little or no incentive to utilize the domestically manufactured less expensive version of a brand name drug. This would clearly impact the entire industry, jeopardizing a safe and affordable alternative for consumers.

There exist legitimate safety concerns about importation that must be addressed to insure our nation is not subjected to undue risk. We need to take a serious look at our current health care infrastructure and system and start making some tough choices. I believe information gathered at today's hearing will help move forward the process of mapping out a plan to make prescription drugs affordable and safe for all Americans.