Statement of

The Honorable Orrin Hatch

United States Senator
Utah
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"Examining the Implications of Drug Importation"

Many Americans -- especially senior citizens - are understandably seeking more affordable prescription drugs and are wondering if drugs imported from Canada and other countries are the answer.

Several bills have been introduced on this topic, including those by, respectively Senator Grassley, Senator Gregg, and Senator Dorgan - whom we will hear from shortly.

The purpose of today's hearing is to begin the Judiciary Committee's deliberation over the many issues related to drug importation that fall under the Committee jurisdiction. Today's hearing will largely focus on whether amending the longstanding, carefully-crafted law, the Prescription Drug Marketing Act of 1988, that established a tightly-regulated, closed system of prescription drug distribution in our country will open the door to counterfeit and otherwise adulterated or misbranded drugs being widely distributed to an unwitting American public.

Representative John Dingell, the Dean of the House of Representatives and a prime sponsor of the 1988 PDMA law, succinctly summarized the problem: "the very existence of a market for reimported goods provides the perfect cover for foreign counterfeits."

We will hear today from the FDA and the Bureau of Customs and Border Protection on the problem of counterfeit drugs. The FDA has documented many cases of what appeared to be FDA-approved imported drugs that, in fact, were contaminated or counterfeit, contained the wrong product or incorrect dose, were accompanied by inadequate directions, or had outlived their expiration date. Unfortunately, FDA has witnessed a sharp spike in such counterfeiting and their partners at Customs will tell us that this is not an easy crime to detect or prevent.

We will hear from Rudy Guiliani, a former tough-nosed prosecutor, who will tell us why we should think twice before we do away with the protections in current law.

I am mindful that on several occasions the Senate has adopted an amendment offered by Senator Cochran that requires the Secretary of Health and Human Services to certify the safety of imported drugs before they can enter the United States. Neither Secretary Shalala nor Secretary Thompson -- one a Democrat, one a Republican -- could make that simple but prudent certification with respect to the additional risk to public health

Given the testimony submitted by the agency today, it seems that the safety of imported drugs remains in doubt in the minds of the experts at FDA and a strong case can be made that Congress would be well advised to retain the protection afforded by the Cochran Safety Amendment.

Frankly, it may be beneficial for Congress to receive the report from the Secretary's Task Force on drug importation before legislation is considered in this area. I recognize that the Report is not due until after the election and the strategy of some is to attempt to use Election Day politics as leverage for legislation and that sound policy will not win out.

We all want medicines to be safe and affordable, yet we do not want to take steps that stifle the innovation that has made the United States the world leader in pharmaceutical development. Importing drugs from other countries in order to take advantage of other countries' price controls has other potential repercussions, including the prospect of diminished research into future life-saving treatments. We need to think carefully about the long term effect of this trade-off.

In this regard, I commend the efforts of Senators Kyl and Thomas for a hearing they recently held in the Finance Committee that examined the critical, yet almost totally overlooked, question of whether U.S. trade policy can be used to see that the citizens of our trading partners are paying their fair share of pharmaceutical R&D. The fact is that American taxpayers are putting up $28 billion of their hard-earned dollars this year for biomedical research at the National Institutes of Health while, year in and year out, many other countries essentially free-ride on U.S. research and development activities and then set price controls the approved drugs products that are the fruits of this U.S.-financed research. It is the American tax payer and consumer that is paying dearly.

Consideration of pharmaceutical importation raises many complex issues beyond the problem of counterfeiting. For example, concerns have been raised about the manner in which Senator Dorgan's bill, S. 2328, affects patent and antitrust law. The bill appears to alter current law with respect to domestic patent rights once overseas sales occur. One of the areas that this Committee should explore as this debate moves forward is how the Doctrine of International Exhaustion of patent rights might be altered by the Dorgan legislation.

I would note that last year this Committee played a constructive role in correcting the excesses in the proposed changes to patent damages by the Gregg-Kennedy-McCain-Schumer bill even after it passed the Senate by an overwhelming majority. It can take time to fully analyze and refine inherently intricate pharmaceutical-related regulation and intellectual property statutes. For example, I think that most objective observers would now agree that last year's Senate-passed bill contained a blatantly unconstitutional provision relating to declaratory judgments that was corrected in large part by this Committee's involvement.

In short, as drug importation legislation is crafted and considered, this Committee must remain vigilant in examining not just the counterfeit problem, substantial as it is, but also patent issues and other matters under our jurisdiction such as any potential antitrust and Takings Clause issues. For example, the extent to which the Dorgan legislation appears to preclude manufacturers from charging exporters market-based prices for drugs, if they are higher than the lowest price-controlled price of the exporting country, deserves the close scrutiny of our Committee. The

forced sales provision also demands further attention. As a defender of, and believer in, property rights, including intellectual property rights, I am always leery of systems that impose government-mandated prices, sales or licenses.

Finally, I must note that I am far from certain that importation is the magic bullet that will -- instantly and without repercussions -- lead to lower drug prices. I am concerned that importation may eventually provide the bullet in a grand-scale game of pharmaceutical Russian roulette.

I am willing to continue to work with my colleagues on ways to make prescription drugs more affordable for the American public, and to devise ways to do so that do not jeopardize patient safety or undermine the incentives for the discovery of the next generation of therapies.