Statement
of the

American Pharmacists Association

Submitted to the House Committee on Government Reform Subcommittee on Criminal Justice, Drug Policy, and Human Resources

On "Pharmaceutical Supply Chain Security"

July 11, 2006

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Chairman Souder, Ranking Member Cummings, and members of the Subcommittee, thank you for the opportunity to appear before you this morning and to present the views of the nation's pharmacists on the issue of securing our pharmaceutical supply chain. I am Susan C. Winckler, a pharmacist and an attorney, and Vice President for Policy & Communications and Staff Counsel for the American Pharmacists Association (APhA). APhA, founded in 1852 as the American Pharmaceutical Association, represents more than 57,000 pharmacist practitioners, pharmaceutical scientists, student pharmacists, pharmacy technicians, and others interested in advancing the profession. APhA members provide care in all practice settings such as community pharmacies, hospitals, long-term care facilities, managed care organizations, hospice settings, and the military.

We commend the Subcommittee for reviewing one of the most critical, but largely unrecognized, issues facing our nation's health care system. Prescription medications are one of the most valuable weapons we have in our health care arsenal today. Unfortunately, because of their value, medications are highly susceptible to counterfeiting. With our current comprehensive federal regulatory system, few consumers perceive a threat from counterfeit medications – and for the most part, that perception matches reality. But counterfeit drugs *have* penetrated our system and we must increase our efforts to protect against future penetrations.

A pharmacist's worst nightmare is providing a patient the wrong medication or a medication that could harm them. We diligently review the accuracy and safety of prescriptions and intervene when necessary. But an even more troubling nightmare is presented by skillfully counterfeited medications. Our work is based on the underlying assumption that the medication we receive from the wholesaler or directly from the manufacturer is legitimate. In the counterfeit situation, the prescriber, pharmacist, and patient have done everything right—but the patient is at great risk. A counterfeit product contaminated with bacteria or poison, containing little active ingredient, or made with the wrong chemicals can cause great harm, permanent injury or disability, and even death. This is why pharmacists have considered anti-counterfeit activities a core of pharmacy practice. And APhA applauds the efforts of the Food and Drug Administration (FDA), the National Association of Boards of Pharmacy (NABP), drug wholesalers, and drug manufacturers to stem these illegal activities.

According to the FDA's 2004 Counterfeit Report[1], the number of counterfeit drug investigations increased four-fold from the late 1990s to 2004. These investigations discovered, for example, counterfeit Epogen®, Procrit®, and Lipitor® on pharmacy shelves and in patients' homes; and counterfeit Ortho Evra® contraceptive patches (with no active ingredient) being sold online by a company based in India. Additionally, a February 2006 World Health Organization (WHO) report [2] states that counterfeits are estimated to represent more than 10% of the global drug market — an estimated 25% of the medications consumed in developing countries. Furthermore, the Center for Medicine in the Public Interest predicts that counterfeit drug sales will reach $75 billion globally in 2010, an increase of more than 90% from 2005.

These statistics reflect a greater number of counterfeit drugs available for consumption, in the U.S. and elsewhere, and requires us to ask whether we can we continue to trust the drug products that we, as pharmacists, dispense to our patients. Can patients, pharmacists, and prescribers trust that the products we ingest, apply, or inject will do what they are supposed to do − and nothing they are not? That trust requires strong systems applied with vigilance, including developing mechanisms to better ensure that drug products are safe and that patient care will not be disrupted or damaged.

The protection of our medication supply, 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 compromised, is critically important to pharmacists, both as consumers and health care professionals. It is likely each one of us took some medication this morning—whether a prescription for a chronic condition or infection or perhaps an over-the-counter pain reliever for a headache. It is highly unlikely that we paused for even a second to consider whether than product contained everything it should and nothing it shouldn't. Hundreds of times a day, pharmacists similarly assume that a product that has gone through the 'normal' supply chain and that appears to be manufactured and labeled according to the FDA's specifications, is legitimate.

Pharmacists serve as the last line of defense in protecting patients from counterfeit medications. Recognition of this role, however, is not consistent. Our role and the impact of anti-counterfeiting initiatives on pharmacy practice are not always fully considered. APhA supports enhanced efforts to combat counterfeiting, including advanced technologies and coordination of efforts by all interested parties: including manufacturers, wholesalers, pharmacists, and patients. Our support is tempered, however, by the need to minimize the impact on our patients and recognizing the reality that as pharmacists, we are working with limited resources. Any anti-counterfeit initiatives must include assessments of both the costs and benefits. As Congress seeks to close gaps in our system, it must assess the impact any proposed solutions might have on pharmacists and our ability to serve patients.

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[1] http://www.fda.gov/oc/initiatives/counterfeit/report02_04.html
[2] http://www.who.int/mediacentre/factsheets/fs275/en/

Role of the Pharmacist

Pharmacists fight counterfeit drugs in their three roles as:

1. Prudent purchasers,
2. Patient educators, and
3. Reporters of possible counterfeit activities.

Pharmacists Fight Counterfeit Drugs by Being Prudent Purchasers

As prudent purchasers, pharmacists limit their purchases to legitimate sources. Buying only from licensed wholesalers is essential, and the quality of that licensure process must be more than a simple administrative process. Our ability to identify legitimate providers is directly related to the legitimacy of the regulation of those entities. If a license merely confirms the validity of the credit card number or check submitted with the application, then the usefulness of the licensure is minimal.

Regulators must have adequate power and resources to assure that participants in the supply chain are held to a sufficient standard and eliminated from the system if they fail to meet that standard. And although we are often bombarded with solicitations for deals on medication, we also know that deals that sound 'too good to be true' likely are. Upon receiving the products, pharmacists and their staff review the shipments to ensure that the products have been handled properly and securely; and pharmacists are vigilant when storing products. In addition to counterfeiting risks, many medications can be affected by temperature, humidity, and light.

Our purchasing efforts require a strong, consistent regulatory system with clear coordination between the federal and state regulators. These regulators must have clear roles, authority, and resources to implement existing and any new anti-counterfeiting initiatives.

Pharmacists Fight Counterfeit Drugs by Educating Patients

As educators, we help our patients understand the medications they take and what effects to expect. We also help patients understand the need to bring certain information to the attention of their pharmacist and their doctor. While much of this education is relevant to the knowledge and skill generally necessary to make the best use of medications, patients also play a role in identifying and eliminating counterfeit medications. Just as pharmacists must be prudent purchasers themselves, the purchasing habits of patients play into this system. But patients who ignore this information by circumventing the US drug regulatory system circumvent its protections. Whether illegally importing medications from another country or frequenting a gray-market provider in their home town, patients themselves support the counterfeit system and increase their risk of taking a harmful or even deadly drug. Importation, particularly personal importation, raises patients' risk of receiving a substandard or fake medication substantially by exposing patients to drug providers who are 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 importation. But few have addressed the increased risk of importing counterfeit drugs.

The FDA has reported[3] that spot examinations of mail shipments of foreign drugs to U.S. consumers revealed that these shipments often contain dangerous or unapproved drugs that pose potentially serious safety problems. Assessing the quality of these products provided outside our regulatory system is challenging in the best of circumstances—where original manufacturer packaging is used and a licensed foreign pharmacy involved. Protecting against counterfeit products is extremely compromised when the products are improperly packaged and shipped loose in sandwich bags, tissue paper or envelopes, or are labeled inadequately, such as those with missing dosage information or labeling that is not in English.

To protect against the harm that may be caused by such products, pharmacists work with patients to help them understand the importance of reporting any changes they notice in the look and feel of their medication, its labeling, and its effect. While many changes in product appearance are the result of expected and regulated manufacturing changes, such differences can indicate a counterfeit product. Similarly, a difference in taste or feel may be nothing to raise concern or it may indicate a compromised supply chain. Bringing such differences to the attention of their pharmacist and doctor can help identify a fake product. But patients need to be aware of the importance of reporting and 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. When a patient reports an atypical adverse reaction, unusual side effect(s), or unexplained treatment failure, pharmacists can use their clinical skills to rule out counterfeit medications.

An often over-looked side effect of counterfeit medications is the effect on legitimate medication use. As news of counterfeit medications emerges in the media, some patients stop taking their *legitimate* prescription medications because of fears about the product. For someone on blood-pressure lowering medicine or asthma medication, stopping therapy could prove deadly. Patients must understand their individual risk of having received counterfeit medication and the need to continue their current therapy. While media reports provide some of this information, the real education occurs between individual patients and their pharmacist.

If counterfeit medications are detected, it is pharmacists who field the vast majority of questions from patients about the products and the individual patient's risk of having received a counterfeit product as well as what risk might have been posed by the product. Essential to this role is receiving accurate information about the scope of the problem and potential effect on patients, as well as clear recommendations for action. This information must reach pharmacists and physicians at least at the same time such information is provided to the mass media. While CNN may be an excellent venue for providing information about the problem, it is the health care system that must provide the translation of that information for individual patients.

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[3] Statement of John M. Taylor, III Associate Commissioner for Regulatory Affairs Food and Drug Administration before the Permanent Subcommittee on Investigations Committee on Governmental Affairs, July 22, 2004

One way APhA focuses on the importance of patient education is through American Pharmacists Month, an annual event each October where our public education campaign encourages patients to get to know their pharmacist and their medications — the name of their medication and why they take it, what their medication looks like and how it makes them feel — and to talk to their pharmacist if they notice any differences.

Pharmacists Fight Counterfeit Drugs by Reporting Suspicious Activities to the Right Authorities

Pharmacists regularly notify the FDA and other appropriate agencies of suspected counterfeit drugs. Pharmacists' visual confirmation of a problem with packaging, labeling, or the medication itself (capsule size, color, smell, etc.) may trigger a formal investigation of the product. To visually confirm legitimate drugs, pharmacists must stay abreast of changes in drug appearances, labeling and packaging. Reporting systems must be simple and easy to navigate to support reporting by pharmacists and other health care professionals.

System Improvements that APhA Recommends Congress Facilitate

1. Access to Information

Essential to fulfilling each of these roles is information. Without accurate and timely information, our efforts are thwarted. We must build upon successful systems and assure that agencies are sufficiently staffed to provide necessary communications. Some infrastructure exists today. In February 2004, the FDA created the Counterfeit Alert Network, a coalition of health professional and consumer groups to facilitate counterfeit drug-related communications. The Network has three goals:

- to disseminate alert messages to a wide audience about specific counterfeit drug incidents in the U.S. and measures to take to minimize exposure (recall information, for example);
- to develop educational information about the roles and responsibilities that consumers, pharmacists, other health professionals, and wholesalers should play to identify counterfeit drugs, report suspect counterfeit drugs, and prevent them from entering the U.S. drug distribution system; and
- to develop a network of national organizations, consumer groups, and industry representatives to help distribute the information.

In the event of a confirmed counterfeit case in the United States, FDA will send an alert to these partners. The agency also will send partners a notice if a counterfeit incident is confirmed elsewhere in the world that could affect U.S. patients. APhA is a member of this important collaborative effort. While we hope it is a resource that we will have little need to use, it is essential infrastructure to mitigating the damage of counterfeit products. To assure the success of this initiative, the Agency must have sufficient funding to support this infrastructure.

2. Make Monitoring More Consistent, and Counterfeiting More Difficult, by Moving to a Nationwide Electronic Pedigree

While pharmacists function as the last institutional protection in the prescription drug supply chain, protection against counterfeit products must occur at every step in the process. Effective protections require strong, consistent oversight. Each Member of this Subcommittee is likely familiar with a common anti-counterfeiting intervention: the pedigree, a mechanism documenting the movement of medication from manufacturer to the pharmacy or other distributor. Legitimate pedigrees provide pharmacists, pharmacies, and other members of the supply chain documentation of the medication's path within the distribution system. Having access to such information is essential, but the pedigree requirement must provide more protection than a paper fig-leaf. Counterfeiters capable of reproducing product labels and medications themselves are quite capable of counterfeiting the accompanying paper pedigree.

Our concerns with a paper-based system have not dissipated since the year 2000 when we submitted comments to the FDA on the topic, although our confidence in the distribution system has changed. 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. 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. Additionally, pedigree requirements must be implemented in a manner that provides the highest degree of valid information with the least disruption to operations. Requiring members of the supply chain to produce and distribute massive amounts of paper that may or may not be legitimate is not a good use of resources.

APhA supports the FDA's recent recommendation to implement relevant sections of the Prescription Drug Marketing Act (PDMA) via regulations regarding the pedigree on December 1 of this year, providing necessary policies are in place. The Agency's Compliance Policy Guide on this topic must be fully discussed and finalized before implementation—and the interests of all stakeholders considered. Manufacturers and wholesalers must implement the 'authorized distributor' in a way that accommodates both parties and does not allow one of those participants to arbitrarily assign 'authorized' status. Any designation of vulnerable products must be carefully developed, and a clear articulation of the agency's enforcement priorities provided.

To facilitate the implementation of these requirements, APhA supports the premise that these standards be applied uniformly across all states. Allowing states to develop and enforce stricter pedigree requirements creates the potential for the opposite to occur: inconsistent requirements for products that we know will cross state lines inherently create loopholes that unscrupulous operators will exploit. While APhA is hesitant to support federal pre-emption of state health regulation in many areas because of the great

role state regulators play in pharmacy practice and health care generally, the anti-counterfeiting success of drug pedigrees requires federal pre-emption.

Finally, the path to implementing 'e-pedigrees' must be clear and supported by these interim efforts. Issues of technology standards, cost, and patient privacy must be addressed by all stakeholders to yield a consistent, quality process. Congress should support discussion and resolution of these issues. E-pedigrees hold great promise, but a coordinated effort is essential to cost-effective implementation.

3. Implement Specific Anti-Counterfeit Packaging Protections

Because counterfeiters have proven themselves sophisticated and adaptable to advances in technology and changes in anti-counterfeiting efforts, APhA supports the use of both covert and overt anti-counterfeiting technologies. 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. Even as 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.

Another example of packaging protections is unit-of-use packaging. APhA supports adoption of unit-of-use packaging as the industry standard[4] for a number of reasons including anti-counterfeit measures. A unit-of-use package is a container system designed to hold a specific quantity of a drug product for a specific use and intended to be dispensed to a patient without any modification except for the addition of appropriate labeling. Such packaging can help enhance patient safety, patient compliance, and efficiencies in drug distribution. Unit-of-use packaging, implemented with yet-to-be-established industry standards, can deter counterfeiting by supporting tracking of each patient-unit of product. Congress can help stimulate the adoption of unit-of-use

[4] 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.

packaging by supporting the development of standards regarding the days supply, package size, and other necessary parameters.

4. Fairly Distributing Costs and Liability

We encourage the Subcommittee to consider that all anti-counterfeiting efforts affect the liability of supply chain participants. For pharmacists, it is important that the liability of the pharmacist equate with our liability in all other areas of practice—a standard of negligence. As health care professionals, we are (and should be) required to meet our responsibilities as that of a 'reasonable pharmacist' and our responsibilities in anti-counterfeiting efforts should be the same. Should counterfeit medications reach patients despite the best efforts of the pharmacists involved, those responsible for the counterfeiting should be responsible—not the health care professionals whose efforts were defeated by criminals. We commit to performing our roles within the health care system, but do not accept liability for the actions of others.

As noted previously, efforts to better protect our medication supply are necessary but the cost and practical implications of such efforts must be considered in identifying and implementing the right solutions. Technology advances present an opportunity to strengthen the safety of our drug supply. 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 policies around anti-counterfeit technologies are developed.

Conclusion

Thank you for your consideration of the views of the nation's pharmacists. APhA applauds your review of this important issue given recent increases in counterfeit medications. Vigilance against counterfeit medications is necessary to mitigate the risk that ineffective and/or harmful drugs could reach the hands of our friends, our family or us. However, as the Subcommittee 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 looks forward to working with the Subcommittee to ensure the integrity of our drug supply and to help decrease the likelihood of unscrupulous operators preying on consumers through their medicine cabinet.