PORZIO
BROMBERG & NEWMAN P.C.

ATTORNEYS AT LAW

TELEPHONE (973) 538-4006 • FAX (973) 538-5146

JOHN PATRICK OROHO
MEMBER, NJ BAR
DIRECT DIAL NO.: 973-889-4302
E-MAIL ADDRESS: JPOROHO@PBNLAW.COM

CHRISTOPHER P. DEPHILLIPS
MEMBER, NJ AND NY BARS
DIRECT DIAL NO.: 973-889-4322
E-MAIL ADDRESS: CPDEPHILLIPS@PBNLAW.COM

February 23, 2006

VIA FEDERAL EXPRESS

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

Re: *Anti-Counterfeit Drug Initiative Workshop and Vendor Display*
Docket No. 2005N-0510
Our File No.: 00236-65769

Dear Sir/Madam:

We represent the PDMA Alliance Inc. ("Alliance") and submit this letter on its behalf in response to the request for comments in the above-referenced docket. The Alliance is a non-profit corporation dedicated to improving the pharmaceutical industry's understanding of the Prescription Drug Marketing Act of 1987 ("PDMA") and meeting the intent and mandates of that law. In that regard, the Alliance serves as the industry's focal point for learning, exchanging ideas, and networking on issues related to PDMA compliance.

The primary focus of our comments is the lack of uniformity in the states involving PDMA compliance. In the absence of a single, controlling standard to govern specific issues, states are taking

100 SOUTHGATE PARKWAY, P.O.BOX 1997
MORRISTOWN, NJ 07962-1997
NEW YORK CITY OFFICE: 212-265-6888
BRICK NJ OFFICE: 732-262-9248
www.pbnlaw.com

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disparate approaches to PDMA enforcement. As a result, pharmaceutical companies are forced to comply with differing requirements in different jurisdictions. The Alliance believes that a single, unitary standard to govern PDMA issues is the best approach that will allow the industry to comply with the law in the most cost-efficient manner, thereby helping to ensure the safe delivery of prescription drugs. Accordingly, we request that the Food and Drug Administration ("FDA") issue a recommendation calling on the states to adopt a uniform pedigree law. The FDA's endorsement of a uniform pedigree law, which would be the one governing standard throughout the country, would be instrumental in helping to convince states to accept such an approach. Replacing a hodgepodge system of inconsistent state laws with a single, uniform standard will alleviate the burdens that pharmaceutical companies currently face in complying with requirements that vary by state and will help promote the safe distribution of prescription drugs across state lines.

Pedigree laws, which require wholesale distributors to document the chain of custody of drugs from manufacturer to pharmacy or other dispenser, is one such area where, because there is no single governing standard, states have stepped into the void and have adopted a host of inconsistent laws. States that have pedigree laws include Arizona, California, Florida, Indiana, New Jersey, New Mexico, Nevada, Oklahoma, and Virginia. In addition, several other states have pending legislation. We do not intend to exhaustively review all of the requirements of each individual state that has such laws; rather, we will highlight some provisions of the different state laws to highlight the burdens that the industry faces in attempting to comply with disparate laws.

For example, in Florida[1] all wholesale distributions of prescription drugs will require pedigree papers. All prescription drugs labeled for human use, including brand-named drugs, generics, and medical devices that contain a prescription drug, are subject to Florida's pedigree requirements. A drug's pedigree papers must detail the amount of the legend drug; its dosage form and strength; its lot numbers; the name and address of each owner of the legend drug and his or her signature; and its shipping information, which includes the name and address of each person certifying delivery or receipt of a legend drug; an invoice number, a shipping document number, or another number uniquely identifying the transaction; and a certification that the recipient wholesaler has authenticated the pedigree papers. Wholesale distribution in Florida means any distribution of a prescription drug to a person other than a consumer or patient, and the law defines "distribution" as "to sell; offer to sell; give away; transfer, whether by passage of title, physical movement, or other; deliver; or offer to deliver." With two exemptions, everyone involved in the chain of wholesale distribution of a prescription drug from, in, or into Florida must provide a pedigree paper. The two exemptions are: 1) the manufacturer when selling or distributing a drug it manufactured; 2) an affiliated group of at least fifty retail pharmacies, warehouses, or repackagers distributing within the group.

In Florida, everyone, except for the patient, must receive a pedigree paper. That includes another wholesaler, a manufacturer, a repackager, a pharmacy, a hospital and a medical practitioner. The Florida Department of Health has stated that when the new law goes into effect on July 1, 2006, it will apply to the wholesale distribution of all existing inventory. Currently, the Florida pedigree requirements apply to 34 listed drugs. As of July, it will apply to all drugs and medical devices,

[1] This description concerns both the enacted law and pending regulations.

including all existing inventory. Consequently, those entities that are required to have pedigree papers will have to start the process well in advance of that effective date in order to comply with the law.

Florida law also imposes an affirmative duty to authenticate the pedigree papers, and there are a number of methods to satisfy that duty. Those methods include receipt of an invoice; a telephone call to the seller; an e-mail; a secure web-based system; and receipt of previous transaction pedigree signed under oath. If a pedigree paper cannot be authenticated, the product is deemed adulterated. Another significant change to Florida law is that as of July 1, 2006, the State will no longer recognize the concept of an authorized distributor of record. As a result, a wholesaler must provide a pedigree to its customer even if the wholesaler is considered an authorized distributor of record by the manufacturer in Florida or in other states. Florida's pedigree law also involves potential criminal liability, as parties involved with adulterated pedigrees are at risk for felony prosecution if they fail to authenticate the pedigree and attempt to further distribute a drug; falsely swear or certify that pedigree papers have been authenticated; or falsely represent the factual content of a pedigree or knowingly omit required information.

New Jersey's pedigree law has criminal provisions similar to Florida's, but has other provisions that differ from Florida's, as well as other states. New Jersey's recently enacted pedigree law defines pedigree to mean a statement or record identifying each previous sale of a prescription drug, from the sale by a manufacturer through acquisition and sale by a wholesale distributor, including each distribution to an authorized distributor, starting with the last authorized distributor, or the manufacturer if the prescription drug has not been purchased previously by an authorized distributor or is a prescription drug on a specified list of products susceptible to counterfeiting. New Jersey law

states that an authorized distributor of record could be established in several ways, including quantity of purchases in a twelve month period. New Jersey's pedigree law also has stringent requirements for obtaining a permit or to renew a permit for an in-state or out-of-state prescription drug wholesaler.

Arizona's pedigree law takes a different approach by requiring wholesale distributors to provide pedigree papers if the prescription drugs leave the "normal" chain of distribution. The state Board of Pharmacy must request a bond from wholesale distributors and requires wholesale distributors to designate a representative. In March 2005, Virginia passed a law that requires its Board of Pharmacy to establish and implement a pedigree system to record each distribution of a controlled substance from sale by a pharmaceutical manufacturer through acquisition and sale by any wholesale distributor, until final sale to a pharmacy or other person dispensing or administering the controlled substance. Unlike some other states, the Virginia board is required to limit the regulations to certain drugs or schedules that it finds are more susceptible to counterfeiting.

In June 2005, Oklahoma enacted a pedigree law that requires in-state and out-of-state wholesale distributors to designate a representative and provide his or her fingerprints to the state board. In addition, the law requires distributors to provide a bond upon application for or renewal of licenses and it requires them to establish a pedigree system. Indiana passed its own pedigree law, with distinctive provisions, in May 2005. The Indiana law defines an authorized distributor, designated representative, and pedigree papers. Under the law, a wholesale distributor may not accept or deliver a legend drug without a current pedigree. The state board also requires a wholesale distributor to submit a surety bond, and the law also clarified storage, handling and written policies and procedure requirements for wholesale distributors.

California passed its pedigree law in September 2005, which significantly alters existing licensing requirements for out-of-state wholesale distributors. In the past, an applicant for non-resident wholesale distributor licensure was required to submit a $100,000 surety bond, or an equivalent means of security, for each site from which dangerous drugs or devices were to be shipped, mailed, or delivered to a site in California. The new law changed that scheme, as California now requires that a single, $100,000 surety bond, or an equivalent means of security, be submitted by an applicant for receipt or renewal of a non-resident wholesale distributor license. Significantly, the law excepts from the surety bond requirement certain non-resident wholesale distributors to whom an approved NDA had been issued by the FDA. The law also reduces various non-resident wholesale license application fee amounts.

As noted previously, it is not our intent to provide an exhaustive analysis of the pedigree laws that have been passed by different states, or to scrutinize pedigree legislation that is pending in different state legislatures throughout the country. Rather, we have simply chosen to highlight some of the different requirements that certain states are enacting. As is evident from the summary of state pedigree laws just provided, the specific requirements for pedigrees can differ significantly from state to state.

As the FDA is aware, the regulation at 21 CFR 203.50 is currently stayed. That regulation lists the information that must be provided in the pedigree, and it is the minimum information that was set forth in the PDMA. Those requirements were promulgated at a time when a paper pedigree was the only means for passing a pedigree. It is undisputed that an e-pedigree requires additional information because of its technological nature, but it may also permit the inclusion of more information. In that

regard, some states are now requiring that certain specific information be included in the pedigrees passed with certain drugs. Consequently, a situation has developed whereby the pedigree information required in one state is different than that required in another state. In short, that is a logistical nightmare for companies required to comply with these state laws that only serves to add more complexities, nuances, and cost to the distribution of prescription drugs, while doing nothing to increase the safe distribution of prescription drugs. In that regard, if a company satisfies the pedigree for a drug for State A, but then wishes to move that drug to State B and State C, which have different pedigree requirements, the company must then go through the process of determining what the current laws in State B and State C are, what the laws mean to its position and status in the distribution chain, and then comply with the laws of State B and State C.

The process of complying with different state laws is burdensome in several respects: first and foremost, it is incumbent upon companies to be aware of the state laws of fifty different states and the District of Columbia. That is not a simple or inexpensive chore, as states are constantly passing new laws and regulations. Once a company determines what the current state of the law is in a given state, it then must interpret that law – which often times is a complicated, complex labyrinth of statutory and administrative provisions. After interpreting the law and determining what exactly each state requires, the company then must go about complying with the law and ensuring that the law has not changed in the interim. Conflicting state laws result in excessive, and unnecessary, administrative costs that hurt the industry and lead to increased prices that will only be passed along to the consumer. The best way to minimize those costs and prices, and ensure compliance with the governing law and the safe delivery of prescription drugs, is to have one standard that controls the entire issue. Having one

standard will reduce the amount of time and money that companies will have to devote to complying with different pedigree laws.

In short, the Alliance suggests that a single, uniform law governing all aspects of the pedigree issue is the fairest, most efficient solution to the problem of dealing with disparate state laws. It is both unreasonable and unfair to place the burden on companies to comply with numerous different states' requirements. The Alliance offers the "Model Rules for the Licensure of Wholesale Distributors," promulgated by the National Association of Board of Pharmacy ("NABP"), as an excellent approach to help deal with this problem. The Alliance would like to work with the FDA and NABP to ensure that an appropriate uniform pedigree standard is implemented – one that is both fair to the industry and protective of the public health.

Another area where there is a need for uniform legislation and one single governing standard is with respect to loss/theft reporting requirements for drug samples. The PDMA regulations require manufacturers or authorized distributors of record to report any significant loss or theft to the FDA within five working days of their becoming aware of the theft or loss. In addition, the manufacturer or authorized distributor must immediately initiate an investigation into the significant loss or known theft and provide the FDA with a complete written report, including the reason for and the results of the investigation, within 30 days after the initial notification to the FDA. Despite the presence of that federal standard, states are enacting their own theft/loss reporting requirements. Thus far, ten states -- Alaska, Colorado, Florida, Indiana, Louisiana, New Mexico, Ohio, South Carolina, Vermont, and Washington -- have additional theft/loss reporting requirements beyond the federal scheme.

Like the issue of pedigree, the Alliance recommends that there should be only one, uniform standard concerning theft/loss reporting requirements. The Alliance has prepared model legislation that mirrors the federal standard, which it has enclosed, and it intends to work with state legislatures to try to convince them to pass the model law. The NABP supports the Alliance's model legislation, and the Alliance would appreciate any assistance or guidance the FDA could provide to the states on this issue.

The Alliance contends that having one standard is beneficial for several reasons. First and foremost, the Alliance wants to prevent a situation (a situation that is already being created by the aforementioned ten states) whereby states enact their own loss and theft reporting requirements that differ from the federal scheme. If states continue to do so, companies will be placed in the untenable position of having to comply not only with the federal scheme, but also different state schemes. Like the problems associated with different state pedigree laws, a patchwork system of state laws imposes a significant financial burden on companies as they are forced to develop expensive systems and expend substantial resources to track and comply with different state schemes.

Having uniform laws in the area of pedigree and theft and loss of drug samples would give the industry the advantage of complying with a single standard, thereby allowing the industry to focus on the safety, quality, and security of the drug supply in a way that minimizes the excessive burdens, costs, and expenses currently facing the industry. The Alliance therefore requests that the FDA endorse the concept of unitary standards and recommend that states adopt uniform laws. The Alliance is ready to work with the FDA and interested parties to ensure that uniform standards are adopted to ensure PDMA compliance across the country.

Thank you for your attention to this matter. Please do not hesitate to contact us with questions or if we can provide additional information.

Very truly yours,

John Patrick Oroho
Counsel to the PDMA Alliance Inc.

Christopher P. DePhillips
Counsel to the PDMA Alliance Inc.

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