

February 24, 2006

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

To Whom It May Concern:

RE: Anti-Counterfeit Drug Initiative Workshop and Vendor Display – Docket Number 2005N-0510

The National Association of Chain Drug Stores (NACDS) is submitting written comments to the Food and Drug Administration (FDA) with our perspectives on initiatives that can help combat the introduction of counterfeit drugs into the United States drug distribution system. These comments follow up on our presentations at the Anti-Counterfeit Drug Initiative Workshop of February 8 and 9, 2006.

NACDS represents the nation's leading retail chain pharmacies and suppliers, helping them better meet the changing needs of their patients and customers. NACDS members operate more than 35,000 pharmacies, employ 108,000 pharmacists, fill more than 2.3 billion prescriptions yearly, and have annual sales of over \$700 billion. Other members include almost 1,000 suppliers of products and services to the chain drug industry. NACDS international membership has grown to include 90 members from 30 countries. For more information about NACDS, visit www.nacds.org.

NACDS believes the drug distribution system in the United States is one of the safest and most secure in the world. We are proud of the systems and initiatives that our members have developed with other industry stakeholders to improve the integrity of the U.S. drug supply chain. There have been a number of initiatives over the past few years by community pharmacy, wholesale distributors and manufacturers, as well as state-level legislation that represent practical and immediate actions that have had immeasurable positive impact on the drug supply chain's integrity.

A. NACDS Supports a Multi-Faceted Approach to Reduce the Risk of Counterfeit Drugs Reaching Consumers

NACDS appreciated the opportunity to testify at the Anti-Counterfeit Drug Initiative Workshop on February 8 and 9, 2006, and we appreciate the opportunity to share with FDA our written comments. It is critical to the chain pharmacy industry that consumers have confidence in their pharmacists and the prescription drugs they dispense. It is equally important that physicians and pharmacists have confidence in

413 North Lee Street
P.O. Box 1417-D49
Alexandria, Virginia
22313-1480

(703) 549-3001

Fax (703) 836-4869

www.nacds.org

the integrity of the drugs they prescribe and dispense. It takes a concerted effort of all parties in the prescription drug supply chain to make our drug distribution system among the safest and most secure in the world.

The community pharmacy industry consists of companies of varying sizes and technical capabilities. Our members range from the largest company in the world to others that have as few as four stores and a little over \$10 million in total annual sales. As we look for solutions that can be adopted by our industry, we need to recognize that not all companies have resources, be it financial, technical, or human, to be at the leading-edge of the technology curve. As FDA looks at potential technology solutions, we strongly urge you to consider that members of our industry have varying levels of resources, and that for a technology solution to work it must utilize nationally recognized and accepted standards, have been tested and proven to function, as well as be cost-efficient, and easy to implement.

In FDA's report *Combating Counterfeit Drugs: A Report of the Food and Drug Administration's Annual Update*, published on May 18, 2005, it was disclosed that while there were more counterfeit drug cases initiated in 2004 compared to 2003 most of the suspect cases were found in smaller quantities. In addition, "most of these drugs were destined for the black market or Internet distribution, rather than widespread distribution in the nation's drug supply chain."¹ At FDA's Anti-Counterfeiting Drug Initiative Workshop, we learned from FDA that the number of counterfeit drug cases in 2005 fell to almost half the number of cases in 2004. We believe that these results are directly attributable to the numerous changes that members of the legitimate drug supply chain have made in recent years.

While not discounting the possibilities that some of today's emerging technologies, such as RFID, may provide future improvements to the drug supply chain integrity, these technologies remain unproven and significant time will be required to fully develop and understand their capabilities. In the meantime, there are practical and immediate initiatives that have been undertaken to improve the integrity of the drug supply chain. Some of these initiatives have been driven by industry and some through legislation.

1. Community Pharmacy Initiatives

Community pharmacy has taken a leadership role in adopting practical and immediate steps to further ensure the integrity of the products they dispense. Many pharmacies have made changes in their purchasing practices such as requiring their wholesale distributors to purchase their products directly from manufacturers. Additionally, community pharmacy has steadfastly supported individual state efforts

¹*Combating Counterfeit Drugs: A Report of the Food and Drug Administration's Annual Update*; May 18, 2005; located at <http://www.fda.gov/oc/initiatives/counterfeit/update2005.html>.

to strengthen existing wholesale licensing requirements. These stricter requirements have removed the unscrupulous wholesale distributors from operating within the legitimate drug supply chain.

2. Wholesale Distributor Initiatives

The wholesale distribution industry has also taken dramatic steps to further ensure the integrity of the products they distribute. Many wholesale distributors, including the nation's three largest wholesale distributors, have indicated they would no longer trade with secondary wholesalers. This practice was historically a potential entry point for counterfeit products and contributed heavily toward drug diversion. The elimination of this practice creates a direct flow of product from the manufacturer to the wholesale distributor to the pharmacy, and finally to the patient.

Additionally, the wholesale industry has migrated towards a Fee-For-Service / Inventory Management Agreement relationship with manufacturers. This move has eliminated the speculative purchasing on the part of the wholesale distributors. Historically, this activity was an integral piece of the wholesale distributors' business model; it allowed them to capitalize on the incremental revenue that could be gained in advance of manufacturers' price increases. With the advent of these agreements, new relationships between wholesale distributors and manufacturers have been developed that have resulted in less excess inventory in the drug supply chain. Less excess inventory in the drug supply chain has helped to eliminate questionable entities from participating in the legitimate drug supply chain.

3. Pharmaceutical Manufacturer Initiatives

Pharmaceutical manufacturers have become more restrictive in their selling practices, ensuring that they sell their products only to legitimate operators within the drug supply chain. Manufacturers have also embraced the Fee-For-Service and Inventory Management Agreements with wholesale distributors as it allows them tighter control of the quantity of product in the drug supply chain at any point in time. Additionally, manufacturers are increasingly using overt counterfeit measures such as color shifting ink to make their products more difficult to counterfeit.

4. State Initiatives

Many states have adopted laws and regulations with more stringent requirements for licensure of wholesale drug distributors and drug distribution records intended to minimize the risk of counterfeit drugs appearing in their state. NACDS has been an active supporter of these efforts, but we believe there should be balance in the regulatory approach to weigh cost, burden, and impact.

Beginning with the state of Florida in 2003, twelve states so far have passed legislation to address counterfeit drugs. In addition, a number of states have made increased wholesaler licensing requirements a priority in this year's legislative agendas. We expect many additional states to follow in the coming years. The provisions that states have enacted greatly exceed the requirements of the PDMA. These state provisions include:

- Requiring wholesale distributors to post a \$100,000.00 bond
- Mandatory and increased inspections of wholesale distributors
- Background checks of wholesale distributor employees
- Requirements that the wholesale distributor have a designated representative who is personally responsible to a state agency for the actions of the operation
- Increased and strict penalties for statutory and regulatory violations
- Various types of pedigree requirements

These state provisions have often caused questionable entities to close down, thus eliminating bad actors from participating in the wholesale distributor market.

While there appears to be uniformity in the states efforts to strengthen wholesale licensing requirements, no two states pedigree requirements are exactly the same. For instance, beginning July 1, 2006 the State of Florida will be requiring paper or electronic pedigrees documenting both the chain of custody and change in ownership for all wholesale distributions, the State of Indiana has adopted the "normal distribution channel" approach which requires pedigrees for only those products that are distributed outside the defined normal distribution channel, and the State of California on January 1, 2007 will require an electronic pedigree beginning with the manufacturer that documents only the ownership changes of a prescription medication. These differences in pedigree requirements present a significant challenge for community pharmacies.

We agree that requirements relating to the licensing of wholesale distributors should be strengthened. Federal regulation should create a minimum floor for these licensing requirements, which should be developed in cooperation with the affected entities. These requirements would continue to reduce the number of illegitimate wholesale distributor operations.

NACDS and our member companies enthusiastically support the efforts of FDA to find solutions that are realistic and cost-effective, and we thank FDA for the opportunity to continue to develop workable solutions. However, we believe that these practical and immediate industry initiatives combined with state-level initiatives represent viable solutions.

5. PDMA and Pedigrees

An option often mentioned to help assure the integrity of the drug distribution system is to require the use of a “statement identifying prior sales,” also known as a drug “pedigree.” Under the Prescription Drug Marketing Act (PDMA), wholesale distributors are required to maintain drug pedigrees to track each sale or other transfer of a prescription drug through the drug supply chain. However, a wholesale distributor that qualifies as a manufacturer’s “authorized distributor of record” (ADR) does not have to pass or maintain pedigrees.

In 1999, FDA published final regulations implementing the provisions of the PDMA. The provisions concerning “ongoing relationships” at 21 CFR 203.3(u) and the pedigree requirements at 21 CFR 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 prescription drugs for consumers is also a major policy concern.

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

In 2004, FDA further delayed the effective date until December 1, 2006 to give stakeholders in the drug supply chain time to focus on implementing widespread use of electronic pedigrees across the prescription drug supply chain and to consider the effects of adoption of electronic track and trace technology on the pedigree requirements of the PDMA.

We appreciate that FDA has delayed the pedigree requirements of the PDMA to give stakeholders time to consider the effectiveness of track and trace technologies, such as RFID. We must respectfully request that FDA continue the delay of the pedigree requirements of the PDMA until Radio Frequency Identification (RFID) technology is widely available. We cannot give FDA an exact date of when RFID technology will be widely available. However, as we heard from various experts at the recent workshop, RFID technology will not be widely available in the drug

supply chain for at least five to ten years. Consequently, we respectfully ask FDA to continue the delay of the pedigree requirements of the PDMA for at least another five to ten years, while simultaneously encouraging state efforts to strengthen wholesale distributor licensing requirements.

i) *Paper Pedigrees Are Unworkable*

A *paper* pedigree system is not the answer to counterfeiting problems. Linking a piece of paper to the billions of products that move through the prescription drug supply chain is logistically impossible. Any attempt to do so would lead to astronomical costs being passed down to pharmacies, which have no ability to absorb these costs. Moreover, raising the cost of drugs would make drug counterfeiting more profitable, so a paper pedigree requirement may inadvertently encourage additional drug counterfeiting and/or adulteration.

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

ii) *Electronic Pedigrees Are a Better Solution*

NACDS supports the direction that FDA is moving to establish *electronic* pedigrees and to promote the promise of RFID technology. As FDA has observed, RFID technology promises to eventually eliminate the need for paper pedigrees. Unfortunately, RFID technology solutions are not yet ready for full implementation across the drug supply chain. FDA can promote the implementation of RFID technology by encouraging the industry to develop and adopt the necessary standards. We believe that any requirement for pedigrees before RFID track and trace technology is widely available and nationally standardized will cause stakeholders to incur incalculable costs resulting from a variety of temporary alternatives to RFID that ultimately will not succeed. This will cause them to invest time, effort and capital into other less beneficial e-pedigree technologies, thus taking resources away from implementing nationally standardized and operational RFID technology. Consequently, RFID technology implementation would be further delayed.

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 related to RFID.

B. NACDS' Recommended Solutions

Again, we ask that FDA continue the stay on the pedigree requirements of the PDMA for another five to ten years, to give the necessary stakeholders in the drug supply chain time to adopt RFID technology. However, if FDA decides that more immediate action is necessary, then we would like to recommend to FDA solutions that are more reasonable than a mandate of pedigree requirements across the drug supply chain starting December 1, 2006.

1. PDMA v. "Normal Distribution Channel"

i) PDMA's "ADR" Designation is Problematic and Should Be Eliminated

Under the PDMA and the subsequent final rule, pedigrees are only required in those instances when a wholesale distributor is not an Authorized Distributor of Record (ADR). We find the ADR approach to be problematic, and we would encourage FDA to work with Congress to amend the United States Code to eliminate this designation. We believe the fact that ADRs are exempt from the pedigree requirements of the PDMA to be a major factor that perpetuates problems in the wholesale distributor market.

First, the ADR exemption provides the opportunity for an unscrupulous wholesale distributor to essentially "launder" a pedigree by passing it to an ADR who is not required to pass a pedigree. Pharmacies then may receive drugs of questionable pedigree, unaware of where the drug has been. This creates an open hole in the drug supply chain and could potentially provide an entry point for counterfeit product.

Additionally, the definition of ADR is vague and subjective, leading many secondary wholesale distributors to believe that they are ADRs, when in fact they should not be considered such.

The ADR concept is difficult to manage from the perspective of the pharmacy and chain drug warehouse. For example, a manufacturer may grant ADR status to a wholesale distributor for certain products in their line, as opposed to the whole line. This is a problem because pharmacies and chain drug warehouses have to constantly manage that ADR status not only by wholesale distributor, but also by product. The ADR statuses of thousands of products have to be managed. This is logistically very difficult. Finally, the ADR status of a wholesale distributor may change at any time without the knowledge of the pharmacy or chain drug warehouse. A manufacturer may choose to revoke ADR status at any point in time and that communication may or may not be transmitted down to the pharmacy or chain drug warehouse. Pharmacies and chain drug warehouses have no way to know if a pedigree should be

required from the wholesale distributor because they don't know the wholesale distributor's ADR status.

Since we believe the ADR concept to be flawed and problematic, we urge FDA to continue to delay the provisions concerning "ongoing relationships" at 21 CFR 203.3(u) and the pedigree requirements at 21 CFR 203.50. If FDA were to lift the stay, it would send a message to the industry, consumers, and Congress that it agrees that the ADR concept is useful in reducing the likelihood that counterfeit drugs would be introduced into the drug supply chain. However, we believe the opposite to be true; that the ADR concept has perpetuated the counterfeit problem by allowing questionable pedigrees to be "laundered" by ADRs. Rather than allowing the rules in question to take effect, we urge FDA to work to establish a system similar to that of the "normal distribution channel" described below.

ii) "Normal Distribution Channel" Addresses Counterfeiting Concerns

NACDS supports a concept that has been adopted by many states including Arizona, Indiana, Oklahoma, and Texas, as well as embraced by the National Association of Boards of Pharmacy (NABP) and other stakeholders in the prescription drug supply chain, namely, the concept of the "normal distribution channel." Normal Distribution Channel has been defined as the: "chain of custody during distribution of prescription medication that goes from [1] the manufacturer to a wholesale distributor to a pharmacy or [2] the manufacturer to a wholesale distributor to a chain pharmacy distribution center to their intra-company pharmacy. Direct sales of prescription medication by a manufacturer to a pharmacy or chain pharmacy distribution center are also included within the normal distribution channel."

Under this concept, pedigrees are not required to be passed for prescription drugs that remain within the normal distribution channel. This approach treats each member of the prescription drug supply chain equally so long as they are purchasing and distributing prescription medication within the defined normal distribution channel.

NACDS believes that while both approaches attempt to achieve the same result, elimination of counterfeit product in the drug supply chain, the "normal distribution channel" approach is much more restrictive and provides greater assurance of a product's origin. We would like FDA to consider supporting and promoting state level initiatives that utilize the "normal distribution channel" approach. Further, NACDS would also request that FDA modify the 1999 Final Rule to incorporate the "normal distribution channel" approach.

To add another layer of security, we would also support a requirement that wholesale distributors be required to place a statement on invoices indicating that all drugs listed on that invoice were purchased originally from the manufacturer. Otherwise,

the wholesale distributor would have to maintain on file an authenticated pedigree for that drug.

2. Other Workable Solutions

i) “One Forward, One Back”

If FDA determines not to delay pedigrees, we would like FDA to consider a proposal that NACDS had recommended to FDA in the past to address the problem of counterfeit drugs, the concept of the “one forward, one back pedigree.” 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 astronomical cost burdens to the drug distribution system.

ii) Pedigrees Only for Susceptible Drugs

If FDA decides to move forward with the pedigree requirements of the PDMA at some time, and not endorse the “normal distribution channel” concept, then we ask FDA to limit pedigrees to only those drugs that are susceptible to counterfeiting, rather than requiring a pedigree for every drug that is distributed regardless of the likelihood that it would be counterfeited and distributed into the legitimate drug supply chain. Requiring pedigrees for generic drugs and other drugs of low cost would add unnecessary expense to the distribution of these drugs as these drugs would not provide profit incentives for counterfeiters. These expenses would be passed down to pharmacies, which have little or no ability to absorb these costs due to non-negotiable reimbursement rates from Medicaid, Medicare, and commercial managed care agreements. Requiring pedigrees only for susceptible drugs would be a cost effective method to reducing the likelihood that a patient would ever receive a counterfeit drug from the legitimate drug supply chain. Moreover, we would ask that FDA develop the criteria for inclusion on this list, and maintain the list, so that there is uniformity throughout all jurisdictions in the country. In the alternative, we ask that FDA not require pedigrees for generic drugs, as brand name drugs are the most likely targets for counterfeiters. This moratorium on generic drugs should not be lifted until RFID is economically feasible for use on these low-cost prescription drugs.

3. Education of Health Care Professionals

Alerting and educating health care professionals in a timely manner about counterfeit drug products is essential. NACDS believes that FDA should work with professional and trade associations representing the components of the drug 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 in a timely manner.

Through our affiliate, ChainDrugStore.net, NACDS is working with FDA to provide an alert system for counterfeit products. ChainDrugStore.net is a secure, online communication vehicle that provides manufacturers, government agencies, and other third party information providers the ability to communicate directly with more than 200 retail chains, wholesalers and independent buying groups representing more than 52,000 retail pharmacies. ChainDrugStore.net can deliver communications on a national level, as well as target by jurisdiction and channel of business.

ChainDrugStore.net is a member of FDA's Counterfeit Alert Network. ChainDrugStore.net can deliver critical information to its entire audience within an hour of notification, whether from FDA, or directly from a manufacturer. 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.

C. Drug Importation and the Black Market

No discussion about the problem of counterfeit drugs would be complete without addressing consumers' accessing prescription drugs from outside the legitimate drug supply chain, such as from foreign sources and through unscrupulous Internet-based vendors. FDA officials have stated that incidences of counterfeit drugs in the legitimate drug supply chain are rare, and that we can have no confidence in the safety or validity of a drug purchased outside the legitimate drug supply chain.

Importation of drugs for personal use from foreign countries poses a serious threat to the health and safety of Americans. Drug importation via unregulated Internet sites and/or "store fronts" in the United States offers a significant and growing avenue for counterfeit drugs to enter the country. The initiatives that we and FDA adopt to strengthen our closed drug distribution system will be in vain if consumers are continuing to access prescription drugs from these illegitimate sources. Greater licensing of wholesale distributors, drug pedigrees, and other proposals will not prevent counterfeiting if counterfeiters are allowed to mail their products directly to consumers from domestic operations and foreign countries.

We strongly encourage FDA to enforce the current laws against drug importation by non-manufacturers. We also urge FDA to continue to educate consumers about the threats to their own personal safety resulting from personal importation of drugs from other countries. In addition to being told that this practice is illegal, consumers may not be aware that this practice is also dangerous and potentially life-threatening.

D. FDA, RFID Adoption, and Standards Development

As we stated earlier in our comments, many states have adopted pedigree requirements. Unfortunately, no two states' pedigree requirements are the same. Moreover, we expect many more states to adopt differing pedigree requirements in the coming years. The U.S. drug supply chain is national in scope with drugs being shipped to and from every state in the nation. We believe an appropriate role for FDA is to work with the states to standardize the pedigree requirements nationwide and to support federal preemption to achieve national pedigree standards.

RFID technology offers much promise to allow electronic pedigrees to be easily transmitted among manufacturers, wholesale distributors and chain drug warehouses. However, presently there are no nationally set standards for RFID technology in the prescription drug supply chain. We urge FDA to work with industry stakeholders and EPCglobal to encourage and influence the adoption of standards for RFID technology and of RFID standards for prescription drugs.

1. Incentives for RFID Adoption

The advocacy of FDA is a powerful incentive for RFID adoption. FDA's support of point-to-point pedigree communication among trading partners and the inclusion of the NDC in the EPC would encourage adoption, especially among community pharmacies. In addition, if and when a track and trace system is deployed across the drug supply chain, we would need federal preemption of state pedigree law to simplify pedigree compliance. It is important to have a common set of data elements for pedigrees so that prescription drugs may move across the U.S. drug supply chain. Varying state pedigree requirements are costly barriers to widespread pedigree and RFID adoption.

It is extremely difficult to define which, if any, financial incentives would be needed for widespread adoption of RFID. Since RFID is still an emerging technology and since there have only been limited pilots of the technology to date, accurate cost assessments are almost impossible to develop. To the extent possible, financial incentives such as tax credits and accelerated depreciation will offset the huge cost of adoption.

As state and federal governments are now the largest purchasers of prescription medications, we would ask that governmental entities grant an increase in the

reimbursement rate for community pharmacy for investing in RFID infrastructure. Note that there is precedent for the federal government to assist industry with adopting RFID technology: The Department of Defense has agreed to pay for their suppliers to apply the RFID tags to the goods that they ship to the Department.

2. Obstacles to Widespread RFID Adoption

i) RFID Standards

There are a number of significant obstacles to widespread adoption of RFID. First and foremost, there are no industry standards for RFID in the drug supply chain. While much progress has been made towards the adoption of RFID standards, we don't have standards in place today. If we look at the three approaches to RFID pilots from the recent FDA workshop, the manufacturers are using two different frequencies. Moreover, the two manufacturers that are using the UHF frequency are using two different ISO standards that were not developed pursuant to drug supply chain requirements. In addition, the system must be interoperable across the prescription drug supply chain, meaning that the system should work no matter what tag a drug manufacturer puts on the product or what type of readers the downstream drug supply chain partners use. Community pharmacy does not have the ability or resources to purchase and support multiple technological approaches.

Currently there is no agreement on the data communication standard. The industry has developed requirements for an item level tag, but we have not yet heard back from the technology providers if they can develop products and services that will meet these requirements. Nor have these requirements been turned into a prototype that can be tested and piloted.

ii) Pedigree Standards

There is no uniform standard for pedigrees. If a pedigree is at the item level, then we must have a single standard pedigree or standard data elements. Products pass through a number of states while traveling through the drug supply chain. Each state could require different pedigree elements resulting in delays, difficulties, and increased costs to pharmacies and wholesalers to distribute the drugs across the supply chain. To enable a reasonable pedigree system, we need uniformity so that compliance is as efficient and as least costly as possible, and without costly interferences and delays. Additionally, as we move to an electronic pedigree, there must be a requirement that all pedigree software be interoperable. It is unreasonable to expect that a pharmacy should have to support multiple software solutions to receive drug products.

iii) Costs of Implementation

Community pharmacy operates on a small and declining net profit margin, industry averages are between 2%-3%. We cannot afford to invest in a technology before it is mature and proven. RFID is a moving target at this time, with unsure frequencies, lack of standards, and performance issues. Until community pharmacies are satisfied with the technical performances of an RFID-based e-pedigree system, have been able to understand the technology to know what the operational impacts are, and understand what the financial costs and benefits are, they will be reluctant to invest their limited resources. Moreover, it makes little sense for pharmacies to invest in the technology until a significant percentage of the drug products that they receive are equipped with RFID tags.

iv) Business Issues

Community pharmacies have serious concerns about data sharing with respect to e-pedigree and RFID in the drug supply chain. Our industry needs time to study the potential impact of data sharing and determine how or if sharing product movement information in real time can benefit all members of the drug supply chain.

Pedigree authentication is a concern for community pharmacy. Some commentators have suggested that pedigree authentication should occur at the pharmacy level; that pharmacists should be responsible for authenticating drug pedigrees. We believe that such comments are disingenuous, at best, and would place inappropriate and unnecessary costly burdens on the dispensing of prescription medications. There are business practices in place today that greatly limit the opportunity for counterfeit products to be introduced into the legitimate drug supply chain. These business practices range from steps manufacturers have taken such as restricting product sales, to wholesale distributors ceasing horizontal trading with other wholesale distributors, to community pharmacy changing their purchasing practices to ensure the integrity of the product they dispense. Pharmacies should be able to rely on the business practices of their partners in the drug distribution chain to protect from the introduction of counterfeit drugs.

Another business concern is liability when an RFID tag cannot be read after it enters the drug supply chain, and what should be done with a drug product with a faulty tag. Millions of dollars are potentially at risk if tag read rates are not 99.999%. How this issue is ultimately decided will affect product availability and patient safety.

There appeared to be a general consensus from the technology vendors and others that the "pilot" phase of RFID testing is largely complete. NACDS was extremely surprised by this sentiment for a number of reasons including the fact that the standards have not been finalized. Additionally, while the results of the pilots

presented at the recent FDA workshop were interesting, each was in an extremely controlled and limited setting. None of the pilots included participation from each drug supply chain participant, especially community pharmacy. NACDS would caution FDA on relying too heavily on the results of the pilots presented since they did not fully represent how products move in the drug supply chain.

We urge FDA to monitor industry actions, not only in the development of RFID technology, but also to understand the various initiatives that industry has undertaken, to engage in a regular dialogue with industry stakeholders regarding these efforts, and to listen to stakeholders beyond the technology vendors who have different incentives than members of the drug supply chain with respect to the readiness and feasibility of e-pedigree technology solutions. It is extremely important for FDA to recognize that while much work remains before any widespread adoption of RFID, industry stakeholders are taking practical and immediate steps to further improve the integrity of the U.S. drug supply. FDA should encourage these steps and engage in a regular dialogue with industry stakeholders regarding other practical and immediate steps that can be taken.

v) Timetable for Industry Adoption

Simply stated, there can be no timetable established for industry adoption of RFID until national standards are developed and are available and interoperable across the drug supply chain. Concurrently more work needs to be done (through pilots) to create a suite of solution components that will address the disparate needs, resources and capabilities of the community pharmacy industry – from the independent pharmacies to a 6,000 store chain.

At the recent FDA workshop it was suggested that a “phased-in” approach for high-risk products would speed up implementation. While certainly this approach makes practical sense for a manufacturer given their implementation costs could be spread over a longer period of time, community pharmacy would still be required to be fully operational on day one. This puts an undue burden on the one participant of the drug supply chain that does not have price elasticity to cover their costs of implementation and requires community pharmacy to meet a deadline that manufacturers themselves cannot meet – complete implementation of RFID.

3. Standard Setting Body

We believe that EPCglobal is the appropriate body for RFID standards development; they have an approach that is industry driven and is consensus based. They have processes in place for standards to be amended once they are established based on new capabilities or new drug supply chain needs. Our only concern is that the cost of EPCglobal membership may discourage broader industry participation, especially by community pharmacies.

FDA has been a valuable resource for the industry as questions arise on issues such as impact of RF energy on product stability. Your continued involvement and guidance on issues such as this will allow the industry to move forward and not get bogged down on these types of issues. The agency can further the standard setting process by highlighting the urgency for standards and supporting standards that will fairly address the perspectives and realities of all segments of the drug supply chain.

4. EPC/RFID Standards should Remain Voluntary

Voluntary EPC/RFID standards will foster innovation and continuously improve the system's performance.

5. Mass serialization

We believe that the capability for mass serialization should be built into the EPC numbering schema. However, as we develop the schema, we need to ensure that the desire to create a single global numbering system does not cause undue costs and systems changes to drug supply chain partners in other countries.

6. EPC Must Include NDC Number

As we consider RFID technology, we are concerned that some commentators believe the numbering scheme that is included in the EPC number should not include the NDC number. The National Drug Code (NDC) has provided a method for drug profiling since the computerization of pharmacies. The NDC and its intelligent structure are commonly used across the entire drug delivery system. Having a system that does not require line of sight for electronically identifying drug products could add great value to the drug supply chain in the following areas: distribution, dispensing, reimbursement, inventory management, reporting, rebates, patient safety, formulary management, benefit management, and manufacturing reporting/analysis. However, creating a system that does not carry the NDC would be of little value to community pharmacies and would preclude our drug supply chain from realizing the full potential of EPC/RFID technology. Thus, RFID would then be viewed by community pharmacies as a cost with no benefit to streamlining pharmacy operations.

7. Data Management

Our members have indicated that for a variety of reasons that a peer to peer distributed approach would work best for them. We already have an existing, secure electronic relationship with our trading partners. A peer to peer model would allow for faster adoption and would eliminate unnecessary costs for all drug supply chain participants. The peer to peer model is also more reliable. Even with the credit card

systems that have been in place for years, we find those systems have slow times as well as times when their servers are unavailable. There is a genuine concern that a central database system similar to credit card systems will add unnecessary costs and, in those cases where access to the database is unavailable, negatively impact patient safety.

8. Privacy and RFID

Community pharmacy is very concerned about patient privacy. We would not support a system where we felt that this privacy could be infringed upon. Having said that, we believe that there are many opportunities to protect patient privacy in the RFID system. First and foremost, it should be noted that the vast majority of prescriptions (80+ %) are not dispensed in the original bottles from the manufacturer.

For the 15%-20% of the products that do utilize unit of dispensing packaging, privacy protection can be built into the tags and readers, not the numbering system. Additionally, the frequency of the tag being used can also provide additional privacy as read ranges can be rather minimal, less than six inches. Tag and reader manufacturers are also aware of this requirement and are developing techniques to ensure that privacy concerns are built into the system.

Additionally, through EPCglobal, we are commissioning a project to look at patient concerns with privacy, both for specific disease states as well as for the public in general. This project will help us develop privacy guidelines for drugs.

FDA can play a role in privacy by providing guidelines for drug manufacturers for RFID tag placement as they begin to tag their products. Current efforts appear to place the tag behind the label. This does not allow a pharmacy to disable or remove the tag before dispensing. Any advice you can provide to drug manufacturers to make them aware that there is a need for community pharmacy to have the option of removing the tag would be helpful.

We also believe that consumers do need to know what RFID can and cannot do. They need to know how RFID can help secure the drug supply chain and what the industry is doing to protect their privacy. This education is best delivered by organizations deemed impartial by the public, such as FDA.

E. Conclusion

We very much appreciate the opportunity to provide our perspectives on the counterfeit drug problem and to recommend solutions to deterring the introduction of counterfeit drugs into the legitimate drug supply chain. We look forward to continuing our work with FDA, state boards of pharmacy, and our drug supply chain partners in assuring the safety and integrity of our drug distribution system.

RFID technology is still relatively new and unproven with respect to addressing drug counterfeiting and being a viable solution for e-pedigrees. Much still remains to be learned and decided. Standards must be adopted. Business issues must be resolved. Obstacles must be overcome. Costs must be determined and assessed. RFID technology remains a possible long-term solution.

We ask FDA to continue the delay of the pedigree requirements of the PDMA for at least another five to ten years, while simultaneously encouraging state efforts to strengthen wholesale distributor licensing requirements. We ask FDA to consider the practical and immediate steps that have already been taken by community pharmacies, wholesale distributors, manufacturers, and the various state governments. Finally, we ask FDA to consider the greater protection that can be provided by adopting the concept of the “normal distribution channel” as opposed to the current regime of ADRs, especially in light of the unresolved issues that are associated with RFID technology.

Any questions about these comments should be directed to me, to Kevin Nicholson, Vice President, Pharmacy Regulatory Affairs, at 703-837-4183, or to Steve Perlowski, Vice President, Industry Affairs, at 703-837-4108. Thank you.

Sincerely,

A handwritten signature in black ink that reads "Mary Ann Wagner". The signature is written in a cursive, flowing style.

Mary Ann Wagner, R.Ph.
Senior Vice President
Policy, Pharmacy, and Regulatory Affairs

cc: Ilisa Bernstein