American Pharmacists Association
Improving medication use. Advancing patient care.
APhA

November 3, 2003

Division of Dockets Management (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MD 20852

Docket No. 2003N-0361

Dear Sir/Madam:

The American Pharmacists Association (APhA) is pleased to submit comments on the Food and Drug Administration's (FDA) Anti-Counterfeit Drug Initiative as published in the September 5, 2003 *Federal Register*. APhA, founded in 1852 as the American Pharmaceutical Association, is the largest national professional society of pharmacists in the nation, representing more than 53,000 practicing pharmacists, pharmaceutical scientists, student pharmacists, and pharmacy technicians.

The protection of our medication supply is obviously of vital interest to pharmacists, including efforts to prevent the introduction of counterfeit products into the system and the quick identification and elimination of such products from the system if the medication supply is infiltrated. Pharmacists rely upon a safe and pure medication supply to help patients make the best use of their medications. APhA applauds the efforts by the FDA to stem these illegal activities which are straining our regulatory system and are putting American patients at risk. The FDA's report that since the year 2000 counterfeit drug investigations have increased to an average of over 20 per year indicates a need to strengthen our regulatory system.

These comments address questions raised in the September 5, 2003 Notice of Public Hearing as well as those questions raised in the FDA Counterfeit Task Force Interim Report in four basic areas: the advantages and disadvantages of various anti-counterfeit technologies; regulatory and legislative challenges; public education needs and strategies; and the role that pharmacists will play in implementing new anti-counterfeit activities. APhA sees value in enhancing our efforts to combat counterfeiting through advanced technologies and coordination of efforts by all interested parties including manufacturers, wholesalers, pharmacists, and patients. APhA's support is only tempered by the reality that we are working with limited resources and therefore must look at both the costs and benefits of any new activity prior to its implementation.

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Technology

Cost-Benefit Analysis

Technology advances present an opportunity to strengthen the safety of our drug supply. However, it is important to recognize that these advances do not come without a cost. As some of these technologies will be implemented at the pharmacy level, pharmacists and pharmacies will bear some of the additional costs necessary to employ new anti-counterfeit technologies. Depending on the technology and the necessary equipment, this may involve a substantial financial contribution. While providing an anti-counterfeit benefit, the burdens associated with infrastructure upgrades must be taken into account as the Agency develops its policies around anti-counterfeit technologies. The benefits of anti-counterfeit technologies should not become overly burdensome, financially or administratively, for the health care practitioners providing patient care.

Numbers & Types of Technology

In determining the number and types of anti-counterfeiting technologies that should be used on packaging and labeling, one overriding consideration is involved: are the technologies sufficient to protect against counterfeiting? Anti-counterfeiting initiatives must be continuously reviewed and updated to keep ahead of counterfeiters. However, we recognize the resource limitations of the Agency and interested parties. In an ideal world with unlimited resources, we would have a sophisticated anti-counterfeit system for every drug — but resources are limited. We recommend that the Agency focus its efforts on those drugs most likely to be counterfeited. We recognize that this list of drugs may change, given the activities of the counterfeiters, and recommend that the Agency equip itself with mechanisms that will allow it to rapidly respond to new counterfeit efforts.

To assist in the identification of these priority products, APhA recommends that the Agency develop criteria for determining what drugs are most likely to be counterfeited. Ideally, that list of criteria would include anything that would stimulate a counterfeiter to counterfeit. We agree that at a minimum, that list should include the following criteria from the Interim Report: potential impact on public health if the product was counterfeited; any history of or potential for counterfeiting, tampering, or diversion of the product; volume of the product sold; the dosage form of the product; approved and unapproved uses of the product; current and potential misuse or abuse of the product; and other products in the class with a history of being counterfeited. It is also important to consider a product's cost when developing this list. But considering drug cost has its limitations. Cost becomes a much less important factor when a counterfeiter is focused on harming a patient population. In that circumstance, they might counterfeit a less expensive medication with a higher potential to cause harm to a broad population.

When considering covert and overt technologies, APhA recommends using a combination of these technologies. Counterfeiters have proven themselves sophisticated and adaptable to advances in technology and changes in anti-counterfeiting efforts. While overt technologies, such as specific colors and fonts for labels, can provide pharmacists helpful clues about the validity of the drug they are dispensing, instituting only overt technologies could provide the counterfeiter a "blue print" on how to circumvent the system. While each type of anti-counterfeit technology, alone, provides a benefit, creating a system builds upon the strength of each technology and helps create a less penetrable system, because advantages and disadvantages exist with each type of technology. For example, bar codes, a type of track and trace technology, are often discussed as an anti-counterfeiting technology that should be adopted industry-wide. Incorporating bar codes may provide many benefits beyond simply assisting in anti-counterfeit efforts, such as inventory control, reducing medication errors, identifying theft and diversion, and implementing recalls. The value of bar codes to anti-counterfeiting initiatives, however, must consider the ease of copying bar codes and circumventing the protections by creating fake bar

codes. While still an important option for a base-line anti-counterfeit strategy, no single technology will prevent counterfeiters. Sophisticated criminal activities require sophisticated countermeasures.

Unit-of-Use Packaging

Many of the Report's technology-related questions focused on unit-of-use packaging. APhA supports adoption of unit-of-use packaging as the industry standard[1]. Unit-of-use packaging may enhance patient safety, patient compliance, and efficiencies in drug distribution. While most other groups will focus on the manufacturers' and re-packagers' role in unit-of-use packaging, it is important to consider the role of the pharmacist, and the accompanying revisions to state law that may be necessary to fully implement the concept. In current practice, pharmacists receive prescriptions for many different quantities — for 28-, 30- or 31-day supplies — supplies that may not match unit-of-use packaging. For effective implementation of unit-of-use packaging, pharmacists must be permitted to modify prescribed quantities to correspond with commercially available unit-of-use packages. Without such authority, pharmacists will bear the burden of contacting prescribers to amend the prescription, not for clinical concerns but to comply with available packaging.

Establishing standards for unit-of-use packaging is another necessary element to successful implementation. Expanding the scope of unit-of-use packaging provides an opportunity to create more consumer-friendly packaging and help pharmacists and patients improve medication use. Allowing for a number of different unit-of-use formats, however, could actually stimulate patient and pharmacist confusion. For example, one drug's unit-of-use packaging could be designed in a circle, requiring a patient to take tablets in a clockwise fashion, and another drug's unit-of-use packaging could be designed in a rectangle, with the patient taking pills from left to right, moving from the top row to the bottom. While arguably self-evident to a patient using just one medication, a patient using multiple medications must then also master multiple types of packaging and presentation of the medication.

Setting standards for unit-of-use packaging could also help address some of the shelf space issues at the pharmacy. Pharmacies are challenged with stocking a multitude of drug products in a limited space. Efficiencies in space are created when product boxes are similar in size. Without standards, manufacturers could greatly vary the box sizes of their products, creating inefficiencies and impacting the ability of pharmacies to stock all products. Standards could preclude great variations in box sizes and therefore could assist pharmacies as they work to appropriately stock pharmacy shelves.

Direct Shipment to End-Users

While an interesting option to solving the challenges created by having too many intermediaries in the supply system, direct shipments to pharmacies and other end-users may pose additional problems. In current practice, multiple pharmaceutical manufacturers deal with a relatively small number of wholesalers and large purchasers, and the wholesalers and large purchasers then distribute products to pharmacies. This system provides efficiencies to both the manufacturer and the pharmacy by allowing

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[1] The following policy statement was adopted in 2003 by the APhA House of Delegates: ***Unit-of-Use Packaging:*** APhA advocates for the adoption of "unit of use" packaging as the industry standard to enhance patient safety, patient compliance, and efficiencies in drug distribution. APhA shall collaborate with the pharmaceutical industry, third party payors, and appropriate federal agencies to affect the changes necessary for the adoption of "unit of use" packaging as the industry standard. APhA encourages the enactment of legislation and regulations to permit pharmacists to modify prescribed quantities to correspond with commercially available "unit of use" packages.

each end of the distribution system to work with a smaller number of distributors. A direct-shipment-to-end-user system that removes the wholesaler function would require pharmacies to work with multiple manufacturers, and manufacturers to work with tens of thousands of pharmacists and pharmacies, creating administrative challenges for all participants in the distribution system.

In an effort to limit those administrative burdens, manufacturers could choose to ship their products only to large pharmacy operators and leave smaller pharmacies and their patients without access to medications. All pharmacies must have access to all medications to ensure that patients may conveniently receive their medications from their pharmacist of choice and in doing so, take advantage of the pharmacist-provided consumer protections against drug interactions, adverse events, etc. Additionally, an end-user distribution system assumes that the pharmacy is the last stop in the medication distribution system. In some circumstances, a pharmacy may provide medications to another pharmacy, such as when there is a shortage of a particular medication. This is an important element of providing patients timely access to necessary medication. Although it is impossible to predict the impact of such a dramatic change in our drug distribution system, it is clear that current efficiencies in the central wholesaler system would be lost, or at least compromised, with a direct-to-end-user system.

Managing the System

The FDA must play a strong role in reviewing the use of various anti-counterfeiting technologies, whether in the form of special packaging, taggants incorporated into the product, or track and trace technologies. To better ensure an effective security system, the FDA should be a leader in managing the system. We would support having some anti-counterfeiting technologies identifiable only by the manufacturer and/or the FDA, as well as efforts to limit the number of persons/entities with access to any anti-counterfeiting-related data. Entities other than the FDA who desire access to this data must demonstrate clear need. As such, the FDA should, at a minimum, set a baseline for industry to meet for all anti-counterfeit activities.

In addition to setting a baseline, the FDA should play a strong role in guiding the industry through this process. In particular, the FDA could help the process of establishing this new system by clarifying the role of each interested party within the new system. One often misunderstood area is the intersection of authority between the FDA and state regulators, such as the state Boards of Pharmacy. State Boards of Pharmacy play a significant role in regulating pharmacies, pharmacists, and wholesale distributors. The new system would benefit from a coordinated, consistent approach from the FDA and other regulators, and including this type of information as part of the industry guidance document.

Regulatory and Legislative Issues

Prescription Drug Marketing Act

In our June 30, 2000, comments on the Agency's final rule implementing the Prescription Drug Marketing Act of 1987 (PDMA) as amended, APhA expressed concerns that the changes to the wholesale distribution of prescription medications would erect barriers adversely impacting pharmacists' ability to obtain prescription drugs. APhA's concerns included creating two categories of drug distributors (authorized and unauthorized), each with their own regulatory requirements, and requiring unauthorized wholesale distributors to provide a drug origin statement or paper "pedigree" detailing each previous transaction of the drug upon each subsequent sale or trade of the drug.

APhA recognizes the value of requiring a trail of transactions for a prescription drug and agrees that pedigrees, in concept, may be an appropriate tool to track prescription drugs from manufacturer, to wholesaler/distributor, to pharmacist. However, our concerns with a paper-based system have not

dissipated since our 2000 comments, although our confidence in the distribution system has changed dramatically. A paper pedigree system could negatively impact the security of our drug distribution system by creating a false sense of security when the mere presence of a paper pedigree could be proof of little. The value of a paper-based system is reduced by the ease of counterfeiting paper pedigrees. A paper-based pedigree system may provide a track record of the product movement, or simply provide a counterfeit record of the product movement—a trail as fake as the product it accompanies. If an entity is sophisticated enough to counterfeit the product, the same entity would be equally capable of counterfeiting a paper pedigree.

Proposals to issue an electronic, universal pedigree address our concerns regarding PDMA's affect on drug availability. Early iterations of PDMA implementation created a two-tiered system by developing a system of authorized and unauthorized distributors. It is highly unlikely that a manufacturer would provide an unauthorized distributor with a pedigree when it is not required to — and forcing unauthorized distributors to construct a pedigree is an insurmountable burden that would likely reduce the number of legitimate distributors in the system. Fewer legitimate distributors could lead to a decrease in competition, an increase in prescription drug prices, and a disruption in drug distribution. Because of these concerns, APhA supports a carefully constructed, electronic universal pedigree.

We continue to support a pedigree requirement in concept and recommend that the Agency consider alternative formats, such as an electronic pedigree system or other approaches less likely to be falsely produced by counterfeiters. As with any new system, such steps should be implemented after a cost-benefit analysis has been conducted.

Access to Quality, Regulated Drugs

APhA firmly believes that one of the greatest risks to patients receiving counterfeit drugs is personal importation of medications from outside the U.S. Importation, particularly personal importation, raises patients' risk of receiving a substandard or fake medication substantially by making the world a patient's pharmacy — a drug provider that is often unregulated or at least regulated very differently. Members of Congress and state policymakers, in an effort to increase access to medications for their constituents, have begun efforts to facilitate and/or legalize this unsafe practice. Simply strengthening existing regulatory enforcement to address importation would reduce the risk of patients receiving a counterfeit medication.

Over the last year, so-called storefront operations have popped up around the country to facilitate personal importation of pharmaceuticals. These facilities are clearly participating in the delivery of medications to patients. State Boards of Pharmacy, with whom enforcement of the practice of pharmacy lies, find themselves struggling with jurisdictional issues when trying to close down these storefront operations. Often walking the fine line of "practicing pharmacy", these storefronts occasionally fall in a regulatory vacuum. Any changes necessary to directly address these entities — thereby providing either federal or state regulators the authority to shut down these operations — must be made. In addition, APhA supports the proposal to increase penalties for counterfeiting medications. Such action would send a strong message to counterfeiters that we do not condone this illegal, unsafe, and unscrupulous practice.

State Pharmacy Practice Acts

As stated previously, personal importation is the greatest risk to patients receiving counterfeit drugs and State Boards of Pharmacy are struggling with jurisdictional issues when trying to regulate "storefront" operations. Therefore, APhA would support efforts to enhance the ability of state Boards of Pharmacy

to regulate all entities engaging in pharmacy practice, including so-called storefronts. Additionally, APhA supports strengthening wholesaler regulations, such as requiring a site visit to a wholesaler before issuing a license. This step would enhance regulators' efforts to ascertain that the wholesalers seeking licensure are legitimate businesses.

Education & Communication

Role of the Public

Patients play a very important role in identifying and reporting suspected counterfeit drugs. Occasionally, counterfeit drugs may be identified only through patient experience with medications — only after the drug interacts with a human body. But for patients to fulfill this role of reporter, they first need to be aware of the importance of reporting. Second, patients must know where to report — that they should tell their pharmacist when a drug looks, smells, feels, or tastes different than what they had previously experienced or expected. Even if the change in appearance or effect is not related to a counterfeit medication, this conversation may help limit adverse drug events or side effects, it may help improve medication use and advance patient care. Third, patients also need to understand how easily drugs can be counterfeited and how difficult it is to detect counterfeit drugs. Without such education, patient may not consider an odd effect the result of a counterfeit drug and may assume that the pharmacist would have "seen" (with the naked eye) whether a drug was counterfeit. Neither assumption is true and should be clarified. A call to action and consumer tips on what to watch for will help patient reporting of suspected counterfeit medications. APhA consumer tips are posted on our website (http://www.pharmacyandyou.org/InternetPharmacy.html) and are attached for your information.

Messaging

Effective and efficient notification of counterfeit medication requires a consistent message in a consistent format. Inconsistent, conflicting messages will only perpetuate unnecessary chaos. Notification should take place in priority order as well, with an optimal situation notifying the pharmacy community first, with immediate subsequent notification of the public and the rest of the health care system. By communicating first with the pharmacy community — both pharmacies and pharmacists — the Agency helps prepare the community most likely to receive questions about the situation, and the community most likely to have the information necessary to proactively contact affected patients. Organizations such as APhA can play an integral role in these emergency communications.

Messages to pharmacists should focus on information the pharmacist needs to address their patient population, such as: name of the product, lot number, specifics about identifying the counterfeit product, and information on the risks to patients. This type of information will allow the pharmacist to determine the likelihood that their drug supply was infiltrated by the particular product in question and to immediately notify the affected patients.

Collaboration

APhA recommends that the Agency collaborate with private stakeholders in designing communication strategies among stakeholders. This public/private partnership could facilitate efforts to standardize anti-counterfeit communications and to augment and coordinate communication systems. APhA specifically recommends utilizing our website of resources for pharmacy professionals, www.Pharmacist.com, to deliver FDA messages about counterfeiting. Pharmacist.com is the single-source site for the professional resources that are vital to the continuous professional development needs of pharmacists, student pharmacists, and pharmacy technicians. Pharmacist.com, a collaborative effort of APhA and the National Association of Boards of Pharmacy, assembles in one place the resources pharmacists need. As a medium developed by pharmacy for pharmacy, Pharmacist.com provides

information in a useful format. Pharmacist.com could be used to link to MedWatch to facilitate pharmacists reporting suspected counterfeits. In addition to Pharmacist.com, APhA has another internet-based communication tool that could be used to send information about counterfeit medication events. Pharmacist.com Focus is a weekly publication that is emailed to more than 65,000 pharmacists and student pharmacists and could be easily used to focus the attention of this audience on anti-counterfeit activities. However, Pharmacist.com Focus is not restricted to a weekly distribution schedule. In a crisis, APhA has the ability to send special alerts to Pharmacist.com Focus subscribers — an invaluable tool during an emergency situation. An advantage of these systems is that they already exist, and it is more efficient to augment a currently existing system than to create a net new one that must be introduced to pharmacists. Pharmacists are already familiar with these systems and will be responsive to their information as they are seen as fair and unbiased resources for information.

Creating efficient and effective public/private collaborations is a challenge when trying to meet the needs of a wide spectrum of interested parties. Involving interested parties early in the process can assist in these efforts. A common understanding of how systems will work will better prepare everyone to handle an emergency situation, and the creation of templates supports efforts to ensure that messages stay consistent. Having as much of a "system" in place prior to an event is an effective way to manage a situation. Creating consistency before an emergency helps prevent unnecessary mishaps.

Industry and Health Professional Issues

Role of the Pharmacist

As the medication experts on the health care team and the health care practitioners with the most comprehensive set of drug information for the patients they serve, pharmacists should take a leadership role in identifying counterfeits, preventing their introduction into the distribution chain, and educating consumers about counterfeits and how to address a suspected counterfeit medication.

Pharmacists have the responsibility of partnering with patients to share information about medication use, to ask patients to report anything different about their medication. Patients need to know, for example, that a drug that stings when injected could, in a rare situation, be counterfeit, or, more commonly, that they could be suffering an adverse reaction. Pharmacists are essential in efforts to help patients make the best use of their medications.

Pharmacists must also play a reporting role, and need education to focus them on the most efficient reporting procedures. While pharmacists better understand the ease of counterfeiting medications, many have not dealt directly with the situation. Pharmacists need information about how and to whom they should report suspected counterfeit medications: reporting to FDA and the pharmaceutical manufacturers. APhA supports efforts to increase the understanding by pharmacists of the role that they play in preventing counterfeit medications from reaching patients, and has published a continuing education piece on protecting the integrity of the prescription medication supply, which will be distributed to more than 120,000 pharmacists in the November, 2003 issue of *Pharmacy Today*.

In addition, the profession can address the practice of safe drug distribution by developing best business practices for buying medications. These guidelines could then be widely distributed to pharmacists to assist them in preventing the introduction of counterfeit medications in their pharmacy and to facilitate the identification of counterfeit drugs.

Finally, APhA commends the Task Force for recognizing that this effort must go beyond our own borders and must include the international pharmacist community. In devising international activities,

APhA recommends that the Task Force work with the International Pharmaceutical Federation (FIP), a world-wide federation of national pharmaceutical (professional and scientific) associations. FIP has expressed concerns regarding the proliferation of counterfeit medications. At its 2003 World Congress in Sydney, Australia, the FIP Council adopted a *Statement of Policy on Counterfeit Medicines,* which can be accessed at http://www.fip.org/pdf/counterfeitmedicines2003.pdf

APhA is pleased that the FDA is addressing this important issue. This review of current policies and systems is timely, given recent increases in counterfeit medications and importation by individual patients. As the FDA considers the steps to limit drug counterfeiting, the analysis must consider the costs associated with the recommendations – costs in terms of both time and money. Pharmacists and other members of the pharmaceutical supply system are ready to invest in appropriate measures, but we should invest wisely in those strategies that will provide the best value for the cost. APhA urges the FDA to consider our recommendations as they finalize their anti-counterfeit drug initiative. Thank you for the opportunity to share our thoughts on this issue. If you need additional information, please contact Susan Bishop, APhA's Senior Manager of Regulatory Affairs and Political Action, at 202-429-7538 or sbishop@aphanet.org.

Sincerely,

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Executive Vice President

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About Importing Medications and Internet Pharmacies

Importing Medications: Getting Your Questions Answered

The American Pharmaceutical Association (APhA), the national professional society of pharmacists, addresses consumer questions regarding the importation of medications and offers helpful advice on the risky practice.

What does "importation" refer to?
Importation refers to patients obtaining medications outside of the United States . It is the practice of bringing medications from one country to another.

Why would a person engage in the practice?
Consumers—feeling the financial pressures of expensive prescription drugs—look for alternative ways of obtaining the medication they need. However, importing medications only offers short-term cost savings, because if the medication is wrong or used incorrectly it can cause greater harm to the patient, thus resulting in higher long-term costs.

Importing drugs sounds illegal. Can just anyone bring drugs from one country to another?
Just as bringing fruit from a foreign country into the U.S. is illegal, importing medications is also illegal. Under federal law, only the manufacturer of a drug may import prescription medications, because the federal government regulates the manufacturing of prescription and nonprescription medications. The federal government has processes to ensure the safety of products manufactured according to its rules—but not an imported product brought in from another country by an individual.

In using the fruit analogy, the U.S. prohibits a person from bringing fruit from a foreign country into the U.S. because the fruit may be contaminated and potentially bring disease and devastation to our nation's harvest. In similar terms, neither the pharmacist nor the public has assurance that imported products are effective, safe, or have been produced under U.S. quality control requirements. Imported products may be subpotent (contain too little active ingredient) or superpotent (contain too much active ingredient). In the worst cases, imported medications may be contaminated, which can harm or permanently damage the body, causing paralysis, organ malfunction, or even death.

Safeguard Yourself with Knowledge & Consider this Advice:

1. **Are you getting what you ordered?** Once a product leaves the U.S. regulatory system, the product is at risk of becoming contaminated. Understand that other distributors are not held to certain storage standards or product labeling. You could be consuming a product that has become faulty due to temperature conditions or one that is simply the wrong product.

2. **Do your local doctors and pharmacists know what you are taking?** Drug interactions with other medications are something doctors and pharmacists consider before prescribing and dispensing prescription medications to patients. You may be taking a medication that will become ineffective or cause harm when taken in conjunction with another medication.

   Patients often see different doctors for different examinations, creating the potential for drug interactions. To protect against this risk, patients should use ONE pharmacy for their medication needs. Pharmacists ensure that a patient receives the right medication in the right dose. Pharmacists also check for interactions by maintaining a patient's medication history, thus protecting the patient from receiving the wrong medication. If you choose to import your medications, be sure to discuss those medications with your doctor and pharmacist.

   In addition, some web sites offer medications for sale without the patient receiving a physical examination. Bypassing direct contact with a doctor or pharmacist puts the patient at higher risk to receive inappropriate medications.

3. **Are you getting the most from your medication?** Medications are powerful technology and are only safe when used appropriately. Appropriate medication use involves more than just getting the product; it also requires understanding how to use the medication, including monitoring for unwanted side effects and potential interactions with other medications. Pharmacists are the patient's partner in making the best use of medications.

What You Should Know About Internet Pharmacies:

There is a portion of our population for whom Internet Pharmacies offer valuable benefits. Some patients may feel more comfortable communicating personally sensitive health information to a pharmacist via the Internet. There are *two important points* patients must be aware of when selecting any pharmacy:

MEDICATIONS ARE SAFE – WHEN USED CORRECTLY.

As part of that correct use of medications, patients should keep the following things in mind when choosing a pharmacy whether a local pharmacy, mail order pharmacy, or an Internet pharmacy.

Preferably, patients should use only *ONE* pharmacy source. Using just one pharmacy decreases the possibility of patients suffering a harmful drug interaction because they've gotten their medications from multiple sources such as an Internet pharmacy *and* their community pharmacy.

If getting acute prescription medications (like an antibiotic) from a local pharmacy, the patient should alert the local pharmacist about other medications they are already taking.

Patients should always have access to a pharmacist. All patients should have a telephone number to contact their pharmacist, whether they use a local pharmacy, mail order pharmacy, or Internet pharmacy. This is particularly significant for patients using a mail order pharmacy or an Internet

pharmacy. They do not have the option of visiting the pharmacist to ask questions about their medications in person.

Some Services Provided by Your Local Pharmacist Cannot be Transmitted over a Modem

Patients choosing to use an Internet Pharmacy should consider the following:

1. **With current technology, an Internet pharmacist cannot check the patient's blood pressure or blood cholesterol level to help the patient monitor his drug therapy.** Unless the Internet Pharmacy and consumer both have video teleconferencing capabilities, allowing the patient and pharmacist to see one another as they interact, pharmacists will not be able to observe signs or behaviors that may be important indicators of symptoms and potential adverse responses to drug therapy.

2. **Are Internet pharmacies licensed to serve patients in my State?** Assuming the internet pharmacy is located in the United States , individual state boards of pharmacy license pharmacists and pharmacies and establish the regulatory framework for protecting the public health.

   The National Association of Boards of Pharmacy (NABP) developed a system to verify licensure of Internet Pharmacies—the Verified Internet Pharmacy Practice Site™ (VIPPS) certification. NABP is located in Park Ridge , Illinois . The organization can be reached by telephone at (847) 698-6227. Their Internet Site URL is http://www.nabp.net.

3. **Will I have access to a pharmacist to answer my questions about medication use?** Regardless of the type of pharmacy, patients should select a pharmacy that has a pharmacist available to answer questions. In order to help make the best use of their medications, patients should consult a pharmacist to make sure that they receive the RIGHT medication, in the RIGHT dose, with the RIGHT information.

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