American Medical Association
Oral Statement by
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HHS Task Force on Drug Importation
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Good afternoon. My name is Rebecca J. Patchin, MD. I am an anesthesiologist, a pain management specialist and a member of the American Medical Association's Board of Trustees.

I am in solo practice in Riverside, CA, where I have had a number of patients cross the border into Mexico in an attempt to buy, more cheaply, the prescriptions I write for them.

Am I concerned about this? Of course.

In fact, this is a concern shared by the AMA and practicing physicians across the U.S.

We are concerned because when patients go outside the country to purchase their drugs, there is no way for physicians to be certain that the drugs we prescribe for them are the drugs they are going to receive.

Whether patients get their prescription drugs from Mexico, Canada, or the European Union the concerns are the same:

That our patients are getting the right drug, in the right dosage, in the right way.

What the "right way" means is that the drugs come from manufacturers, wholesalers, or retailers, whether Internet or "brick and mortar," that can assure quality while at the same time, balancing against the need for patients to get their prescriptions at the lowest possible price.

But when it comes to drug importation, patient safety is the AMA's number one priority.

At its 2003 Annual Meeting, the AMA's House of Delegates chose not to adopt a resolution supporting prescription drug importation.

Concerns over patient safety were at the center of the AMA's debate.

On the legislative front, the AMA also opposed HR 2427, The Pharmaceutical Market Access Act of 2003, primarily because the bill lacked a provision that would have required the Secretary of HHS to certify the safety of imported drugs.

The only way to assure the safety of imported drugs is to make certain that all drugs for sale to patients in the U.S. are FDA approved.

That means, among other requirements:

?? the drug has been reviewed and approved by the FDA for safety and efficacy;

?? the drug manufacturer has met all U.S. laws and regulations for good manufacturing practices;

?? the FDA has the authority to inspect all manufacturing facilities;

?? the drug has met all FDA labeling and packaging requirements; and finally

?? that the drug's chain of custody can be assured and traced.

Admittedly, these requirements would demand significant federal revenue but if we are to allow drug importation, these measures are necessary to protect the American people and to preserve our stringent and very effective drug approval process.

Another AMA concern is drug counterfeiting.

In a recent FDA report, drug counterfeiting outside the U.S. was described as "widespread and affecting the drug supply of both developing and developed countries."

In some instances, counterfeit drugs accounted for more than half of a country's drug supply.

The AMA has concerns that if prescription drugs are allowed to be imported from foreign countries, counterfeit drugs will be more likely to enter our now - well protected - drug distribution system.

If we allow importation, the distribution system must be closed, and all drugs must be subject to reliable, electronic track and trace technology - to secure the integrity of the drug supply chain - and to prevent the importation of counterfeit drugs.

The AMA is also concerned with whether or not individual patients will be allowed to import drugs directly via the Internet. This is a largely unregulated area with a number of rogue web sites already selling prescription drugs of unknown quality, and often without a valid prescription.

This problem will likely increase if direct importation by patients is legalized.

Without the safeguards I have described, the American people cannot be certain that the imported drugs they are taking are safe, effective, and of high quality.

These may seem like high standards to demand, especially when many patients struggle to pay the high costs of their prescription drugs.

However, if we permit unsafe, ineffective, adulterated, misbranded, expired or counterfeit drugs to reach our patients it may result in harm to those patients, or even death.

In the field of pain management, for example, a subpotent drug can mean the difference between a pain score of 6 on a scale of 1 to 10 and a pain score of 9 which, if you have ever experienced such pain, is a significant difference.

While the AMA's goal here today was to lay out the patient safety concerns with respect to drug importation, other questions will also need to be answered such as:

Whether an adequate supply of FDA-approved drugs in foreign countries would exist to make importation feasible,

-and-

What the economic reaction of the drug companies or other countries would be to widespread importation.

These, and especially the patient safety issues must be weighed carefully before a decision should be made on drug importation.

Thank you for your time and I welcome any questions.