

Testimony of
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Secretary's Task Force on Drug Importation

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Surgeon General, members of the Task Force on Importation, Ladies and Gentlemen, I am Alastair Wood from Vanderbilt University School of Medicine where I am Professor of Medicine, Professor of Pharmacology, Associate Dean and a practicing physician. I have spent my professional life studying and writing about drugs. I have advised the Food and Drug Administration through both my current and past service on FDA advisory committees. Finally I am the Drug Therapy Editor of The New England Journal of Medicine which is widely regarded as the world's premiere medical Journal.

The issue of drug Importation is a difficult one and I certainly do not envy your task. It is one of those issues where every position is simultaneously wrong and right making it an extraordinarily difficult circle to square. But, I also think that we have to look beyond the surface and recognize the problems driving the demands for drug importation, and start working on solutions to them now.

Our economic model encourages consumers to shop for the best bargain which for identical products translates into the best price with some discount for any loss of convenience. Consumers' ability to find the best price is hugely strengthened by access to clear pricing information. Such pricing transparency is now available to all through the internet and can result in substantial and potentially disruptive changes for business. Look at what happened to the airlines when everyone could find the lowest airfare at the click of a button. Once price transparency exists major pricing differentials among countries cannot be sustained without artificial barriers such as limiting supplies or preventing importation to the US, and drug companies are currently trying to do both.

Major pricing differential in drugs has developed between the United States and Canada because price regulation in Canada forces drugs to be sold there for substantially less than in the US. Normally that would result in manufacturers being unwilling to sell their product at the reduced price producing shortages in Canada. However drugs are different from most goods in that the incremental cost of producing an additional tablet is very small, often trivial, while the real cost is the cost of drug development, drug discovery and drug approval. Pharmaceutical companies and their investors are entitled to a financial return that adequately reflects the cost and risks of drug development but they will have to ensure that the cost of drug development is borne equally and appropriately by all consumers whatever their nationality. Both sides are right.

Another example of both sides being right relates to safety. Some will say Canadian drugs are safe while others will disagree. Clearly drugs sold in Canada to Canadians by Canadian pharmacies are of high quality and are as safe and effective as those sold in the United States. Frequently brand name drugs sold in Canada are made in the same factories and on the same machines as those on sale in the United States. To suggest that such drugs are unsafe and that Canadians are dying from the brand name drugs that major pharmaceutical companies sell there is simply foolish. However when a US consumer orders drugs over the internet purporting to be from Canada the consumer has no means of knowing from whence these drugs come. In fact, those drugs may be from anywhere in the world and our confidence in the Canadian drug approval process

does not extend to many other countries. Such drugs from unknown sources may be mislabeled, adulterated or counterfeit and are clearly unsafe.

If drug importation from other countries is to be permitted then we need to develop a reliable tracking system that tracks the history of drugs from manufacture to final point of sale such as those proposed using radio frequency identification (RFID) tags. Importation can only be truly safe when the consumer knows with certainty that the drugs she is taking are indeed the ones which her doctor prescribed from the original manufacturer.

I could go through each of the arguments you will and have heard and make the point that both sides are right but frankly that would not contribute much to your deliberations. Therefore I want to try to offer solutions to the current problem.

It is my position that the reimportation issue is really a symptom of a deeper problem and it is critical that we address the root causes and not allow society to become distracted by the illusionary “quick fix” of reimportation.

Much of this controversy has arisen because we have failed to explain to the American people that medical treatment, has changed dramatically in the past twenty-five years in ways that will forever change the economics of purchasing outpatient prescription drugs. Until very recently patients were treated for discrete episodes of disease usually for a limited period of time. Because of that they became accustomed to buying drugs for relatively short courses. Think of the usual ten day course of an antibiotic.

We are now in the age of livable chronic disease, and recent large studies have demonstrated that we can even prevent future disease by treating patients with drugs now—so called primary prevention. Examples include lowering cholesterol or blood pressure. In addition, preventing or postponing further disease (secondary prevention) in patients who have already had one episode of disease is also now possible—examples include subsequent heart attacks, strokes and heart failure.

In all of these cases patients (many of them currently relatively young and healthy) will take medications every day, month in and month out, for the rest of their lives, which means that we have moved from short courses of treatment to life-long therapy in large populations with profound financial implications. Patients would not look to Canada to buy a ten day course of antibiotic but they will for a medicine that they will take every day for the rest of their lives. We have to articulate this change to the public and lawmakers because although the financial implications may appear negative the long-term health implications are hugely positive. The proportion of our health care dollar spent on drugs will increase in the future. It should increase in the future and that is good news because much of that expenditure is going into prolonging our disease-free lives.

Let me also address some of the other issues.

It is estimated to cost upwards of \$800 million to develop a new drug today. That cost is too high and is, frankly, unsustainable. Although that estimate is an average cost spread across all successful drugs it means that it may be too expensive to develop drugs for smaller markets. Companies are looking for blockbusters, which will be taken by everybody. However, the problem with that strategy is that as we learn more from genetics and proteomics we will be better able to predict which subset of the population will respond to drugs and we will be able to develop drugs with greater efficacy and less toxicity, but targeted to smaller markets. One of the imperatives, therefore, is to reduce the cost of drug development.

In spite of all the scientific advances that we have made in the last few years the clinical drug-development process has changed little in the last three decades except that trials have become ever larger and more expensive. This continued upward spiral in drug development costs is unsustainable and we are already seeing a reduction in the development of successful new drugs. It is therefore essential that we think creatively to develop new clinical drug development paradigms to address this problem. Drugs to prevent and treat many common diseases in our aging population, such as Alzheimer's and osteoarthritis, are still tantalizingly out of sight. We need to be prepared to consider really radical approaches to this problem. For example we have learnt that the patent extension offered by the pediatric rule has encouraged drug studies in children.

Perhaps we need to have drug approvals that can be staged—first, more rapid approval for surrogate endpoints (and hence smaller, cheaper trials) with patent extension offered for later studies that demonstrate efficacy in clinically relevant, meaningful endpoints. Perhaps we need to offer longer patent life for truly novel therapies. I think most of us would happily grant longer patent protection to the first preventive agent for Alzheimer's disease. Again we need to create incentives to reward the most risky and innovative research. We need to encourage valid comparative trials among drugs. Why should data be readily available on which airline has a better baggage handling or on-time record when no such comparison exists for pharmaceuticals? Again introducing market-based financial incentives is most likely to be successful.

Therefore, in conclusion, our future health—your and my future health is utterly dependant on the development and marketing of new drugs to treat the many common diseases for which we currently have no effective therapy. We need to make sure that we do not allow ourselves to become distracted by reimportation as a solution rather than recognizing the true issue which is reducing the cost of drug development and spreading that cost evenly across all consumers.