

**Testimony at the Food and Drug Administration Public Meeting on April 14, 2004
Regarding the Importation of Prescription Drugs**

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I appreciate the opportunity to speak at this public meeting held by the U.S. Food and Drug Administration regarding the potential impact of prescription drug reimportation. My name is Raymond Keating and I serve as chief economist for the Small Business Survival Committee (SBSC). SBSC is a nonpartisan, nonprofit small business advocacy organization with 70,000 members across the nation. Our group works on a wide range of policy issues that affect the entrepreneurial sector of our economy.

Allowing for the reimportation of prescription drugs has become a hot political issue at the federal level and in the states in recent years. However, the idea of allowing for the reimportation of drugs from nations that impose price controls is another unfortunate example whereby some politicians choose to ignore economic reality in favor of scoring a few, short-term political points. Allowing reimportation from countries in which the government sets the price of prescription drugs would be quite dangerous.

Now, danger can come in different forms. Many worry about the dangers of importing counterfeit drugs, or mishandled or tampered with medicines. For example, Health and Human Services Secretaries for both President Bill Clinton (D) and President George W. Bush (R) – Donna Shalala and Tommy Thompson, respectively -- have declared that they could not assure the safety of imported drugs. Obviously, safety is a major issue when it comes to prescription drugs, and the fact that HHS secretaries from both sides of the political aisle note that safety cannot be affirmed should give serious pause to this movement.

But there are additional dangers. I would like to focus on the economic dangers involved with reimportation.

A key reason why consumers in other nations, like Canada and those in Europe, see lower prices for prescription drugs is because those governments impose price controls. To some, including various elected officials in this country, this sounds just great. If consumers in other nations pay less for prescription drugs because of price controls, then the U.S. should impose price controls. Imposing price controls here, though, would face formidable political and legislative obstacles, so the next best thing would be to let U.S. consumers reimport drugs from countries that have price controls. That surreptitiously and effectively would import price controls from those nations.

Unfortunately, as is the case whenever the government inserts itself in the market, price controls come with mighty and, in this case, deadly costs.

Small businesses – specifically, small pharmacies -- would pay a big price. Make no mistake, competition is a good thing for consumers and the economy. And if small pharmacies were challenged in the marketplace by more efficient and innovative competitors, so be it. That's the free-market process. However, allowing for importing drugs from countries that impose price controls is not competition. It's government regulation that would have the effect of severely crippling local pharmacies, with many simply being forced out of business.

Then there is the entrepreneur. It's easy to envision a doctor or scientist with a love for research, and a passion for improving and saving lives. Perhaps that person has the talent, knowledge and vision to pursue a cure for some kind of cancer or another illness, and is on to a potential breakthrough. However, undertaking such research is a high-risk endeavor. Capital must be raised from investors in order to proceed.

Consider the example of biotech. Venture capitalist John Clarke was quoted in the March 21st *Palm Beach Post* noting: "For the past two decades, it has been the premise that the smaller biotech companies would be the true engines that fuel the biopharmaceutical industry." Biotech ventures are entrepreneurial, high risk, and need capital to discover, develop and commercialize new medicines. As the article reported: "These early-stage biotech companies need enormous sums of money to sustain them."

But how many entrepreneurs and investors will be willing to take such risks if, in the end -- even if they wind up beating the very long odds by succeeding -- the government is going to set the price of their new medicine and thereby limit their returns? For anyone with a basic understanding of economics, the answer to this important question is clear: Few, if any, would make such investments.

Of course, the same goes for established pharmaceutical firms. Researching and developing new medicines is risky and costly for these firms as well. Just consider the following as reported by the Pharmaceutical Research and Manufacturers of America (Phrma):

- In 2000, the average cost to develop a new drug was \$802 million, up from \$138 million in 1975.
- It takes 10 to 15 years to bring a drug from the laboratory through FDA approval.
- The risks are formidable, as only 1 in every 5,000 compounds screened is approved, and only 3 in 10 of those produce revenues that reach or exceed the average research and development costs.
- Member firms in Phrma increased their research and development investments from \$1.3 billion in 1977 to \$32.1 billion in 2001. In addition, at 18.2 percent of domestic sales, these companies claim the highest R&D rate of investment among any major U.S. industry.
- Meanwhile, over the past decade, investment in research and development has accelerated twice as fast in the U.S. compared to Europe, and eight of the top ten worldwide drugs in terms

of sales originate in the U.S., and only two in Europe. Again, Europe has price controls, and the U.S. does not.

Indeed, innovation gets hit hard when price controls are imposed. A report written by Bain & Company presented at the annual meeting of the Governors of the World Economic Forum for Health Care in January of this year noted the ill effects of price controls on Europe. The authors noted that:

- From 1992 to 2002, a dramatic shift in pharmaceutical profits occurred away from Europe and to the U.S., and rates of return on R&D investment are much higher in the U.S. Therefore, the authors note, “the U.S. has become the key source of returns on R&D investment for the industry.”
- But the authors also found that this was not a free ride for Europeans, as Europe suffers from lost investment to the U.S., fewer high value-added jobs, fewer first drug launches, and slower access to drugs, all of which obviously hurt patients.
- In the end, the authors conclude: “Despite spending significantly less on drugs than the U.S., Europe suffers a net loss when all the economic and societal costs of the ‘free rider’ model are added together.”

Price controls – including through the reimportation of prescription drugs – might sound good to some, but the economic reality is quite grim. It is instructive to note that in all but five years from 1979 to 2003, pharmaceutical companies boosted their research and development spending by double-digit percentage amounts. Of the years falling below double-digit increases, in 1994 and 1995, the Clinton health care plan threatened to impose price controls, and in 2002 and 2003, the re-importation debate heated up and patent protections for pharmaceuticals came under attack. University of Connecticut professor John Vernon projects that 50 years of price controls would reduce the number of new medicines for patients by 60 percent to 73 percent – and if the U.S. had price controls from 1980 to 2001, there would be between 330 and 365 fewer new medicines today.

Price controls through reimportation of prescription drugs will hurt small businesses, entrepreneurs, investment, innovation, and therefore, ultimately, patients.

Thanks for this opportunity, and I will be glad to answer any questions.