NACDS
NATIONAL ASSOCIATION OF
CHAIN DRUG STORES

November 3, 2003

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

Subject: Counterfeit Drug Task Force Interim Report – Docket Number 2003N-0361

To Whom it May Concern:

The National Association of Chain Drug Stores is submitting written comments to the Food and Drug Administration (FDA) with our perspectives on initiatives that can help combat the introduction of counterfeit pharmaceuticals into the United States drug distribution system. These comments respond to the recommendations in the FDA Counterfeit Drug Task Force Interim Report (October 2003).

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NACDS represents 210 chain pharmacy companies that operate nearly 35,000 community retail pharmacies. Our members provide almost 70 percent of the 3.1 billion retail prescriptions dispensed annually.

The drug distribution system in the United States is efficient, and the safest and most secure in the world. We are proud of the systems that we have developed with our trading partners in the pharmaceutical distribution system to assure the delivery of prescription medications to consumers in a timely manner.

While safe, the pharmaceutical distribution system is not impervious. There are gaps in the distribution system where opportunities exist for introducing counterfeit products that would compromise the integrity of the system. Counterfeiters' tactics demonstrate a high level of sophistication. Therefore, solutions must be developed that are equally or more sophisticated. Retail pharmacies have an interest in assuring the integrity of the drug products they dispense to patients.

I. NACDS Supports Steps to Assure the Integrity of the Drug Distribution System

NACDS appreciates the FDA's call for ideas on how to increase the security of the drug distribution system. It is critical to the chain drug industry that consumers have confidence in their pharmacists. It is equally important that physicians and pharmacists have confidence in the integrity of the drugs they prescribe and dispense. It will take a concerted effort of all affected parties to make the system more safe and secure. We agree with the FDA that there is no "magic bullet" to solve these very serious counterfeiting problems, but we stand ready to work with the FDA to develop solutions that will work.

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NACDS and its member companies are enthusiastically supporting the efforts of the FDA to study the issues surrounding drug counterfeiting and to help them find solutions that are realistic and cost-effective. While NACDS is taking the opportunity to submit comments here, a parallel NACDS effort is underway to develop a list of more comprehensive suggestions. The NACDS Leadership Council, which consists of manufacturers, wholesalers and retail pharmacy chains, has taken on prescription drug counterfeiting as a priority concern. To help the FDA and the drug distribution supply chain develop options to reduce the chance for the introduction of counterfeit drugs, we have formed three interdisciplinary working groups to target specific policy issues relative to counterfeiting: Regulatory and Enforcement Measures; Business Policies and Practices; and Technology Prevention Measures.

We are reviewing federal and state laws and regulations on drug distribution, examining current business practices, and considering suggested recommendations and guidelines for the future. We are studying technology solutions and considering the financial impact on the drug distribution industry. We are looking at the current penalties for counterfeiting and suggesting that they be changed or increased. We will have our final report available to the FDA in early December, 2003. We hope that the FDA will consider these recommendations when making its final report in January 2004.

II. NACDS Response to FDA Interim Report and Initial Suggested Solutions

NACDS and its member companies are eager to quickly develop solutions that ensure greater integrity of prescription drug products. However, it is important to take a multi-pronged and phased-in approach over an appropriate period of time to cause the least disruption to the current system.

In its interim report, the FDA lays out potential options to address prescription drug counterfeiting. While there are many suggestions listed in the FDA interim report that pharmacies can support, some suggestions raise concerns because they could have a counterproductive impact on our industry and our ability to provide cost effective pharmacy services. Because the high cost of drugs is a primary issue driving counterfeiting, solutions that increase costs could backfire. In our final report to the FDA, we will identify the most realistic and cost effective options to address this problem industry-wide.

The following is our perspective on various steps or solutions that have been suggested to help reduce the opportunities for counterfeit drugs to enter the pharmaceutical supply chain.

A. PDMA and Pedigrees

An option often mentioned to help assure the integrity of the pharmaceutical distribution system is to require the use of a "statement of origin," also known as a drug "pedigree." Under the Prescription Drug Marketing Act (PDMA), drug wholesalers would maintain drug pedigrees to track each sale or other transfer of a prescription drug through the drug distribution chain. However, a wholesaler that qualifies as a manufacturer's "authorized distributor of record" (ADR) would not have to maintain pedigrees.

In 1999, FDA published final regulations implementing the provisions of the PDMA. The provisions concerning the pedigree requirements at 21 CFR 203.3(u) and 203.50 were stayed by FDA because of valid concerns expressed by industry, trade associations, and Congress about implementing these provisions. Those concerns included the high cost and logistics of maintaining a paper pedigree system and the inability to obtain a pedigree from an ADR, thus calling into question the usefulness of the pedigree. These requirements would impose substantial costs at a time when access to affordable drugs is also a major policy concern.

In 2001, the FDA submitted a Report to Congress outlining the concerns raised by the secondary wholesale industry. The FDA noted that in order to enable secondary wholesalers to fully comply with the pedigree requirements, Congress would have to amend section 503(e) of the Act to enable secondary wholesalers to obtain the transaction history from all prior purchasers of the drug, since ADRs are exempt from providing this information. To give Congress time to consider the information and conclusions contained in the FDA's Report to Congress, and to determine if legislative action was appropriate, the FDA instituted a stay of the provisions until April 1, 2004.

The FDA should carefully consider what it will do after April 1, 2004. Radical measures to implement a comprehensive paper pedigree system would be significantly disruptive, cost inefficient, and would do little to solve the problem.

1. The Costs of Paper Pedigrees Outweigh the Benefits

A paper pedigree system is not the answer to counterfeiting problems. A paper pedigree requirement would raise the cost of drugs by adding significant administrative expense to the distribution system. Raising the cost of drugs could make drug counterfeiting more profitable, so a paper pedigree requirement may inadvertently encourage additional drug counterfeiting.

In addition to being costly, tracing a drug pedigree on paper is subject to multiple record keeping failures and fraud. Failure to require ADRs to maintain pedigrees would create a major recordkeeping hole in the pedigree requirement. Worst of all, sophisticated drug counterfeiters would no doubt find it easier to counterfeit a paper pedigree than it is to counterfeit the drugs themselves.

We also believe that any pedigree system must enable pharmacies to return outdated or unused products to pharmaceutical manufacturers. This is an important part of pharmacies' inventory management control, and eliminating the ability of pharmacies to make returns would be significantly disruptive to the pharmaceutical supply chain.

2. Electronic Pedigrees May be a Better Solution

NACDS supports the direction in which the FDA is moving to establish electronic pedigrees. As the FDA has observed, there are many promising developments in anti-counterfeiting technology that will enable the creation of an electronic pedigree for a drug product, thus reducing the need for paper pedigrees. This approach is consistent with the desired movement toward electronic health information systems to prevent errors and adverse events. This would also make it easier

to maintain the high level of diligence needed throughout the drug distribution system to prevent the introduction of counterfeit drugs.

Unfortunately, track and trace technology solutions are not yet ready for full implementation of an electronic pedigree system. FDA can promote the rapid implementation of track and trace technology by encouraging the industry to develop and adopt technology standards.

3. A Possible Interim Solution: "One Forward, One Back"

Because it will take time before an electronic pedigree system can be implemented, some have proposed that FDA should impose a paper pedigree requirement as an interim measure. Rather than a full paper pedigree, we are considering the impact on the pharmaceutical supply chain of a "one forward, one back" system for high risk drugs.

This one forward, one back system would be analogous to the system established for food distributors in recent bioterrorism legislation. Rather than requiring a complete pedigree all the way through the system, Congress deemed it sufficient to require participants in the food distribution system to maintain only those records necessary to identify "the immediate previous sources and the immediate subsequent recipients of food...in order to address credible threats of serious adverse health consequences or death to humans or animals." *See* Public health Security And Bioterrorism Preparedness And Response Act Of 2002, P.L. 107-188, § 306. This innovative approach could help guard against drug counterfeiting without adding inappropriate cost burdens on the drug distribution system

B. Wholesaler Licensing Requirements

As part of the implementation of PDMA, FDA published a final rule containing "Guidelines for State Licensing of Wholesale Prescription Drug Distributors." *See* 21 CFR Part 205. The guidelines included the minimum standards for storage and handling of prescription drugs and for the establishment and maintenance of records of their distribution. The guidelines followed the "Model Regulations for Wholesaler Drug Distribution" (Model Rules) issued by the National Association of the Boards of Pharmacy (NABP), which were previously issued as an example for states to adopt in order to comply with the PDMA. Subsequently, all 50 states have enacted legislation to implement the PDMA.

As the introduction of counterfeit drugs has increased over the past several years, some states, such as Florida and Nevada, have adopted laws and regulations with more stringent requirements intended to minimize the risk of counterfeit drugs appearing in their state. NACDS favors more stringent licensing requirements for wholesalers, but we believe there should be balance in the regulatory approach to weigh cost, burden and impact.

For example, Florida enacted a law in 2003 that has been suggested as a nationwide model for regulations that will help solve counterfeiting problems. However, the Florida law is overly restrictive and burdensome on retailers.

- Florida requires paper pedigrees for 30 specified drugs that identify each previous sale back to the manufacturer, including lot number and invoice number. In July 2006, all prescription drug purchases will be affected by the new regulations. Retailers cannot maintain such histories down to the lot and container. Wholesalers in Florida have notified retail chains that they will no longer be able to return any of the 30 specified drugs for any reason, citing the paper pedigree requirement as their justification. The fact that pharmacies cannot return overstocked or outdated pharmaceutical items, which is a common industry practice, will affect pharmacy's purchasing practices and thus may affect the cost and supply of drug products within pharmacies available to be dispensed to patients.

- Under the Florida law, chain distribution centers are considered secondary wholesalers and have to meet the same requirements as secondary wholesalers. This was not the intent of the legislation and we hope to correct that in the next legislative session.

The FDA Task Force is working closely with the NABP to update the Model Rules and is in the process of reviewing the 50 state practice acts that govern wholesale distribution of prescription drugs, identifying strengths and weaknesses of those acts, and suggesting where the Model Rules can be updated. NACDS has been invited and will be part of this process. We will advocate more stringent licensing requirements, while protecting the interests of retail pharmacies from an overly burdensome regulatory and licensing regime.

Overall, requirements relating to the licensing of wholesalers should be strengthened. NACDS suggests that states enact stricter requirements for licensure of wholesalers, require more frequent inspections of wholesalers, and require that significant bonds be posted by wholesalers. Federal regulation should create a minimum floor for these licensing requirements, which should be developed in cooperation with state boards of pharmacy and affected entities. These requirements can help reduce the number of "fly by night" or illegitimate secondary wholesaler operations that are established mainly for the purpose of selling counterfeit drugs.

C. Repackagers

NACDS supports strengthening regulation and licensing of pharmaceutical repackagers, but we do not support the elimination of repackaging. Some repackaging operations are more insular and protected than others that are more susceptible to diversion. We recognize that any track or trace technologies that are eventually adopted for use in the pharmaceutical supply chain would have to be applied to products that are repackaged for retail pharmacy distribution outlets.

Some NACDS members repackage bulk quantities of pharmaceutical products into smaller prescription-size quantities of product, and send them to their own retail distribution outlets for subsequent distribution to patients. Repackaging operations are a benefit to pharmacies and the consumer because they reduce drug costs and offer convenient and manageable quantities of delivered drug product. Some repackaging operations, however, have been identified as a vulnerable link to counterfeiting in the drug supply chain. We support addressing how these vulnerable operations should be eliminated or required to adhere to more strict regulations.

D. Direct Purchasing from Manufacturers

FDA's interim report suggested that certain products should be purchased directly from drug manufacturers and sent to pharmacies, rather than shipped through the traditional wholesaling channel. The administrative complexities of requiring pharmacies to purchase directly from drug manufacturers would be enormous, even if the requirement applied to only a limited number of products. There are 55,000 retail pharmacy outlets and dozens of brand name drug manufacturers. Both pharmacies and manufacturers realize the value that wholesalers bring to the system by serving as a convenient conduit between the makers and dispensers of drug products. There is no realistic way that every pharmacy can order and track shipments of pharmaceutical products from multiple manufacturers. Likewise, manufacturers would rather deal with a limited number of wholesalers rather than 55,000 pharmacies in terms of shipping and tracking their products. These various administrative tasks would only increase costs to the system, without providing much of a tangible benefit.

E. Unit of Use Packaging

Unit of use packaging has been proposed as one solution to the counterfeit pharmaceutical problem. NACDS believes that such packaging can be useful for some products. However, for the majority of prescription products on the market, a quick migration to such a system would be unworkable. Many prescription drug therapies do not lend themselves to standardized quantities for dispensing, such as 30 units or 100 units. As a result, pharmacies would likely have to keep double inventory of the same products; that is, drugs available in unit of use packages, but also bulk quantities of the same medications for orders that did not conform to the commercially-available unit of use package size. There are many third party payor issues with unit of use. For example, many third party programs pay for a limited number of days' supply of medication. Quantities in unit of use packaging beyond the limit would not be reimbursable. These are significant issues, given that up to ninety percent of the average chain pharmacy's prescription business is reimbursed by third party payors.

State pharmacy regulations would need to be revised for pharmacists to independently change the prescribed quantity of medication in order to use a standardized unit of use package. Obtaining physician approval to change a significant volume of prescriptions from the prescribed amount to a unit of use quantity would be incredibly burdensome, and would necessitate a significant number of phone calls by pharmacies to physicians' offices each day.

F. Education of Health Care Professionals and Consumers

Alerting and educating health care professionals and consumers in a timely manner about counterfeit pharmaceutical products is essential. NACDS believes that the FDA should work with professional and trade associations representing the components of the pharmaceutical supply chain on these efforts. Real time exchange of information is the best way to communicate this information, given the potential negative public health consequences of not removing these products from the system.

When the FDA is ready to implement an alert system on counterfeit products, it should seriously consider ChainDrugStore.Net as a proven tool that can quickly reach many of the stakeholders. ChainDrugStore.Net is a targeted retail pharmacy industry platform that will ensure real-time communication of critical information from the FDA the moment it is released. Many chains provide information from ChainDrugStore.Net down to the pharmacy level, providing a quick, reliable way to inform practicing pharmacists about counterfeit products, diverted products, or recalled products.

G. Drug Importation

Importation of drugs for personal use from foreign countries poses a serious threat to the health and safety of Americans. Drug importation, via foreign websites or "store fronts" in the United States, offers a significant and growing avenue for counterfeit drugs to enter the country. The proposals we and the FDA have discussed to strengthen our closed drug distribution system will be in vain if personal importation of drugs is legalized. Greater licensing of wholesalers, drug pedigrees, and other proposals discussed in the FDA Task force's report will not prevent counterfeiting if counterfeiters are allowed to mail their products to consumers from foreign countries.

Therefore, we strongly support the FDA's recent efforts to enforce the laws against illegal drug importation. We also urge the FDA to continue to educate consumers about the threats to their own personal safety resulting from personal importation of pharmaceuticals from other countries. In addition to being told that this practice is illegal, consumers may not be aware that websites may not be providing drugs from the country they say they are.

III. Conclusion

We very much appreciate the opportunity to provide our preliminary reaction to concepts outlined in the FDA's interim report, as well as our perspectives on potential solutions to deterring the introduction of counterfeit drugs. We reiterate that we will have a more complete report ready for the agency's review in December that we hope will provide consensus suggestions from the pharmaceutical distribution supply chain. We look forward to working with the FDA, state boards of pharmacy, and our supply chain partners in assuring the safety and integrity of the pharmaceutical distribution system. Any questions about these comments should be directed to myself, or Mary Ann Wagner, Vice President, Pharmacy Regulatory Affairs, at 703-549-3001 X 136. Thank you.

Sincerely,

S. Lawrence Kocot
Senior Vice President and General Counsel