

Opening Statement of Chairman Dan Burton

Subcommittee on Human Rights and Wellness

At the Subcommittee on Human Rights and Wellness

Hearing

“International Prescription Drug Parity:
Are Americans Being Protected or Gouged?”

April 3, 2003

2247 Rayburn House Office Building

2:00 pm

Given that this is the first hearing of the Subcommittee, I want to take a moment to welcome all of my colleagues. I am pleased to be joined on the Subcommittee by Congressman Chris Cannon of Utah, Congressman Christopher Shays of Connecticut, and Congresswoman Ileana Ros-Lehtinen of Florida.

I am also pleased to have my distinguished colleague from California, Congresswoman Diane Watson as the Ranking Minority Member, as well as Congressman Bernard Sanders of Vermont, and Congressman Elijah Cummings of Maryland serving as members from the other side of the aisle. During my tenure as Chairman of the Full Committee each of these members was actively involved in our health oversight hearings. I am pleased that they are joining me on the Subcommittee. The diverse membership of this Subcommittee covers the entire spectrum of political philosophy. However, we all share a common desire to improve the policies and programs that affect the health and well-being of all Americans.

It is often the case that Congress acts as a fulcrum seeking to find the appropriate balance between opposing parties on key policy discussions. The subject of today's hearing is no different.

On one side of the debate is the importance of preserving the free enterprise system. The pharmaceutical industry tells us that it now takes between \$500 and 800 million dollars to bring a drug to market. This estimate is a bit misleading though. While the actual costs of research and development on bringing a single drug to market can be high, the actual dollar figure may be much less. Only 10 to 30 percent of the products in development actually make it to the marketplace. Thus, companies add the costs of these failed

products into the R&D of drugs which ultimately are approved. Thus, the American consumer, buy and large, shoulders the costs associated with drug research and development.

On the other hand, Congress must consider the needs of American consumers to access safe and affordable prescription drugs. As many as 108 million Americans have one or more chronic health conditions such as diabetes, high blood pressure, asthma, and heart disease. Many require prescription drugs to manage these conditions. Seventy-five percent of Americans age 50 to 64 are on at least one prescription drug, and fourteen percent of women aged sixty-five are on five prescription drugs in any given week. As we all know, the price of prescription drugs is higher in the United States than in any other country in the world.

As one mechanism to address this issue, in 2000, Congress overwhelmingly passed and the President signed into law, the MEDS Act to allow U.S. consumers, pharmacists, and wholesalers to purchase FDA-approved prescription drugs on the international market. However, the FDA has never implemented the law.

Today's hearing is focusing only on consumers' access to prescription drugs purchased from Canadian pharmacies. One of the witnesses we will be hearing from today is Mr. William Hubbard, Senior Associate Commissioner of the FDA. Mr. Hubbard was quoted in the media two weeks ago as saying that anyone facilitating Americans importing prescription drugs from Canada faced potential "civil and criminal liability." He went on to say, "insurance companies and health plans that pay for prescription

drugs purchased outside the United States may be violating the law.”

Mr. Hubbard further stated, “Those who aid and abet a criminal violation of the act, or conspire to violate the act, can be found criminally liable.” He went on to state, “We [the FDA] believe that virtually all drugs imported to the United States from Canada by or for individual U.S. consumers violate U.S. law.”

I, for one, am puzzled. How can FDA officials feel that Americans are violating U.S. law when three years ago the President signed into law a bill that Congress had passed? This bill clarified that it was legal for American’s to purchase prescription drugs internationally?

We are a country with three branches of Government – Judicial, Executive and Legislative. It is not the FDA’s job to make laws. It is their responsibility to implement the laws that Congress passes. And that includes the MEDs Act. So far, the FDA has shirked its responsibility in this area. This needs to change. The FDA claims they cannot implement this law because they cannot assure the safety of the products being shipped into the US. I believe that the FDA needs to do some innovative, “out of the pillbox” thinking. HealthCanada’s regulatory model offers safeguards to insure the safety of products for Canadians. Last week, Mr. Hubbard told me that he was not aware of a single incident that an American had been harmed by a product purchased in Canada. Obviously if the FDA wanted to find a solution to implementing the law, they could.

I am pleased that we will be hearing from my old friend and fellow Hoosier, former Congressman Roger Zion. Roger serves as Chairman of the Sixty Plus Association. We will also hear from Mr. Robert Hayes of the Medicare Rights Center in New York. Dr. Elizabeth Wenner from the Coalition for Access to Affordable Prescription Drugs, and Dr. Andy Troszok the Vice President of Standards for the Canadian International Pharmacists, will be bringing us information from the Canadian perspective.

Earlier this year, GlaxoSmithKline sent letters to Canadian pharmacies threatening to suspend shipments to them if they continued to sell drugs to American consumers. I find these strong-arm tactics very disturbing. This is a company that during tough economic times had a 15 percent growth last year. Just last week, a Glaxo representative told me that even with Canada's price controls, Glaxo makes a profit – just not as much as they make in the U.S. marketplace. I have co-sponsored legislation with Congressman Sanders and fifty-four other legislators that will institute monetary fines on pharmaceutical companies that reduce access of Americans to lower-cost drugs via the internet from Canadian pharmacies.

I invited Dr. J.P. Garnier, the Chief Executive Office of GlaxoSmithKline to testify at the hearing today. However, he declined to participate, or, even to submit testimony. He also declined to voluntarily provide another Glaxo representative. His unwillingness to participate at the Subcommittee hearing today speaks volumes!

Thank you all for coming. I look forward to hearing from our witnesses. I now recognize Ranking Minority Member, Congresswoman Diane Watson, for an opening statement.