BEFORE

THE UNITED STATES OF AMERICA

DEPARTMENT OF HEALTH AND HUMAN SERVICES

FOOD AND DRUG ADMINISTRATION

COUNTERFEIT DRUG TASK FORCE

DOCKET NO. 2003N-0361

PHARMACEUTICAL DISTRIBUTORS ASSOCIATION COMMENTS ON SELECTED GOALS, PLANS AND QUESTIONS POSED BY THE FOOD AND DRUG ADMINISTRATION'S COUNTERFEIT DRUG TASK FORCE INTERIM REPORT

The Pharmaceutical Distributors Association ("PDA") is a trade association of state-licensed wholesale distributors of prescription drugs, most of which are small companies who are not authorized distributors for all of the manufacturers of drugs that they distribute. PDA thanks the Food and Drug Administration for the opportunity to speak and to participate in FDA's public hearing on this subject. PDA is pleased to submit these comments on the Selected Goals, Plans and Questions Posed by the Food and Drug Administration's Counterfeit Drug Task Force Interim Report. PDA is interested in assuring that the FDA develops and recommends regulations and procedures that address the risks of counterfeit drugs and otherwise illegal drugs entering the marketplace but that do not diminish the remaining competition in an already highly concentrated drug wholesaling industry. As explained in these comments, several of the concepts that are being considered have the potential for adversely affecting small licensed prescription drug wholesalers, companies that not only provide needed services, but also inject competition into the marketplace. Small prescription drug wholesalers are necessary and appropriate in this industry and serve the public interest.

PDA has consistently taken the position that FDA's Final Rule on identifying statements for prescription drugs (the "pedigree") should not require reporting of all transactions back to the manufacturer because Authorized Distributors of Record ("ADR") do not need to provide pedigree to their customers. Small wholesalers buying from ADRs would not be able to resell the products they purchase. Competition is also affected if the drug pedigree requirement is implemented in this fashion. These smaller wholesalers in the distribution chain will be unable to survive. The largest wholesalers, who are typically ADRs, can eliminate thousands of smaller wholesalers simply by

lawfully declining to provide pedigrees, none of them provide pedigrees now, and an already concentrated industry will be reduced to only a few giants.

Similarly, track and trace technology has the potential to assure parties in the distribution stream that particular drugs are genuine. However, this same technology can be used by manufacturers to determine who may be selling drugs to secondary wholesalers. Manufacturers often object to this practice because competition from secondary wholesalers undermines their efforts to limit the distribution of lower priced drugs. FDA should take care that pedigree requirements and tracing and tracking and any other technology be implemented in a fashion that will not eliminate thousands of wholesalers. PDA therefore requests that FDA consider the competitive implications of the various proposals made by those who provide it with comments on the interim report. A safe and secure drug supply can and should coexist with a vibrant competitive marketplace.

PDA has not commented on the totality of the Interim Report. Instead, PDA sets forth below selected FDA goals, plans and questions followed by PDA's comments on each.

FDA GOAL - *Achieve the goal of the pedigree requirements by phasing in track and trace technology (i.e., electronic pedigree) for all drugs and biologics starting at a case and pallet level for products at "high risk of being counterfeited" and progressively including all products at the case, pallet, and package level. The technology should have an integral infrastructure that is able to track and trace products at all points in the distribution chain from manufacturer to end user.*

PDA generally agrees with this goal. PDA believes, however, that FDA should be conscious of the potential for this technology to be used by manufacturers to limit the purchase and resale of their products and to maintain high prices. FDA should consciously seek to create a system that will avoid these impacts.

FDA GOAL - *On an interim basis, because the technologies described above may take several years to implement, all drugs and biologics "at high risk of being counterfeited", should be tracked and traced either (1) By limiting the number of transactions of the product (e.g., shipping the product from the manufacturer either (a) directly to the retailer or health care entity, (b) to the retailer or health care entity through a single licensed wholesaler who would sell the product directly to retailers or health care entities, (c) identifying steps that multiple wholesalers can implement to reduce the risk of counterfeit instructions), or (2) By using available track and trace technology, identifying*

the drug at least at the case and pallet level, and preferably at the product level, throughout the distribution system.

PDA does not support limiting the number of transactions for prescription drugs "at high risk of being counterfeited." Once a drug is in the wholesale market, there are often valid reasons why that drug might pass through more than a "defined" number of hands, and limiting the number of transactions puts the party holding the product just before the "last transaction" in an awkward marketing position. That is because that party may end up at the mercy of the purchaser, who knows that they are the last person who can legally buy this product.

PDA suggests that manufacturers that want to limit the distribution of products they consider to be "high risk" know how to establish and enforce those limits. And in putting on those limits, they should inform the trade so that the trade knows that if it sees such a "high risk" prescription drug product available at wholesale that such product should not be available. And if FDA feels that a particular drug should be put on limited distribution as a "high risk" drug, FDA knows how to suggest to manufacturers that this should be done.

FDA GOAL - *Issuance of an FDA guidance document concerning physical site security and supply chain integrity.*

PDA supports this FDA goal and PDA members have helped draft and edit the HDMA's Recommended Guidelines for Pharmaceutical Distribution System Integrity. Those Guidelines have not been made final by HDMA. Attached hereto are the Guidelines that PDA's members have accepted. PDA encourages FDA to promulgate a guidance document that will serve as the basis for licensed prescription drug wholesalers to engage in effective due diligence for supply chain integrity. In this regard, FDA should give thought to whether carrying out such due diligence could serve as a "safe harbor" from any strict criminal liability that might attach with respect to the unknowing and unintentional commerce in counterfeit or otherwise unlawful prescription drugs.

FDA PLAN - *Continue to work with NABP to update their Model Rules for Licensure of Wholesale Distributors, using the Florida statute as a model where appropriate, in the following areas; requirements for licensure, qualifications of employees (especially those who handle drugs), storage and handling of drugs, site security (both for facilities and information), inspection and examination of drugs, record keeping, availability of records to inspectors and law enforcement personnel, due diligence with respect to business partners and contractors, administrative subpoena power, and criminal penalties; update FDA regulations under 21 CFR 205, as appropriate, to make*

it consistent with updates to the NABP Model Rules for Licensure of Wholesale Distributors.

PDA supports FDA's plan to work with NABP with respect to these issues. PDA reiterates its position that their must be one Federal definition of "Authorized Distributor of Record" and Federal requirements only for the identifying statement required by the Prescription Drug Marketing Act.

FDA Plan - *Develop sets of "secure business practices" which would be voluntarily adopted by manufacturers, wholesalers, repackagers, and pharmacies. Best practices would be identified in areas such as: employee qualifications, security of physical facilities and information systems, package disposal, dealings with business partners and contractors, inspection and examination of products, record keeping, etc.*

PDA supports this plan and the attached Guidelines for Pharmaceutical Distribution System Integrity which are a strong first step in developing "secure business practices" for wholesalers.

FDA Plan - *Designate, by entities such as manufacturers, wholesalers, repackagers, and pharmacies, an individual or team to coordinate security and anti-counterfeiting activities. Such activities would include quality improvement, monitoring and use of anti-counterfeiting technologies, and regular review of the entities security and anti-counterfeiting measures.*

PDA supports the designation of individuals or teams within wholesale companies to coordinate security and anti-counterfeiting activities.

FDA Plan - *Create a counterfeit alert network through use of existing, or newly developed, communication tools that allow reception, dissemination, and sharing of information about counterfeit drugs in a timely manner (e.g., to pharmacists, manufacturers, wholesalers, and law enforcement and public health officials).*

PDA encourages FDA to create this counterfeit alert network. The prompt transmission of this kind of information will allow suspect products to be frozen in place and for prompt notification to FDA of the location of such product so that its source can be investigated.

FDA Question - *Should any specific anti-counterfeiting technologies be utilized? Should covert technologies always be utilized? Should overt technologies always be utilized*?

As a long-term goal, PDA supports the use of overt technologies that allow any person in the chain from manufacturer to dispenser to verify the integrity of the product. In PDA's view this means there must be tamper evident seals and, second, a means to determine that the product is the USFDA approved version of the prescription drug.

In the first instance, existing tamper evident seal technologies should be adequate to address this requirement, and these technologies are in a state of constant upgrade due to the highly competitive nature of the supplier industry. FDA should establish expedited approval mechanisms so that companies can upgrade these technologies if they wish.

With respect to verification of the integrity of the prescription drug, i.e., that it is the USFDA approved version of the drug, it is PDA's view that this should be a mandated technology that can be read by anyone in the chain of distribution. Technology to do this does not now exist. However, this is the kind of technology that could close the loop on counterfeiting. If each part of the chain of distribution can install a relatively inexpensive device (less than $250) that will verify the integrity of any manufacturer packaged prescription drug, then integrity can be verified down to the dispenser.

FDA Question - *On what dosage forms and products should taggants, other markers, or unique characteristics be utilized? All dosage forms and products? High-risk dosage forms and products? Are there unique characteristics of products that can be utilized in lieu of taggants or chemical markers for forensic analysis*

It is PDA's view that all prescription drugs should have tamper evident seals.

With respect to integrity verification, PDA's view is that this requirement should be applied to all pioneer drugs until such time as they have generic competition. This would also include the requirement that integrity verification be required for repackaged pioneer drugs. PDA sees no need for these requirements to be applied to generic drugs because the risk that these drugs would be counterfeited is, in PDA's view, quite low.

FDA Question - *Tracking and tracing drugs and biologics throughout the drug distribution chain may result in the creation of a large database that includes tracking data from each entry that "handles" the product. Who should create and maintain such data? Where and how should the data be housed? Who should have access to the data? How can appropriate confidentiality be assured?*

PDA is concerned about the use of track and trace technology insofar as it could be used to facilitate limitations on a robust and competitive market in prescription drugs. If this technology were put in place and there were no prescription drug pedigree requirement in place, then this information should only be available to law enforcement. If there is a prescription drug pedigree requirement, then track and trace technology is a logical vehicle to record and provide this information. If this were the case, care must be given not to facilitate its use to limit robust and competitive markets in prescription drugs.

FDA Question - *Are there additional benefits beyond the ability to detect counterfeit product that anti-counterfeiting and track/trace technologies can provide for industry (e.g., inventory control, facilitation of product recalls, and identification of theft and product diversion)? Give specific examples.*

PDA believes that track and trace technology will assist in inventory control and identification of product theft. Such technology could also be used to identify product diversion. To the extent that such diversion is unlawful, the use of this technology should be utilized in this fashion. To the extent that such technology is used to control lawful market functions, it will have an adverse impact on robust competition in prescription drugs.

FDA Question - *Should all products be considered at high risk of being counterfeited? How can products at high risk of being counterfeited by identified? Which, if any, of the following criteria should be considered: (a) potential impact on public health if the product were counterfeited, (b) any history of, or the potential for, counterfeiting, tampering, or diversion of the product, (c) wholesale and retail price of the product, (d) volume of product sold, both on a unit and dollar basis, (e) the dosage form of the product, e.g., injectable, (f) approved and unapproved uses of the product, (g) current and potential misuse or abuse of the product, e.g., "street value", (h) other products in the class with a history of being counterfeited, (i) the length of remaining patent life for the product?*

PDA believes that all pioneer drugs are at risk of being counterfeited. PDA further believes that identification and countermeasures with respect to drugs at high risk of being counterfeited will only result in felons proceeding to focus their efforts on drugs not so identified.

FDA Question - *Discuss what could be included in an FDA guidance on physical site security and supply chain integrity.*

PDA endorses the enclosed Guidelines for Pharmaceutical Distribution System Integrity and suggests that these should be included in any such FDA guidance.

FDA Question - *Discuss the most effective ways to achieve the goals of the wholesale distribution rule (21 CFR 203.3(u) and 203.50). Given recent or impending advances in technology, comment on the feasibility of using an electronic pedigree in lieu of a paper pedigree.*

PDA believes there is a definite role for tack and trace technology. However, it is important to protect the confidentiality of where product has moved once it has left the manufacturer, so "access" to the electronic pedigree must be restricted to each subsequent handler of the product. This suggests track, rather than "trace" technology, except with respect to its use by law enforcement.

PDA believes that the objective of the wholesale distribution rules (21CFR 203.3(u) and 203.50) can best be addressed by technology. Given recent or impending advances in technology, electronic tracking provides significantly more promise in safeguarding the distribution channel than paper pedigrees. In fact, counterfeiting does not appear to be deterred in any way by the present pedigree requirement.

In the interim, however, PDA believes that the definition of Authorized Distributor of Record should be modified to read as follows:

1. The distributor appears on the manufacturer's list of ADR's, or
2. The distributor has a written agreement currently in effect with the manufacturer, or
3. The distributor has a verifiable account number with the manufacturer (by phone check or invoices with account numbers), and a minimal transactional or volume requirement as follows:
    - 5000 sales units (unit is the manufacturer unit of sale, e.g., bottle of 100 100 mg. tablets) within 12 months, or
    - 12 purchases (invoices) from the manufacturer within 12 months

In addition, PDA believes that the requirement for identifying statement should be that it report transactions back to the last authorized distributor of record, or, where their has been no intervening authorized distributor of record, back to the manufacturer. Otherwise, the pedigree requirement will destroy small wholesalers who purchase from ADRs.

If these changes are made to the final rule, the regulations can be made effective and rules will be in place until technological improvements are available.

FDA Question - *Discuss the advantages and disadvantages of the new Florida and Nevada requirements for wholesale distributors, including the cost involved with compliance.*

The advantages of the Florida law include the strengthening of licensing standards, the establishment of a "designated representative", and tougher criminal penalties for offenders. It is clear that too many unscrupulous people have been able to obtain licenses, thus giving them the ability to introduce counterfeit or unlawful products into the drug supply. Many of Florida's new requirements will help to "weed out" these individuals. The counterfeit drug problem is caused by people who have easily obtained licenses because of lax licensing requirements and enforcement, and because of loose criminal penalties which are not "threatening' enough to scare off felons, who see the potential for huge monetary rewards with little personal freedom risk.

There are many disadvantages and problems with the Florida law. First, the Florida law burdens interstate commerce. Today, a listed drug that originates outside of Florida (for example, with a Texas wholesaler who does not do any direct selling into Florida, and therefore has no need for a Florida wholesaler permit) and which is sold to a "out of state" Florida licensee who then sells it into Florida, will NOT be able to occur. This is because the Texas wholesaler has no obligation, nor should he be expected to comply with the Florida requirement that the pedigree go back to the manufacturer. In 2006, this requirement will apply to all drugs.

Second, the Florida laws seriously slow the flow of prescription drugs because of the pedigree verification requirements. Product is already sitting on the receiving docks of wholesalers who cannot re-sell the products before completing the verification procedures. Wholesalers are experiencing delays in getting the requisite responses from the companies listed on the pedigree papers. In addition, the fact that the suppliers invoice number needs to appear on the pedigree which is passed by the selling wholesaler is quit problematic, since it often takes several days to receive a vendors invoice after receiving the actual product, However, without providing this invoice number on the pedigree, it is unlawful to sell the goods. The pharmaceutical industry is fast paced, low margin business (at least from a wholesaler's perspective) and relies on rapid inventory turnover in order to remain profitable and to adequately service its clients. The slowdowns caused by the new Florida requirements are hampering the ability of wholesalers to promptly provide goods to their customers.

FDA Question - *Discuss the advantages and disadvantages of requiring a pedigree if track and trace technology is also being utilized for a given product?*

If track and trace technology were introduced, there would be little if any benefit to the paper pedigree.

> FDA Question - *Identify areas where the NABP Model Rules for Licensure of Wholesale Distributors could be strengthened. Please give specific language for new provision.*

PDA is addressing this question with respect to the issuance of Guidelines for State Licensure that FDA may promulgate. This is how the NABP Model Rules were used in the past and how PDA understands FDA may use NABP Model Rules in the future. The Prescription Drug Marketing Act ("PDMA") amended the Federal Food, Drug & Cosmetic Act ("FFDCA") by providing, in pertinent part, that:

> (A) No person may engage in the wholesale distribution in interstate commerce of drugs subject to subsection (b) in a State unless such person is licensed by the State in accordance with the guidelines issued under subparagraph (B) . . . .
>
> (B) The Secretary shall by regulation issue guidelines establishing minimum standards, terms, and conditions for the licensing of persons to make wholesale distributions in interstate commerce of drugs subject to subsection (b). Such guidelines shall prescribe requirements for the storage and handling of such drugs and for the establishment and maintenance of records of the distributions of such drugs.

FFDCA, § 503(e)(2).

Following this direction by Congress to issue guidelines establishing minimum requirements for licensing, drug storage and handling, and maintenance of drug distribution records, FDA promulgated regulations that are set forth in 21 CFR Part 205. 55 Fed. Reg. 38012 (September 14, 1990). In the final rule, FDA made clear that States are free to adopt licensing standards that exceed the FDA-established minimum requirements. *See e.g., id.* at 38013.

In the section setting forth minimum qualifications for licensing, 21 CFR § 205.6, FDA sets forth a list of non-exclusive factors that States must consider when assessing a wholesale prescription drug license application, including the applicant's: past convictions (including felonies); past experience in the manufacture or distribution of prescription drugs; furnishing of false or fraudulent material in any application made in connection with drug manufacturing or distribution; compliance history under previously granted licenses (including

consideration of any suspension or revocation thereof and compliance history with regard to maintenance of required records). 21 CFR § 205.6(a)(1)-(7). The state licensing authority is also free to consider other factors it considers relevant to and consistent with the public health and safety. 21 CFR § 205.6(a)(8). A state may deny a license to an applicant if it "determines that the granting of such a license would not be in the public interest." 21 CFR § 205.6(b).

In its summary of § 205.6 in the preamble to the final rule, FDA stated,

> [t]he agency believes that careful screening of applicants is necessary and prudent in reducing the opportunities for diversion of prescription drugs. State authorities must consider an applicant's history, which may reflect upon the applicant's ability to prevent drug diversion. Where granting a license would not be in the public interest, State authorities may deny a license to an applicant.

55 Fed. Reg. 38012, 38012 (Sept. 14, 1990). In the Preamble to the final rule, FDA specifically "declined" to set a federal standard for what was meant by "not in the public interest." *Id.* at 38018.

It is PDA's position that FDA is authorized by PDMA to do more than it has done with regard to establishing minimum standards for state licensure while leaving the States vested with, and primarily responsible for, such licensure. As it did after PDMA became law, the FDA is looking to the NABP for advice regarding state licensure of prescription drug wholesalers. In this regard, PDA supports those aspects of the NABP's Model Act ("Model Act") and NABP's Model Rules ("Model Rules")[1] and those aspects of state legislation (such as in Florida and Nevada) that enable state licensing authorities to increase their scrutiny of the integrity of companies, and individuals associated with those companies, seeking licensure and strengthen state enforcement powers. State licensing authorities should have all tools legally available to them to ensure that those in the business of wholesaling prescription drugs in their state have the requisite business integrity and experience to do so as to prevent and deter bad actors from entering the licensed field. Thus, the PDA supports a federal requirement for the following types of minimum requirements and qualifications for licensure, above and beyond those currently recommended in the guidance set forth at 21 CFR §§ 205.5 and 205.6.

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[1] References to the NABP's Model Act and NABP's Model Rules are to the June 2003 Model State Pharmacy Act and Model Rules of the National Association of Boards of Pharmacy available from the NABP website.

Specifically, PDA supports, and believes FDA has the authority to implement, the following types of provisions currently present in recently enacted in the Florida Prescription Drug Protection Act (C.S.. 2312, Chapter 2003-155 Laws of Florida). PDA's President, Sal Ricciardi sat on the panel that proposed the tightening of the Florida prescription drug wholesale distribution application process by requiring extensive sworn background information, fingerprints, and statewide and national criminal background checks. In addition, this law requires licensed prescription drug wholesalers in Florida to submit a bond of $100,000 (or other equivalent means of security) to the Florida Department of Health. The Department of Health is authorized to deny an application for licensure for no less than eighteen separate reasons, including the following:

- management, officers, or directors of the applicant or any affiliated party are incompetent or untrustworthy
- lack of experience in distribution of prescription drugs
- lack of experience in managing a wholesale distributor as to make the issuance of the proposed permit hazardous to the public health, or to jeopardize the reasonable promise of successful operation;
- past experience in manufacturing or distributing prescription drugs that indicates that the applicant poses a public health risk;
- affiliation (directly or indirectly) with any person or persons whose business operations are or have been detrimental to the public health;
- guilty finding or plea, or nolo contendere plea by applicant or affiliated party to any felony or crime punishable by imprisonment for 1 year or more under the laws of the United States, any state, or any other country;
- applicant or affiliates are currently charged with a felony;
- applicant has submitted false information to Florida or any other state in connection with obtaining a distribution permit
- any distribution permit previously granted to applicant or affiliated party by any federal, state, or local authority has been disciplined, suspended, or revoked
- lack of financial and physical resources to operate in compliance with the permit
- receipt of financial support/assistance by applicant or any affiliated party by a person whose permit was subject to discipline, suspended, or revoked
- receipt of financial support/assistance by applicant or any affiliated party from a person found guilty of any violation of Florida drug laws or regulations, or any federal or state drug law, or any felony where the underlying facts relate to drugs

- failure to comply with requirements for distribution of prescription drugs under Florida laws, similar federal laws, similar laws in other states, or regulations adopted under such laws.

In addition, Florida requires that each licensed wholesaler have a designated representative with respect to the company's licensure.

I is PDA's position that FDA could, consistent with the mandate of FFDCA § 503(e)(2)(A) & (B), affirmatively require the state licensing authority to investigate an applicant's prior violations relating to the handling of prescription drugs, *and affirmatively preclude that authority from granting a license to an applicant with any such history.* Stated differently, FDA can and should by regulation identify a non-exclusive, categorical, list of prescription drug-related or fraud-related activities that are "not in the public interest" and accordingly require the states to deny licenses for individuals with criminal records in these activities. That list would not be exclusive and the States would be free to add other disqualifying conditions or criminal offenses. FDA likewise has the authority under § 503(e)(2)(A) & (B) to determine that certain other minimum protective measures must be in place before a wholesale distributor license can issue, such as a requirement that the licensee carry a bond and/or carry product liability insurance. Accordingly, PDA endorses those parts of the NABP models that contain these requirements

Using the authority of existing law to promulgate stronger minimum requirements for state licensure in light of new information and threats to the integrity of the prescription drug supply raises no special legal issues and should not be controversial. Under PDMA, FDA has the authority to revisit its regulations and to strengthen them to better effectuate the intent of Congress. Nor would such action be properly characterized as an unfunded mandate for State action. It is common and usual for States to increase licensure fees to account for the costs of processing licenses and overseeing the activities of licensed industries and Florida followed this course in 2003.

PDA firmly believes, however, that once the integrity of companies have been verified through mechanisms such as those identified above, and the companies are duly licensed to wholesale prescription drugs in a given state, neither PDMA not the commerce clause of the Constitution permits states to unduly restrict the interstate business of wholesaling by licensed wholesalers. Both the Model Act and the laws of several states currently have provisions that go beyond licensure to restrict the business of wholesaling – either by limiting the quantity of product that can be sold or purchased to particular categories of licensed entities, and/or by having more stringent definitions of who may be an "authorized distributor of record" or what must be contained in the "identifying

statement" that are presently the subject of FDA's stayed PDMA final rule. 21 C.F.R. 203.50. The result of these types of state laws is to create divergent state specific requirements that impose an impermissible burden on interstate commerce in prescription drugs.

Accordingly, PDA opposes provisions present in the Model Act and in recently enacted Nevada legislation which in one way or another limit the category of entities from whom drugs can be purchased and to whom drugs can be sold. The Model Act provides that a Board of Pharmacy may suspend, revoke, deny, or refuse to renew the license of a wholesale distributor upon:

> The transfer during any consecutive twelve (12)-month period by a Wholesale Distributor to a Wholesale Distributor of more than ten (10%) of the total amount of prescription Drugs or Devices purchased by Wholesale Distributor in the immediately preceding twelve (12)-month period.

NABP Model Act, § 504(c)(9). In comments attendant to this provision, the NABP further provides that, "[s]tates may choose to reduce the ten percent (10%) threshold indicated in this paragraph to five percent (5%). Id., Comment to § 504(c)(9).[2]

In these definitions NABP seeks to define who may be a wholesale distributor. Yet NABP and its member State Boards know that wholesale distributor to wholesale distributor purchase and sales are common and legitimate practices of wholesale distributors. Moreover, it is common for wholesalers to have a mix of business with respect to those they sell to. It is PDA's position that neither the States, NABP nor FDA's focus should seek to define the lawful business of licensed wholesalers, but instead should solely focus on ensuring that those licensed to wholesale prescription drugs have the requisite integrity to do so. There is nothing unlawful with respect to carrying on a wholesale business that solely or as a majority of its business makes sales to other licensed wholesalers.

Similarly, although the Nevada legislature recently amended its state pharmacy law by expressly providing that the Nevada Board of Pharmacy "shall not limit the quantity of prescription drugs a wholesaler may purchase, sell, distribute or otherwise provide to another wholesaler, distributor or manufacturer," 2003 NV S.B. 425 (SN),[3] the balance of the amendments enacted nevertheless

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[2] This basis for suspension, revocation, denial, or refusal of a license is not expressly repeated in the model minimum qualifications for licensure in the Model Rules accompanying the Model Act, *see* Model Rules § 2.

[3] We assume that this determination by the Nevada legislature will result in deletion of Board of Pharmacy regulations that do restrict certain wholesale transactions

continues to inappropriately limit to whom and from whom licensed wholesalers may buy and sell prescription drugs.

Under the new Nevada amendments, Nevada wholesalers may sell prescription drugs only to: (a) a pharmacy or practitioner; or (b) to another wholesaler, if the purchasing wholesaler is licensed by Nevada or other relevant authority of another state AND the sale is a "bona fide transaction." A sale is deemed a "bona fide transaction" if there is a reasonable assurance by the wholesaler that purchases the drug that the wholesaler will sell the drug directly and only to a pharmacy or practitioner. What this provision essentially does is limit to whom a wholesaler may sell product to either: (a) retail; or (b) a wholesaler intending to sell to retail. While it is unclear what sort of assurance would satisfy the "reasonable assurance" requirement,[4] it is wholly improper, PDA submits, for the state licensing authorities to limit the business transactions between duly licensed entities that have satisfied all of the requirements to do business in this field by the Nevada Board of Pharmacy.

Likewise, a Nevada wholesaler may purchase a prescription drug only from: (a) a manufacturer; or (b) another wholesaler, if the selling wholesaler is licensed by Nevada[5] and the sale is a "bona fide transaction." A purchase is deemed a bona fide transaction if, the selling wholesaler purchased the drug directly from the manufacturer or purchased the drug with a reasonable belief that the drug was originally purchased directly from the manufacturer.[6] Again, there

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based on quantity. For example, the Nevada Administrative Code Section 639.5975 provides, in part, "[i]n any calendar month, a wholesaler shall not sell, distribute, transfer or otherwise provide more than 10 percent of its total amount of prescription drugs to another wholesaler, distributor or manufacturer."

[4] The amendments did not address what might constitute the required "reasonable assurance."

[5] The legislation also removes a previous exemption that permitted out of state wholesalers and manufacturers to furnish restricted drugs to Nevada licensed wholesalers or manufacturers without obtaining a license from the Board.

[6] Additional criteria for a bona fide purchase include the following: the circumstances of the purchase reasonably indicate that the drug was not purchased from a source prohibited by law; unless the drug is purchased by the wholesaler from the manufacturer, before the wholesaler sells the drug to another wholesaler, the wholesaler who sells the drug conducts a reasonable visual examination of the drug to ensure that the drug is not: counterfeit, adulterated or misbranded under Nevada law, mislabeled, damaged/compromised by improper handling, storage, or temperature control, from a foreign or unlawful source, or manufactured, packaged, labeled or shipped in violation of any state or federal law; the drug is shipped directly from the selling wholesaler to the purchasing wholesaler; and the documents of the shipping company concerning the shipping of the drug are attached to the invoice for the drug and are maintained in the

should be no requirement on a duly licensed wholesaler to limit the drugs it purchases from other duly licensed wholesalers to drug product that was purchased directly from the manufacturer.[7]

The new Florida law also places impermissible burdens on interstate commerce through its pedigree requirements and through its definition of "authorized distributor of record." The Florida law requires that effective July 1, 2006, each person engaged in the wholesale distribution of a prescription drug (other than the manufacturer) must before each wholesale distribution of such drug, provide to the person who receives the drug (including end-user hospital, pharmacy, or practitioner) a pedigree paper tracing the history of all sales of that unit back to the manufacturer. This requirement is implemented through a phased-in approach, whereby:

- Prior to July 1, 2006, the pedigree requirements are:
- (a) For drugs on a specified list, a wholesaler must either provide to another wholesale distributor: (i) a pedigree paper that traces the history of all sales of each unit back to the manufacturer or (ii) state that the unit was purchased directly from the manufacturer by the seller or a member of its affiliated group; and
- (b) For drugs not on the specified list, wholesalers who are not authorized distributors of record must pass on to another wholesale distributor a pedigree paper tracing the sales history back to an authorized distributor of record. Drugs on the specified list are those that have been found in the past to be counterfeited or tainted.
- An authorized distributor of record is defined by the Florida statute as "a wholesale distributor with whom a manufacturer has established an ongoing relationship to distribute the manufacturer's products." Under current Florida regulations, an "ongoing relationship" means for a non-specified drug "an association that exists when a manufacturer and a distributor enter into a written agreement under which the distributor is authorized to distribute the manufacturer's product(s) for a period of time or for a number of shipments, at least one sale is made under that agreement, and the name of the authorized distributor of record is entered

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records of the wholesaler. These types of provisions are reasonable, appropriate and consistent with 21 C.F.R. Part 205.

[7] Under the Nevada legislation, purchase or sale includes, without limitation, the distribution, transfer, trading, bartering or any other provision of a prescription drug to another person by a wholesaler. A transfer from a wholesale facility of a wholesaler to another wholesale facility of the wholesaler shall not be deemed a purchase or sale if the wholesaler is a corporation whose securities are publicly traded and regulated by the Securities and Exchange Act of 1934.

on the manufacturer's list of authorized distributors of record or equivalent list. An ongoing relationship may also be documented by at least 3 purchases of a manufacturer's product(s) directly from that manufacturer within a six month period from the date for which the authorized distributor of record relationship is claimed.

- For a specified drug, there is no "authorized distributor of record" and a pedigree must be provided in all cases.
- Until July 1, 2006, an "ongoing" relationship will exist when a wholesale distributor, including any affiliated group of which the wholesale distributor is a member is: a) listed on the manufacturer's current list of authorized distributors of record; b)annually purchases not less than 90% of its purchases of a manufacturer's prescription drug products, based on dollar volume, directly from that manufacturer and has total annual prescription drug sales of $100 million or more; or ,c) if the manufacturer has failed to file its list of authorized distributors or has a list containing fewer than ten wholesale distributors licensed in Florida, has reported to the department that it has total annual prescription drug sales of $100 million or more, and has a verifiable account number issued by the manufacturer authorizing the wholesale distributor to purchase the manufacturer's drug products directly from that manufacturer and that wholesale distributor makes not fewer than 12 purchases of that manufacturer's drug products directly from the manufacturer using said verifiable account number in preceding 12 months.

These provisions, PDA submits, burden interstate commerce. Moreover, the drug list concept will have the effect of stabilizing the prices of those drugs at high levels. Today, the issue is preventing counterfeit and unlawful drugs entering the distribution system. PDA wants to be a part of the solution to that problem. Today and tomorrow, the high cost of drugs is burdening our health care system. PDA wants to be able to continue to be part of the solution to that problem as well. It cannot do so it commerce in prescription drugs is burdened by each of the fifty states.

PDMA provides that authorized distributors of record are "those distributors with whom the manufacturer has established an ongoing relationship to distribute such manufacturer's products." FFDCA, §503(4)(a). In the 1988 Food and Drug Administration PDMA Guidance ("1988 Guidance"), FDA provided that an "ongoing relationship"

> may be interpreted to mean a continuing business relationship in which it is intended that the wholesale distributor engage in wholesale distribution of a manufacturer's prescription drug product or products. Evidence of such intent would include, but not be limited to, the existence of a written

> franchise, license, or other distribution agreement between the manufacturer and wholesale distributor, and the existence of ongoing sales by the manufacturer to the distributor, either directly or through a jointly agreed upon intermediary. The Agency would consider two transactions in any 24-month period to be evidence of a continuing relationship.

1988 Guidance. In final rules promulgated by the FDA in 1999, [which have since been stayed,[8]] FDA defined an "ongoing relationship" for the purposes of determining whether one is an authorized distributor of record in 21 C.F.R. § 203.3(u) as follows:

> Ongoing relationship means an association that exists when a manufacturer and a distributor enter into a written agreement under which the distributor is authorized to distribute the manufacturers' products for a period of time or for a number of shipments. If the distributor is not authorized to distribute the manufacturer's entire product line, the agreement must identify the specific drug products that the distributor is authorized to distribute.

In its PDMA Report to Congress, the FDA agreed that the ongoing relationship definition of the final rule "is restrictive and places control of who can be an authorized distributor in the hands of manufacturers," and that "it could prohibit many secondary distributors, including those who make regular purchases from manufacturers, from qualifying as authorized distributors of record." PDMA Report to Congress at 19. The FDA also concluded that "this could have anticompetitive consequences without the corresponding benefit of protecting the public health." Id. Moreover, the FDA determined it "could broaden the definition of authorized distributor – although this change could result in even fewer wholesalers than before maintaining and passing on pedigrees for prescription drugs." The PDA has provided FDA with extensive comments on the anticompetitive impact of § 203.3(u) as it is presently drafted. Those comments concluded that two transactions in the previous twenty-four month period should be sufficient evidence of the on-going relationship required by PDMA. Moreover, in its PDMA Report to Congress, FDA stated that it "believes that an on-going relationship could be demonstrated by evidence of two sales within the previous 24-month period." PDMA Report to Congress at 20.

PDA now believes that the definition of ADR should be enhanced from the 1988 Guidance to incorporate elements of the Food and Drug Administration's 1999 regulation and objective criteria that can be met based on transactions with

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[8] See 68 Fed. Reg. 4912 (January 31, 2003)

the pharmaceutical manufacturer. PDA's recommended guideline for the federal definition of the ADR is as follows:

- must be on a manufacturer's list
  - list to be updated monthly (FDA should maintain and update this list on its website)

    OR
- have a written agreement currently in effect with the manufacturer

    OR
- have a verifiable account with the manufacturer (by phone check or invoices with account numbers) and minimal transactional or volume requirement thresholds as follows :
  - 5000 sales units (defined as the units of sale a manufacturer uses when it invoices that product, i.e., a bottle of 100 100 mg tablets) within 12 months

    OR
  - 12 purchases evidenced by invoices from the manufacturer within 12 months.

In conclusion, PDA supports enhanced licensing and enforcement of prescription drug wholesaler licensing requirements. PDA supports enforcement of laws against commerce in counterfeit or otherwise illegal drugs. PDA does not support a hodge podge of state laws regarding who may be an ADR and what must be in a prescription drug pedigree. These latter definitions are and should be Federal definitions of national applicability and effect.

> FDA Question - *Discuss the strengths and weaknesses of a pedigree as a means of tracking product integrity. Is there a deterrent value in having a pedigree? What is the most cost-effective approach to obtaining reliable pedigree information?*

The reality is that any type of "manual" pedigree system does nothing in terms of assuring product integrity. While the pedigree could indicate that the drug has passed thru the hands of only licensed wholesalers, there is no protection that the products themselves are actually authentic. In fact, no pedigree will ever give that type of assurance. However, if there is an embedded technology that is provided by the manufacturer, one can certainly determine if a product is authentic. Regardless of the number of hands a particular item has passed thru, the overall objective is to assure that products are authentic, so even in the absence of any pedigree statement, this objective can be achieved. Moreover, drug pedigrees may provide the purchaser with a false sense of protection regarding the integrity of the product that they have acquired.

FDA Question - *Discuss the advantages and disadvantages of increased penalties for counterfeiting drugs.*

The advantage of increased penalties for counterfeiting drugs is that it will be deterred from counterfeiting. The disadvantage is those who choose to be felons.

FDA Question - *Identify areas where business practices could be changed to prevent the introduction, and facilitate the identification, of counterfeit drugs.*

PDA believes that manufacturers of pioneer drugs should be required to manufacture their USFDA approved new drugs for the sale in the United States in a color, or in a color and shape that is different than the same product that they or their licensees or partners manufacture for sale in other countries. If this is done, felons will not be able to acquire those drugs oversees and then smuggle them into the United States.

In PDA's view, uniquely distinguishing the USFDA approved drug to be sold in the United States from the version to be sold overseas will shut off a principle source of counterfeits and a felon mentality that provides a market for smugglers to sell such drugs on the claim that they are manufactured by the same company or even at the same facility as the drug sold in the United States.

PDA further understands that one manufacturer of a controlled substance that has become a drug of abuse, made its color and shape exclusive for the United States in order to inhibit smuggling of their drug from outside the United States. FDA can certainly inquire as to whether this change helped prevent smuggling of this drug into the country.

FDA Question - *Describe the current use of designated personnel and teams to implement and monitor anti-counterfeiting measures by manufacturers, wholesalers, re-packagers, and pharmacies.*

Some PDA members have libraries of drug purchased directly from their manufacturer to compare against product received from other wholesalers. Designated personnel compare incoming product to the product in these libraries to look for counterfeits.

FDA Question - *Comment on the advantages and disadvantages of manufacturers sharing market data with the FDA for use in identifying counterfeit products.*

Present FDA regulations, 21 CFR Sec. 314.81(b)(2)(ii), provide for annual reports for new drugs.

FDA Question - *Comment on the need for FDA guidance dealing with site security and supply chain integrity in light of the importance of drug treatment for bioterrorism incidents.*

The threat of bioterrorism is an additional reason for FDA guidance dealing with site security and supply chain integrity.

FDA Question - *What capabilities should a communication network have in order to be part of a counterfeit alert system? For example: Should the system be accessible to all stakeholders (e.g., pharmacies, wholesalers)? How fast should the system be able to disseminate information about suspect product? Should messaging be active? How should the system flag messages about suspect product as opposed to urgent information? Should access be at no cost? Should all networks in the system have a uniform method of presenting and distributing information? How secure must the system be? Should access to information be selective? Should the system be capable of direct linkage to the FDA? Should the system be able to transmit educational information?*

PDA believes any system should include all stakeholders to include wholesalers. The most important goal of this system should be to freeze suspect product until it can promptly be evaluated and secured or released.

PDA appreciates the opportunity to provide its views to FDA on these important issues.

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Attachment to Pharmaceutical Distributors Association Comments on Docket No. 2003N-0361

Recommended Guidelines for Pharmaceutical Distribution System Integrity

Preamble

Prescription drug wholesalers, like all nongovernmental entities, do not have the investigative powers and resources to guarantee that certain products are not counterfeit. But they are uniquely situated to perform due diligence in order to protect the integrity of the pharmaceutical distribution system. Even with due diligence, in today's fast paced, just-in-time market, it is not always possible to determine the authenticity of specific prescription drugs being offered for sale. But rigorous due diligence can establish whether the sources of those prescription drugs meet certain criteria which provide a greater level of assurance that those sources are legitimate and present no reasonable probability of distributing counterfeit prescription drugs.

Experience with counterfeit drug distributors indicates that they are distinctly different from legitimate prescription drug wholesalers. Therefore, the first step in defining due diligence criteria is to identify the pertinent characteristics shared by legitimate prescription drug wholesalers. Once identified, these pertinent characteristics are the basis for the due diligence requirements contained herein. The logical nexus between the characteristics of legitimate prescription drug wholesaler and the due diligence criteria is an important safeguard to help assure the integrity of the prescription drug distribution system without disadvantaging law abiding wholesalers.

Legitimate prescription drug wholesalers share the following pertinent characteristics:

1. Their business is structured as a "going concern"
2. They demonstrate appropriate financial responsibility
3. They have robust operational standards
4. They have rigorous compliance systems
5. They can demonstrate their corporate and compliance history

An entity that does not display these characteristics may be identified as a suspect source of prescription drugs, or a source that may present an unreasonable risk to the integrity of the pharmaceutical distribution system and the public health.

The due diligence criteria and due diligence best practices in this guideline have been designed to identify facts and information about an entity that would demonstrate whether that entity displays the characteristics of a legitimate prescription drug wholesaler or, in the alternative, is reasonably likely to be a suspect source of prescription drugs. It is recommended that a prescription drug wholesaler:

1. Independently apply these Guidelines when evaluating proposed purchases from prescription drug wholesaler;
2. Use the due diligence best practices to determine whether the source of the prescription drugs meets the due diligence criteria; and
3. Purchase prescription drugs from sources that substantially demonstrate the characteristics of a legitimate prescription drug wholesaler in accordance with 2, above.

These Guidelines, therefore, outline best practices for the exercise of due diligence by prescription drug wholesalers to enhance the detection and elimination of illegitimate sources which market counterfeit products.

The public interest in drug product safety and efficacy is well served by this industry effort to detect and prevent counterfeit products from entering the prescription drug distribution pipeline in the United States.

I. Initial Information Request

When a prescription drug wholesaler is considering making purchases from another prescription drug wholesaler for the first time, it is recommended that a completed information request be obtained from the prospective selling wholesaler prior to the purchase. The information request should include the following information and it is recommended that this information request be updated annually:

1. A listing of states the company is domiciled in and shipping into and copies of all current state/federal regulatory licenses/registrations including license/registration number(s). (Note: purchaser is advised to check to ensure expiration dates have not passed);
2. The company's most recent site inspection(s) dates and inspection reports or resolutions (both state and federal inspections);
3. The minimum liability insurance limits the company maintains including general as well as product liability insurance;
4. All other "doing business as" (d/b/a's) names, and formerly known as (f/k/a's), including all affiliated businesses;
5. A complete list of all corporate officers;
6. A complete list of all owners of greater than 10 percent of the business unless it is a publicly-held company;

7. A list of all disciplinary actions by state/federal agencies against the company as well as principals, owners or officers over the last ten years, or since the company was first licensed, or any of the listed individuals were first in the prescription drug wholesale business;
8. The number of employees at the facility and screening procedures for hiring;
9. A full description of each facility/warehouse. Include all locations utilized for drug storage and/or distribution), including:
    a. Square footage;
    b. Security and alarm system description;
    c. Terms of lease/own;
    d. Address; and
    e. Temperature and humidity controls.
10. A description of prescription drug import/export activities, including:
    a. A listing of all countries importing from and exporting to;
    b. A listing of what products are being imported/exported from each country identified in 10a;
    c. The nature of the company's import/export activities pertaining to prescription drugs (i.e., repackaging, re-labeling, etc.); and
    d. How are products designated for import/export separated from domestic inventory?
11. A description of the process the company uses to validate and certify its suppliers and purchases including the supplier's ADR status, (particularly if the process differs from the Recommended Guidelines for Pharmaceutical Distribution System Integrity).
12. A list of the classes of trade (e.g., manufacturer, wholesale, retail, hospital, institutional, clinics, etc.) the seller is purchasing from or selling his/her product from or to.
13. Available financial statements or SEC filings.
14. Systems and procedures in place for prompt reporting of any suspected counterfeit, stolen or otherwise unlawful prescription drug products or buyers or sellers of same to the appropriate state and federal authorities and manufacturer(s) of the product(s).

II. Certification of ADR Status

If the selling prescription drug wholesaler claims to be an ADR, it is recommended that the purchaser obtain a written statement from the seller stating that it is an ADR and on what basis. It is also recommended that the purchaser independently verify the seller's ADR status on the initial purchase and then at least annually thereafter.

III. Background Check

It is recommended that the purchaser conduct a background check of any prescription drug wholesaler it conducts business with prior to the initial transaction. This background check should include:

1. Subject to the requirements of the Fair Credit Reporting Act:
    a. A criminal background and criminal and civil litigation check of all company officers, key management, principals and owners with 10 percent or greater interest in the company (the latter applying to non-publicly held companies only);
    b. A driver's license and social security verification of all company officers, key management and owners;
    c. Before completing a background check on the referenced individuals in 1a and 1b above, the purchaser must obtain the written consent of each such individual, clearly indicating how the information will be used. If the purchaser decides not to purchase from the prescription drug wholesaler based on the background information obtained, the purchaser must notify the individual (orally or in writing) in accordance with the notice requirements of the Fair Credit Reporting Act, 15 U.S.C. §1681(a);
2. A credit history maintained by an independent third party credit evaluation organization;
3. A check of the national database of licensed prescription drug wholesalers (if such a database is created);
4. A check to determine if civil/criminal litigation exists against the company; and
5. Verification of the date of incorporation and years in business, place of incorporation and form of entity.

IV. Physical Site Inspection

It is recommended, prior to an initial purchase, that a purchaser conduct a physical site inspection(s) of any prescription drug wholesaler seller it intends to do business with to ensure that the company's facility (ies) is/are in compliance with appropriate storage and operational conditions and practices. These inspections should be conducted on a biannual basis. A third party, so long as not a prescription drug wholesaler, may be used to conduct the inspections on behalf of the purchaser. A standard checklist for site inspections should be utilized and incorporate the following:

<u>Administrative/Management</u>

It is recommended that the purchaser:

1. Establish the authority, training, and experience of each individual providing the required information to them on behalf of the seller and each individual who

controls and is responsible for the direct supervision of all persons who inspect, handle or have access to prescription drug products;
2. Request and examine the seller's organizational chart to identify key management and structure of the company; and
3. Verify the number of employees at the facility.

Building (size, physical conditions, etc.)
It is recommended that the purchaser check the
1. Structural appearance and general integrity based on a visual inspection;
2. Square footage;
3. Year of construction;
4. General security and alarm system;
5. Climate control; and
6. Surrounding area (e.g., zoning)

Operations
It is recommended that the purchaser examine the following:
1. Documentation of PDMA compliance status including receipt and provision of "identifying statements," ADR status, requirements for PDMA compliance guarantees, recordkeeping and compliance with state and federal laws relating to the purchase and sale of prescription drugs.
2. Procedures for stock rotation;
3. Policies and procedures for conducting inspections of samples of product purchases;
4. Visually inspect a sample of the seller's product;
5. Temperature monitoring program and documentation;
6. Systems/procedures for detecting adulterated/misbranded product, including systems and procedures to verify that manufacturer-identified anti-tampering devices are intact;
7. Systems/procedures for validating Identifying Statements;
8. Condition of medical product inventory in the warehouse;
9. Compliance with 21 CFR 1304.22 DEA recordkeeping requirements; and
10. Form of payment the seller uses to purchase product.

V. Seller Qualification

Once the site inspection has been completed, the results should be discussed with those employees or representatives of purchaser who are responsible for approving new suppliers. If the seller's background check, the completed information request, and the site inspection are determined to be satisfactory and the purchaser obtains the appropriate internal approval of the new supplier, the seller should execute signed agreements or

contract provisions with language specific to PDMA compliance and compliance with all state and federal laws relating to the purchase and sale of pharmaceuticals and that the purchaser will be notified if the seller receives information that the integrity or legal status of prescription drugs sold to purchaser has been called into question by the manufacturer, retailers, wholesalers, or state or federal authorities. The signed agreements should include language stating that the seller agrees to notify the purchaser of any changes in its information request within 30 days.

VI. Ongoing PDMA Compliance Review

It is recommended that the purchaser conduct ongoing compliance reviews and document all findings. These reviews should include:

1. Verifying that the seller is meeting the requirements for obtaining an "Identifying Statement", and that the "Identifying Statements" contain the required information;
2. Verifying that the seller has an effective process in place to authenticate the accuracy and integrity of the "Identifying Statement."
3. Performing appropriate supplemental review actions when:
    a. The "Identifying Statement" has more than three entities on it; or
    b. The price of the product being sold is substantially less than the prevailing market prices.

VII. Additional Purchaser Responsibilities

In addition to all the previous steps, it is also recommended that the purchaser:

1. Maintain an internal company list of non-complying/at risk companies that are not reputable, or otherwise suspect, whose products prescription drug wholesaler would not purchase, based upon prior experience or other criteria;
2. Maintain an internal list of non-complying/at risk products (i.e. biologics, previously counterfeited drugs) that the prescription drug wholesaler would not purchase from a non-manufacturing vendor (NMV) or non-ADR;
3. Have systems and procedures in place for prompt reporting of any suspected counterfeit, stolen or otherwise unlawful prescription drug products or buyers or sellers of same to the appropriate state and federal authorities and manufacturer(s) of the product(s).
4. Cooperate with state and federal regulatory authorities by promptly providing copies of requested records and other information relevant to administrative, civil and criminal investigations related to prescription drug products.