Statement of Senator Kyl, Chairman of the Subcommittee on Health Care

Joint Hearing by Subcommittees on Health Care and International Trade of the Senate Committee on Finance

"International Trade and Pharmaceuticals"

April 27, 2004

I want to thank Chairman Grassley for scheduling this joint subcommittee hearing. The Committee does not often have joint subcommittee hearings, but I believe the subject matter of this hearing, covering both health care and international trade issues, is uniquely suited to this format. I also thank the chairman of the Subcommittee on International Trade, Senator Thomas, for co-chairing this hearing with me today.

I was very pleased that our U.S. Trade Representative, Ambassador Zoellick, raised the issue of prescription drug pricing policies for the first time during negotiations of the recently concluded U.S.-Australia Free Trade Agreement and that he expects to raise it in future negotiations.

I have long thought that the prescription-drug price controls employed by foreign countries amount to an unfair trade practice because they block the access of U.S. products to foreign markets. Worse, perhaps, is that such price controls impose unacceptable burdens on U.S. citizens, who pay up to 60 percent more for prescription drugs, compared to citizens in countries that use price controls. In my opinion, the answer is not that the U.S. should adopt price controls—a solution

with tremendous downsides, which I hope today's hearing will explore—but that we should work with other countries to eliminate their price controls.

The primary reason to use trade negotiations to address foreign price controls on prescription drugs is the health and well-being of the American people and of people around the world. Because the United States is the only major country to allow market pricing for pharmaceuticals and medical devices, companies are forced to finance their research and development costs through prices charged to U.S. consumers. They simply cannot recoup their R&D costs in countries that impose price controls. The resulting cost-shift of the R&D burden to U.S. consumers is unfair.

Another result is that much of the pharmaceutical R&D has migrated from Europe, which had been the R&D leader, to the United States —we actually insource tens of thousands of research jobs in the industry from foreign-based companies. But while the jobs and the breakthrough therapies created are a tremendous benefit, American consumers cannot continue to finance medical R&D for the entire world.

As Dr. Mark McClellan, the former Commissioner of the Food and Drug Administration noted, "Everyone's effort to get a free ride on new drugs will grind the global development of new drugs to a halt." He said it is "unfair to Americans, who are bearing an increasing share of the burden, and cannot be expected to do so indefinitely."

Americans have begun objecting to this unfairness. The wrong solution is to move toward price controls in this country. If Americans import price-controlled drugs from other countries, we are in effect adopting the price controls of other countries.

The long-term effects of such a policy could be devastating to future R&D breakthroughs. As *The Wall Street Journal* editorialized just yesterday, "The politicians and lobbyists in the U.S. who have been clamoring for drug-reimportation laws to lower the costs of prescription medicines would do well to look at the devastation price controls have brought to Europe's drug industry." Europe used to produce two-thirds of the new drugs, but now produces less than one-third—the shift all coming to the U.S., precisely because we don't control prices here…yet.

It takes 10 to 15 years and costs more than $800 million to do the research and testing to successfully bring a new medicine to patients. Only 250 of 5,000 screened compounds enter pre-clinical testing, and only one of five drugs that enter clinical trials is approved as a new medicine. Only three out of 10 marketed drugs produce revenues that match or exceed average R&D costs. If U.S. companies had to finance breakthrough drugs only with the prices that were set by governments, we could well see pharmaceutical companies scale back their R&D activities. Many companies have, for example, already reduced or even ended their research and production of antibiotics. We may find that other areas face similar threats as a result of price controls.

We must begin discussing the negative repercussions of price controls with our allies in the G-8 and the Organization of Economic Cooperation and Development. Our European allies have seen the flight of their drug companies' R&D activities to America; they understand the effect price controls have had on their economies. They know that price controls inevitably lead to shortages—shortages in available drugs and a reduction in the development of new, innovative pharmaceuticals.

The world has not yet felt the full impact of price controls reducing the supply of drugs because the United States is making up much of the difference for others by paying the bulk of the world's R&D expenses. If we were to adopt price controls, either by allowing reimportation or by adopting actual price controls, the result for the future health of the world would be devastating.

I look forward to hearing the testimony of our two panels today as we begin exploring how the United States can address this very serious issue.