

Statement
of the
American Medical Association
to the
Committee on Government Reform
U.S. House of Representatives

**Hearing Entitled: “A Prescription for Safety:
The Need for H.R. 3880 the ‘Internet Pharmacy Consumer Protection Act’ ”**

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The American Medical Association (AMA) appreciates the opportunity to present our views on Internet prescribing and dispensing of medications to the Committee on Government Reform. We thank the Chairman and Representative Waxman for their leadership on this important issue.

The Internet can be an extremely valuable medical resource, and the AMA supports the use of the Internet as a mechanism to prescribe and dispense medications as long as appropriate safeguards are in place to ensure that the standards for high quality medical care are fulfilled. Web sites that prescribe and dispense prescription medications based solely on an online questionnaire; Internet pharmacies that fail to meet minimum standards for the storage and distribution of prescription medications; and rogue web sites that sell unapproved or even counterfeit drugs are just a few of the grave concerns the AMA has over the current misuse of the Internet for accessing prescription medications.

Another concern of the AMA is the growing availability of controlled substances over the Internet. Today, the nonmedical use of prescription drugs ranks second (behind marijuana) as a category of illicit drug abuse among adults and youth. The National Survey on Drug Use and Health conducted by the Substance Abuse and Mental Health Services Administration (SAMHSA) found that in 2002, an estimated 6.2 million persons in the U.S. over the age of 12 reported “past month” use of prescription stimulants, sedatives, tranquilizers, and analgesics for non-medical purposes. This was a significant increase from 2001 and 2000, when roughly 3.5 million and 1.6 million persons respectively reported such drug use. Additionally, more than 1 in 4 persons aged 18 to 25 report having used prescription drugs for a nonmedical purpose at some time in their lives. A major contributor to the problem has been the ease in which persons can access these drugs over the Internet.

A recent Washington Post article on the “multibillion-dollar shadow market” for prescription drugs stated, “Rogue medical merchants set up Internet pharmacies that serve as pipelines for narcotics, selling to drug abusers and others who never see doctors in person or undergo tests. The sellers move tens of millions of doses of hydrocodone, Xanax, Valium, Ritalin, OxyContin and other controlled substances. Scores of customers have become addicted, overdosed or died.” *Washington Post Oct. 19, 2003; p.A01.*

The AMA and a number of national organizations and agencies, including the Federation of State Medical Boards (FSMB), the Food and Drug Administration (FDA) and the National Association of Attorneys General, believe that the prescribing and dispensing of prescription

medications without a valid patient-physician relationship constitutes substandard medical care and is a threat to the public health.

In general, the AMA believes that any Internet communications between a physician and patient, or between a physician and pharmacy on behalf of a patient, should supplement and enhance, but not replace, the critical interpersonal interaction that is the very basis of the patient-physician relationship. The AMA's policy guidance for physicians who prescribe medications via the Internet is clear with respect to the criteria necessary to establish a valid patient-physician relationship, and we believe that serious care should be taken to ensure that these minimum standards of medical care are protected in any effort to regulate Internet prescribing. Our policy (H-120.949) states, a physician shall:

1. Obtain a reliable medical history and perform a physical examination of the patient, adequate to establish the diagnosis for which the drug is being prescribed and to identify underlying conditions and/or contraindications to the treatment recommended/provided;
2. Have sufficient dialogue with the patient regarding treatment options and the risks and benefits of treatment(s);
3. As appropriate, follow up with the patient to assess the therapeutic outcome;
4. Maintain a contemporaneous medical record that is readily available to the patient and, subject to the patient's consent, to his or her other health care professionals; and
5. Include the electronic prescription information as part of the patient medical record.

Exceptions to the above criteria exist in specific instances. These include: instances when treatment is provided in consultation with another physician who has an ongoing professional relationship with the patient and who has agreed to supervise the patient's treatment, including the use of any prescribed medications; and in on-call or cross-coverage situations.

The AMA recognizes that there are a growing number of problems with the use of the Internet for prescribing and dispensing of medications. However, care must be taken to protect and even enhance legitimate electronic prescribing and dispensing practices. The use of the Internet as a source for obtaining prescription medications is not necessarily inappropriate, and a number of appropriately licensed Internet pharmacy practice sites are legitimately dispensing prescription medications pursuant to a valid prescription.

Some examples of the Internet being used for legitimate electronic prescribing purposes are:

- *Computer order entry and on-line transmission of prescriptions.* When a physician sees a patient and does an adequate history and physical, computer order entry and on-line transmission of the prescription to a pharmacy provides an alternative mechanism for prescription transmission. Many experts believe computer order entry of prescriptions can reduce errors that occur from failure to understand handwritten prescriptions. Existing technology allowing for the validation of electronic signatures and the encryption of prescription information can make these transactions even more secure.
- *Ordering refills – either patient to pharmacy, or physician to pharmacy.* There are legitimate clinical circumstances where the physician does not see the patient at the time a refill is ordered, but the patient has been and remains under that physician's care and has been seen in person in the recent past. If the refills are authorized on the original prescription, the patient could electronically contact the pharmacy directly and request the refill. This could be conducted through a community, mail service, or legitimate Internet pharmacy. When no refills are remaining on the original prescription, the patient

could call or electronically contact the physician requesting that a refill be authorized. If the physician believes the refill is needed, the physician could electronically send the renewed prescription to the pharmacy.

- *Electronic consults between physician and patient where the outcome is an ordered prescription.* At times, legitimate clinical circumstances can exist where a physician does not see the patient at the time a new prescription is ordered. This occurs when the patient is under that physician's care, the physician has the patient's history and physical information in the medical record, and the patient has been seen in person in the recent past. For example, a patient may inform his or her physician via telephone or email of a flare up in a seasonal allergy, a documented problem, and the physician may then electronically transmit a prescription for an antihistamine to the pharmacy without an additional office visit. The key here is that the physician and patient have an ongoing relationship, the patient routinely sees this physician, and history and physical information are already in the medical record.

In addition to legitimate electronic prescribing via the Internet, there also are appropriately licensed Internet pharmacy practice web sites that provide an alternative consumer option for the dispensing of prescriptions. Such Internet pharmacies may offer patients a number of benefits including the convenience of ordering their prescriptions from their home or office, as well as the potential to purchase medications at comparative cost savings. However, with the growth and proliferation of Internet pharmacy web sites, it is becoming difficult for patients to distinguish

safe and legitimate sites from fraudulent sites or sites operating below accepted pharmacy standards.

To address this issue, the AMA has worked with and supported the National Association of Boards of Pharmacy (NABP) in its development of the Verified Internet Pharmacy Practice Sites (VIPPS) program. The VIPPS program verifies the licensure of Internet pharmacy practice sites and informs the public, through a database on the NABP web site, whether or not these web sites are licensed in good standing with the appropriate state board(s) of pharmacy or other regulatory agencies. In addition to the VIPPS program, current AMA policy requires physicians who prescribe via the Internet, to clearly disclose physician-identifying information on the web site, including (but not necessarily limited to) name, practice location (address and contact information), and all states in which licensure is held.

Although the AMA supports the VIPPS program, we also recognize that rapid changes inherent in Internet technology may require new efforts or programs to certify Internet pharmacies. Therefore, the AMA stands ready to work with any government or private organization in an effort to develop a program whereby patients will have assurances that an Internet pharmacy, from which they purchase prescription medications, will meet or surpass the standards set for the operation of pharmacies.

For the most part, states have primary jurisdiction over matters relating to medical licensure or the licensing and regulation of pharmacies, both brick and mortar and those operating via mail or over the Internet. Under existing law in the majority of states, prescribing drugs to a patient

outside the state where the physician is licensed is considered the unlicensed practice of medicine. [NOTE: An exception is when the clinical encounter occurs in the state where the physician is licensed.] Every state medical board agrees that prescribing drugs without physically examining a patient or reviewing his or her medical history is, in most cases, practicing medicine at a level far below the accepted standard of medical care. Pursuant to our policy, the AMA has worked and will continue to work with state medical societies in urging state medical boards to ensure high quality medical care by investigating and, when appropriate, taking necessary action against physicians who fail to meet these accepted standards of medical care when issuing prescriptions through Internet web sites that dispense prescription medications. In addition, we expect that states will continue their efforts to regulate prescription-selling web sites while exploring various methods of regulating the manner and medium in which prescription drugs may be prescribed.

In addition to supporting state regulatory activity, the AMA also recognizes that the federal government has a role to play in ensuring the appropriate sale of prescription medications over the Internet by assisting and building on state efforts. The very nature of the Internet makes it virtually impossible for states alone to address the problems surrounding the sale and distribution of prescription drugs between states and between countries. The federal government, especially the FDA, has an especially important role to play with respect to addressing web sites of primarily foreign companies that are illegally promoting, distributing or selling unapproved prescription drug products in the United States. These web sites have multiplied with the growth of the Internet. Typically, these companies will post a price list and advertise that they can sell

United States-patented prescription drug products at greatly reduced prices. In many cases, the advertisements state that the medication can be ordered and obtained without a prescription.

Among the concerns with illegal distribution of drugs from foreign sources is the product quality of these “foreign versions” of prescription drugs and whether patients are at risk of harm due to lack of physician oversight and inadequate directions for use. If obtaining prescription drugs from foreign companies without a prescription through the Internet becomes common, it threatens to potentially render the whole concept of legend (by prescription only) drugs meaningless in the United States. While the FDA has used its authority to prevent this illegal activity by some foreign companies, it has been difficult to stop these and other companies from simply continuing these illegal activities from another web site. The AMA will continue to work with and encourage both federal and state entities to regulate and monitor the Internet sites of companies, whether foreign or domestic, that are illegally promoting and distributing prescription drug products in the United States. The AMA is also hopeful Internet providers, as well as other web sites, will take the initiative to remove links to illegal Internet pharmacy web sites when they are discovered.

The AMA would like to thank Chairman Davis and Representative Waxman, as well as their staff, for allowing us to express our policy positions on H.R. 3880, the “Internet Pharmacy Consumer Protection Act.” It is clear that something needs to be done at the federal level to address the myriad of problems surrounding the illegal use of Internet pharmacies.

There are currently several bills that have been introduced or are being prepared for introduction in Congress, including the Chairman's bill, that address the problems of Internet prescribing and distribution. While the AMA has not yet taken a position on any particular piece of legislation, it looks forward to and appreciates the opportunity to work with all Members of Congress in order to craft a solution that will protect patients by preventing substandard or illegal Internet prescribing and dispensing of medications and ensure that the standards for high quality medical care are fulfilled.