



Government and Community Relations Department

February 24, 2006

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

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

Dear Sir or Madam:

Thank you for the opportunity to comment on behalf of Walgreen Co. (“Walgreens”) as follow up to the Anti-Counterfeit Drug Initiative Workshop and Vendor Display held on February 8th and 9th, 2006. Walgreens agrees with the Food and Drug Administration (“FDA”) that pedigrees documenting both physical and title movement of prescription drugs through the pharmaceutical supply chain aid in creating a more safe and secure prescription drug supply. We believe that advocacy by the FDA is a critical incentive for the industry to take action on pedigree.

Walgreens is the nation’s largest drugstore chain with fiscal 2005 sales of \$42.2 billion. Walgreens currently operates 5,122 stores in 45 states and Puerto Rico. Walgreens also provides additional services to pharmacy patients and prescription drug and medical plans through Walgreens Health Initiatives (a pharmacy benefits manager), Walgreens Mail Service, Walgreens Specialty Pharmacy and Walgreens Home Care.

Standardization of Pedigree Data Elements

Walgreens would prefer pedigrees to be supplied to us from our trading partners in an electronic format. Paper pedigrees are cumbersome, labor intensive, subject to forgery and could cause product shortages to Walgreens' patients due to manual receiving procedures at our distribution centers (“DCs”). FDA’s support of point-to-point pedigree communication among trading partners and the inclusion of the National Drug Code (“NDC”) in the Electronic Product Code (“EPC”) are critical to achieving a national standard for pedigree data elements. The pharmaceutical industry as a whole needs federal preemption of disparate

state pedigree laws to simplify pedigree compliance and ensure a data set standard. Financial incentives such as tax credits and accelerated depreciation will help to offset the enormous cost of full adoption of pedigrees for prescription drugs nationally. The critical elements necessary in an e-pedigree are: the NDC, lot number, expiration date, ship to address, ship from address, purchase order number, distributor license number, permit number and unique reference number. These key elements support track and trace technology necessary to ensure a safe, secure, and efficient pharmaceutical supply chain.

As a wholesale distributor and retailer, we need to identify the drug in every step of the supply chain process, including receiving into our DCs, putaway, picking orders for our pharmacies, auditing the orders, receiving into our pharmacies, putaway in the pharmacy, recall and return, etc. The NDC is also used by our pharmacists to verify the accuracy in the dispensing process and checking for potential drug interactions. If we have to add a process to translate the serial number on the product to the NDC each time that we scan a bottle, we will have to perform a massive re-write of our supply chain and dispensing systems. To go outside of our network to retrieve the linkage, there will be an even higher cost and delays in our operations. In addition, patient access to life-saving drugs may be delayed or interrupted if the linkage between the serial number and the NDC is unavailable due to system or network failure. The adoption of Radio Frequency Identification ("RFID") without the NDC will add tremendous cost to adoption of full e-pedigree nationwide. Conversely, if the NDC is included in the RFID tag, retailers can then utilize the information to reduce shrink, enhance accuracy and efficiency of returns and recalls, and improve overall efficiency in the supply chain. The RFID with NDC offers the potential to improve efficiency in our supply chain and dispensing process, which will partially offset the cost of RFID adoption. Another consideration is the potential role that the NDC will play in future at-home patient use of the RFID. If we omit the NDC, the end user may have to acquire more advanced technology to utilize the tag. They may also need the ability to store and interpret the linkage between the serial number and the NDC.

Walgreens is concerned with the cost to our industry of complying with numerous state requirements. We have individual DCs that service up to eleven (11) states, and with each state having unique pedigree requirements the task of complying at this level can become overly complicated and expensive. We prefer to see a uniform solution take hold throughout the country. We support pedigree legislation that does not unduly impact retail pharmacies or hinder the ability of the public to receive needed prescription drugs in a timely manner.

Authorized Distributors of Record (ADR)

Under the Prescription Drug Marketing Act ("PDMA"), drug wholesalers are required to maintain drug pedigrees to track each sale or other transfer of a prescription drug through the drug distribution chain. However, our

understanding is that a wholesaler that qualifies as a manufacturer's authorized distributor of record ("ADR") does not have to pass or maintain pedigrees.

Unfortunately, we find the current acceptance of ADRs to be problematic. We 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 secondary wholesaler market.

For example, the definition of ADR is vague and subjective, leading many secondary wholesalers to believe that they are ADRs, when in fact they may not be considered an ADR. Also, because ADRs are exempt from the pedigree requirements of the PDMA, secondary wholesalers often seek to "launder" questionable drugs through the ADRs. Pharmacies then may receive drugs of questionable pedigree, unaware of where the drug has been. ADRs are difficult to work with from the perspective of a pharmacy or chain drug warehouse. For example, a manufacturer may grant ADR status to a wholesaler for certain products in their line, as opposed to the entire line. This is a problem because pharmacies and chain drug warehouses have to constantly manage that ADR status not only by wholesaler, but also by product. The ADR status of thousands of products then has to be managed by pharmacies. This is logistically very difficult, unnecessary, and potentially creates a ripe environment for unscrupulous wholesalers. Finally, the ADR status of a wholesaler 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 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 wholesaler because they don't know the wholesaler's ADR status. For these reasons, Walgreens respectfully requests that FDA consider supporting removal of ADR status from the PDMA.

Pedigree from a Chain Pharmacy Perspective

Walgreens supports legislation that exempts from pedigree requirements those pharmaceutical products purchased directly from a drug manufacturer; or from pharmaceutical wholesalers who certify that they will sell Walgreens only those pharmaceutical products purchased directly from the original manufacturer of said product. Walgreens would like to see pedigree requirements carried out at the DC level and not with intra-company transfers from our own DCs to our individual pharmacies, thus removing a costly and redundant duplication of processes.

Because Walgreens operates a closed-loop system, and does not distribute pharmaceuticals outbound to third parties, we would like to keep pedigree requirements out of our individual pharmacies. Our pharmacists are trained to provide patient counseling and to ensure that all prescriptions that are dispensed are safe and effective for our patients, not to validate pedigrees of

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pharmaceutical products. We want our pharmacists to function as pharmacists and we strongly believe that pedigree should reside at the wholesale level.

PDMA

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 temporarily 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 wholesalers to be able to fully comply with the pedigree requirements, Congress would have to amend section 503(e) of the Act in order to enable secondary wholesalers 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 in order to give stakeholders in the drug supply chain time to focus on implementing widespread use of e-pedigrees across the drug supply chain and to consider the effects of adoption of electronic track and trace technology on the pedigree requirements of the PDMA.

Walgreens appreciates the consideration that FDA has given to the industry in recognition for the need to delay 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 FDA to continue the delay on the pedigree requirements of the PDMA until RFID technology is widely available and economically feasible and that FDA work with Congress to eliminate the ADR standard from the PDMA. Walgreens does not want pedigree legislation to hinder, inadvertently, our ability to treat our patients by creating restricted levels of product availability.

Pedigree and RFID standards

Walgreens wants to work with our suppliers to create a mutually beneficial electronic means of complying. We support electronic pedigrees and believe that pedigrees should be initiated at the prescription drug manufacturers level.

Unfortunately, there are presently a number of obstacles to implementation of electronic pedigrees including: (1) lack of EPC standards; (2) lack of a data communication standard; (3) cost of implementation; (4) maturity of the technology; and (5) data sharing agreement among trading partners in the supply chain, all of which must be addressed prior to achieving a national standard for e-pedigree or RFID.

Walgreens encourages FDA to continue to be a champion of RFID technology, by supporting development of standards that address the needs of all stakeholders in the pharmaceutical supply chain, and to educate the public on the benefits of RFID in securing the supply chain and emphasizing the efforts of the industry to protect patient privacy.

The widespread adoption of RFID is dependent on: (1) the availability of EPC standards and data transmission standards; (2) maturity of the technology to the point that read rate is no longer an issue; (3) reduction in the cost of the technology; (4) trading partners reaching agreements in data sharing; and (5) retrofitting of legacy supply chain and dispensing systems being completed. We believe that EPC/Global is the appropriate standard setting body to assure all segments of the pharmaceutical supply chain are fairly and adequately represented. However, the cost of joining the organization can be prohibitive to smaller retail pharmacies.

There has been talk in the industry about product serialization as a proposed solution. Serialization without RFID is not workable in the Rx supply chain. We cannot expect wholesalers and retailers to open each case of prescription drug product and scan the 2-D bar code of each bottle. Some have indicated that we can reduce costs by scanning the case label and infer that all the individual bottles are in the case. The reality is that there are wrong labels on cases, and more importantly, misspicks, overages, and missing products in split picked cases. We will not see widespread mass serialization until we see the adoption of the RFID.

The “central database in the sky”

Walgreens does not think that a central data base will be able to support the real time operations in the prescription drug supply chain because: (1) There will be seconds of delay to access the data for authentication, adding delays and costs; (2) The supply chain will be crippled if the central data base is unavailable or compromised for any reason; (3) There will be data ownership and access issues, slowing down deployment; (4) We have not yet seen a central data base of this magnitude that works. For example, even credit card authorization servers are unavailable at times. We believe that a distributed model where

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trading partners communicate data in a peer-to-peer fashion will work best because we are doing it successfully in today's EDI world. In addition, available electronic signature technology will guarantee that the data is authentic and unaltered.

Conclusion

Walgreens very much appreciates the opportunity to provide our perspectives on the counterfeit drug problem as it relates to pedigree, RFID, and PDMA. We look forward to continuing to work closely with FDA, state boards of pharmacy and our supply chain partners to ensure the safety and integrity of the drug distribution system. Any questions about these comments should be directed to me, Debbie Garza, Director, Government and Community Relations, at 202-756-4961. Thank you.

Sincerely,

Debbie Garza, R.Ph. /s/
Director, Government and Community Relations
202-756-4961
debbie.garza@walgreens.com