Enforcement Committee Report

John Jones, Chair
Stan Goldenberg
Bill Powers


FOR ACTION

RECOMMENDATION 1

That the Board of Pharmacy support the proposed citation and fine statute for wholesale violations and the proposed statutes regarding wholesale drug transactions.

Discussion

The Enforcement Committee has been engaged in a process of developing rules designed to strengthen the regulation of drug wholesalers. The committee has considered a number of different proposals. Based on discussions at prior committee meetings and discussion at the October 2003 board meeting, staff developed a legislative proposal for the committee’s consideration. The proposal includes elements that have been considered previously, most notably expanded citation and fine authority for certain violations, and elements drawn from recent legislation passed in Florida. The recent Florida legislation focused on preventing the introduction of counterfeit drugs into the system by implementing stricter licensing requirements for drug wholesalers, increasing the criminal sanctions for counterfeiting prescription drugs, and requiring pedigrees. Most notably, the National Association of Boards of Pharmacy (NABP) has issued a “draft” model rule for the licensure of wholesale distributors. (Attachment A)

The proposal is designed to address challenges presented by the existing distribution system for prescription drugs. During the board meeting, Supervising Inspector Judi Nurse will report on those challenges. The proposal also includes changes to wholesale licensing requirements approved by the board at its October 2003 meeting. The principal elements are described as follows:

- Require pedigrees for all drug shipments beginning January 1, 2006.
- Generally prohibits the wholesaling of prescription drugs by pharmacies.
- Require wholesalers to obtain a $100,000 bond to secure payment of administrative fines and penalties.
- Permit the board to issue fines on a per occurrence basis for specified violations (e.g., sale of counterfeit drugs, sale of outdated drugs, failure to preserve records, etc.)
- Defines “closed door pharmacy” as one serving skilled nursing and intermediate care facilities and prohibits the owners of a closed-door pharmacy from owning a wholesale facility.
There was considerable discussion regarding the proposals. Many supported better screening procedures prior to the issuance of a wholesale license that would enhance product safety. There was reference to the Healthcare Distribution Management Association’s (HDMA) guidelines to assure integrity of the pharmaceutical distribution system to strengthen efforts to prevent the counterfeiting of products. The HDMA guidelines recommend that distributors conduct due diligence, background checks, on-site inspections and ongoing reviews of suppliers and purchasers to ensure compliance with federal and state laws pertaining to prescription drugs.

Comments were made regarding the proposed pedigree requirement. It was discussed that electronic tracking capabilities will significantly prevent counterfeiting. However, the technology will not be available until the middle of 2004. Meanwhile, Florida requires a paper pedigree for “high risk” drugs and then in 2006, will require pedigrees for all drugs. It was argued that a pedigree requirement would slow down the distribution of drugs and restrict commerce.

**Background Documents**

Attachment B – NABP “Draft” Model Rules for the Licensure of Wholesale Distributors
Attachment C – Profile of the Prescription Drug Wholesaling Industry – February 12, 2001
Attachment E – Public Comments

At the October board meeting, the board received copies of the articles that the *Washington Post* did on the U.S. prescription drug system.

**RECOMMENDATION 2**

That the Board of Pharmacy consider the proposal from the Joint Task Force on Prescriber Dispensing regarding dispensing by a medical group. The Enforcement Committee did not make a recommendation on the proposal.

**Discussion**

The Medical Board of California (MBC) and the Board of Pharmacy held a joint task force meeting on the issue of prescriber dispensing. The meeting was held on May 27, 2003, and the task force reached consensus on the following: (1) Under current law, an individual prescriber can own his/her own prescription stock and dispense to his or her own patients as specified and such practice should be allowed to continue with the goal of strengthening and educating prescribers regarding the record keeping requirements; (2) Allow a medical group to dispense prescription medications pursuant to a special permit issued by the Board of Pharmacy and specified conditions that require one physician from the medical group to be responsible and accountable for the security of the prescription medications, record keeping requirements, and a consultant pharmacist reviews the dispensing process; (3) Establish the authority for a pharmacy
to place an automated dispensing device in a prescriber’s office; and (4) Provide for joint oversight by the appropriate licensing agencies.

The task force agreed that staff from the two boards would work together to draft language for each board to consider as a possible joint legislative proposal for 2004. Draft language was developed and the Medical Board task force members provided comments on the draft. The language was reworked to address their comments. The proposal would require a special clinic licensure for these group practices, which would have a significant fiscal impact to the board. (Attachment F)

The language was first provided to the Enforcement Committee at its September meeting. However, it was requested that the committee postpone its discussion until the interested parties had more time to review the proposal and submit comments. The Enforcement Committee agreed to discuss the issue at its December meeting.

There was considerable discussion that the legislative proposal would authorize the Board of Pharmacy to issue a clinic permit to a medical group and this was not in the best interest of the public. Moreover, it was argued that it was contrary to current law, which prohibits prescribers from owning pharmacies. There was also concern about the proposed amendment to Business and Professions Code section 4170(a), which would allow a registered nurse to hand to a patient the medication that is dispensed by the prescriber. Although there is an Attorney General Opinion (57 Op. Att’y Gen. 93 (1974)) that states that a nurse may assist, at the prescriber’s direction, in the dispensing of such drugs, including handing them to the patient, it was noted that this opinion was prior to the most recent amendments to this section code.

**NO ACTION**

**Importation of Drugs from Canada**

The board has been discussing and has sought comments on the issue of prescription drug importation from Canada and from other countries. This has been a sensitive and controversial issue. The board has been tasked with balancing consumer access to affordable prescriptions against the safety and effectiveness of drugs obtained from foreign sources. The board has heard from many interested parties on this issue during its committee meetings and at its quarterly board meetings.

During its October meeting, the board decided to hold a summit on prescription drug importation. The plan was to invite leaders representing all sides of the issue in an effort to fully discuss the health care policy concerns inherent with this topic.

Since the last board meeting, the United States District Court for the Northern District of Oklahoma ruled on November 6, 2003, that Rx Depot/Rx Canada violated federal law by causing the importation of prescriptions drugs from Canadian pharmacies. Rx Depot/Rx Canada assists individuals in procuring prescription medications from pharmacies in Canada. Each location has
one or two employees who accept prescriptions from U.S. customers. Customers are asked to fill out a medical history form and other forms provided by Rx Depot/Rx Canada. Customers can deliver these documents to Rx Depot/Rx Canada’s stores in person, or can mail or fax them to the nearest Rx Depot/Rx Canada store.

Once a Rx Depot/Rx Canada customer has submitted the required forms and prescriptions, the papers and the customer’s credit card information or a certified check are transmitted to an operating pharmacy in Canada. A Canadian doctor rewrites the prescription, and the Canadian pharmacy fills the prescription, ships the prescription drugs directly to the U.S. customer, and bills the U.S. customer’s credit card. Rx Depot/Rx Canada receives a 10 to 12 percent commission for each sale they facilitate for the Canadian pharmacies. They also receive commissions for refill orders, which generally are arranged directly between customers and the Canadian pharmacies. It was noted in the decision that Rx Depot/Rx Canada stores are essentially commissioned sales agents for Canadian pharmacies.

The decision called for immediate closing of the 88 nationwide Rx Depot/Rx Canada affiliates, including 17 California locations. Rx Depot/Rx Canada appealed the decision. On November 21st, the 10th Circuit Court of Appeals decision denied the motion from Rx Depot to stay the District Courts ruling. (Attachment G)

Implementation of Enforcement Provisions from SB 361

SB 361 (Figueroa) was the legislative vehicle for the Board of Pharmacy sunset extension and contained statutory recommendations approved by the Joint Legislative Sunset Review Committee. The following compliance provisions were added to California Pharmacy Law effective January 1, 2004.

- **Section 4083 – Order of Correction**
  Allows an inspector to issue an order of correction to a licensee directing the licensee to comply with pharmacy law within 30 days by submitting a corrective action plan to the inspector, or the licensee can contest the order of correction to the executive officer for an office conference. If an office conference is not requested, compliance with the order does not constitute an admission of the violation noted in the order of correction and the order of correction is not considered a public record for purposes of disclosure. A copy of the order of correction and corrective action plan must be maintained on the license premise for at least three years from the date the order was issued.

- **Section 4315 – Letter of Admonishment**
  Authorizes the executive officer to issue a letter of admonishment to a licensee for failure to comply with pharmacy law and directs the licensee to come into compliance within 30 days by submitting a corrective action plan to the executive officer documenting compliance, or the licensee can contest the letter of admonishment to the executive office for an office conference. If an office conference is not requested, compliance with the letter of admonishment does not constitute an admission of the violation noted in the letter of admonishment. The licensee must maintain on the licensed premises a copy of the letter of admonishment and corrective action plan.
plan for at least three years from the date the letter was issued. The letter of admonishment will be considered a public record for purposes of disclosure.

- **Section 4314 – Issuance of Citations**
  Allows the board to issue an order of abatement that will require a person or entity to whom a citation has been issued to demonstrate how future compliance with the pharmacy law will be accomplished and provides that such demonstration may include, but not be limited to, submission of a corrective action plan, as well as requiring the completion of up to six hours of continuing education courses in subject matter specified in the order of abatement.

The committee discussed the implementation of these new changes into the board’s investigation process. *(Attachment H)*

**Implementation of SB 151 (Chapter 406, Statutes of 2003) – New Prescription Requirements for Controlled Substances and the Elimination of the Triplicate**

Senate Bill 151 (Burton) repeals the triplicate prescription requirement for Schedule II controlled substance prescriptions and substantially revises California law regarding the prescribing of controlled substances generally. The committee was given a memorandum that outlined the changes contained in the legislation. Flow charts were provided that displayed the prescription dispensing process for controlled substance prescriptions. *(Attachment I)*

It was stated that generally, SB 151 repeals the triplicate and replaces it with a tamper resistant prescription form that may be obtained from approved printers. This new form will be required for all controlled substance prescriptions after the phase-in period. The bill also will require pharmacies to report Schedule III controlled substance prescriptions to the CURES system.

**Enforcement Committee Meeting Summary of December 10, 2003 (Attachment J)**

Meeting dates for 2004 are: March 18th, June 23rd, September 29th and December 15th (this was changed from the 2nd).

**Enforcement Team Meeting Summary of December 10, 2003(Attachment K)**

**Report on Enforcement Actions (Attachment L)**

Attachment A
Memorandum

To: Board Members

From: Paul Riches

Date: January 13, 2004

Subject: NABP Draft Rules for Wholesalers

The National Association of Boards of Pharmacy (NABP) has recently completed draft model rules (rules) for wholesalers. The rules present a model for regulating wholesalers including definitional provisions, licensing standards, transaction standards and enforcement provisions. This memo will summarize the rules and provide comparisons to proposed language regarding wholesalers that has been recommended by the Enforcement Committee.

NABP Draft Model Rules

Licensing Provisions:

1. Requires submission of detailed personal information from each owner, partner, or corporate officer of the wholesale applicant.
2. Requires detailed personal information from the “designated representative” who is analogous to the exemptee-in-charge required by California law.
3. Requires each applicant to provide a $100,000 bond to secure payment of any administrative fines or penalties imposed by the regulator.
4. Requires inspection of the wholesale facility prior to the issuance of a wholesale license and at least every three years thereafter.
5. Requires the conduct of a criminal background check for the applicant.
6. Requires the applicant to have a “designated representative” in charge of day to day management that is similar to California’s exemptee-in-charge requirement.
7. Requires the designated representative to complete continuing education programs as required by the regulator.
8. Requires a criminal background check for all employees handling dangerous drugs or dangerous devices.
9. Prohibits the issuance of a wholesale permit to a residence.
10. Prohibits the issuance of a wholesale permit to an applicant that owns a closed pharmacy. “Closed Pharmacy” means a pharmacy serving a limited patient population.

Transaction and Handling Standards:

1. Requires drugs to be stored in accordance with USP standards.
2. Requires wholesale facilities to meet basic requirements relating to security, climate control and cleanliness.
3. Requires wholesale facilities to maintain quarantined areas for the storage of adulterated or outdated drugs.
4. Requires wholesalers doing business with entities not licensed by the regulator to engage in due extensive due diligence regarding that business partner and requires extra measures to authenticate drugs purchased from that business partner.
5. Effective January 1, 2007, requires an electronic pedigree for all wholesale drugs.
6. Prior to January 1, 2007, requires either an electronic or a paper pedigree for selected high risk drugs.
7. Requires wholesalers to preserve records of the acquisition and disposition of all dangerous drugs and dangerous devices for three years.
8. Requires wholesalers to report suspected counterfeit drugs to the regulator.

**Enforcement:**

Establishes felony offenses relating to counterfeits, contraband, and for numerous violations of wholesaler rules.

**Revised Draft for Board Consideration**

The enforcement committee has been engaged in a process of developing rules designed to strengthen the regulation of drug wholesalers for some time. A number of different proposals have been considered by the committee and commented on by interested parties.

Based on discussions at the December 2003 Enforcement Committee meeting on a prior draft, staff has developed a revised proposal for the board’s consideration. The proposal includes elements that have been considered previously, most notably expanded citation and fine authority for certain violations, and elements drawn from recent legislation passed in Florida. The recent Florida legislation focused on preventing the introduction of counterfeit drugs into the system by implementing stricter licensing requirements for drug wholesalers, increasing the sanctions for counterfeiting prescription drugs, and by requiring pedigrees.

Generally, the proposal does the following:

2. Generally prohibiting the wholesaling of prescription drugs by pharmacies.
3. Require wholesalers to obtain a $100,000 bond to secure payment of administrative fines and penalties.
4. Permit the board to issue fines on a per occurrence basis for specified violations (e.g., sale of counterfeit drugs, sale of outdated drugs, failure to preserve records, etc.)
5. Defines “closed pharmacy” as one serving a limited patient population and not open to the general public and prohibiting the co-ownership of a closed pharmacy and a wholesaler.

Attached to this memo is a revised draft (dated January 21, 2004) of changes to wholesaler statutes based on discussions during the December 2003 Enforcement Committee meeting. This draft incorporates some comments made by the Healthcare Distribution Management
Association (HDMA) and elements drawn from a recent draft of model rules from NABP
discussed above. Also included for your reference is a copy of the draft proposal considered by
the Enforcement Committee in December 2003.

Specifically, the draft makes changes based on HDMA comments as follows:

1. Permits electronic pedigrees.
2. Extends the implementation date of the pedigree requirement to January 1, 2007. This
   extended implementation date is consistent with the NABP model rules as well.
3. Narrows the enhanced citation and fine provision relating to counterfeit drugs to
   include a “reasonable knowledge” standard for violations related to the sale of
   adulterated or misbranded drugs. This change was made to ensure that good faith
   distributors are not punished for unknowingly selling counterfeit drugs.
4. The bonding requirement was clarified to allow a surety bond or equivalent security.
5. Eliminates the application of the pedigree requirement to dangerous devices.

The draft makes changes based on the draft NABP model rules as follows:

1. Adopts the NABP definition of a “closed pharmacy.”
2. Adapts language regarding the content of a pedigree.
3. Adopts the January 1, 2007 implementation date for pedigrees.
Add Section 4021.5 to the Business and Professions Code, to read:

4021.5. “Closed Pharmacy” means a pharmacy that purchases dangerous drugs or dangerous devices for a limited patient population and is not open for dispensing dangerous drugs or dangerous devices to the general population.

Add Section 4034 to the Business and Professions Code, to read:

4034. “Pedigree” means a record, in written or electronic form, containing information regarding each distribution of any given dangerous drug, from sale by a manufacturer, through acquisition and sale by any wholesaler, until final sale to a pharmacy or other person administering or dispensing the drug. A pedigree shall include:

(a) The source of the dangerous drug, including the name, California license number, and principal address of the seller.
(b) The amount of the dangerous drug, its dosage form and strength, the date of the purchase, the sales invoice number, container size, number of containers, expiration date(s), and lot number(s) of the dangerous drug.
(c) The business name, address and, if appropriate, California license number of each owner of the dangerous drug, its shipping information, including the name and address of each person certifying delivery or receipt of the dangerous drug;
(d) A certification, under penalty of perjury, from the a responsible party of the seller of the dangerous drug that the information contained in the pedigree is true and accurate.

Add Section 4126.5 to the Business and Professions Code, to read:

4126.5. A pharmacy may only furnish dangerous drugs or dangerous devices as follows:
(a) To the wholesaler or manufacturer from whom the dangerous drugs or dangerous devices were purchased.
(b) To a licensed reverse distributor.
(c) To another pharmacy or wholesaler to alleviate temporary shortages that could result in the denial of healthcare.
(d) To a patient or other provider of health care authorized to purchase dangerous drugs and dangerous devices.

Amend Section 4160 of the Business and Professions Code, to read:

4160. (a) No person shall act as a wholesaler of any dangerous drug or dangerous device unless he or she has obtained a license from the board.
(b) Upon approval by the board and the payment of the required fee, the board shall issue a license to the applicant.
(b) No selling or distribution outlet, located in this state, of any out-of-state manufacturer, that has not obtained a license from the board, that sells or distributes only the dangerous drugs or the dangerous devices of that manufacturer, shall sell or distribute any dangerous drug or dangerous device in this state without obtaining a wholesaler's license from the board.
(c) A separate license shall be required for each place of business owned or operated by a wholesaler. Each license shall be renewed annually and shall not be transferable.
(d) The board shall not issue or renew a wholesaler license until the wholesaler designates an exemptee-in-charge and notifies the board in writing of the identity and license number of that exemptee. The exemptee-in-charge shall be responsible for the wholesaler's compliance with state and federal laws governing wholesalers. Each wholesaler shall designate, and notify the board of, a new exemptee-in-charge within 30 days of the date that the prior exemptee-in-charge ceases to be exemptee-in-charge. A pharmacist may be designated as the exemptee-in-charge.

(e) For purposes of this section, "exemptee-in-charge" means a person granted a certificate of exemption pursuant to Section 4053, or a registered pharmacist, who is the supervisor or manager of the facility.

(f) Notwithstanding any other provision of law, the board shall not issue or renew a wholesaler license if the applicant is beneficially interested, as defined in Section 4201, in a closed door pharmacy.

(g) A drug manufacturer licensed pursuant to Section 111615 of the Health and Safety Code that only ships drugs of its own manufacture is exempt from this section.

Repeal Section 4161 of the Business and Professions Code:

4161. (a) No person shall act as an out-of-state manufacturer or wholesaler of dangerous drugs or dangerous devices doing business in this state who has not obtained an out-of-state dangerous drug or dangerous device distributor's license from the board. Persons not located in this state selling or distributing dangerous drugs or dangerous devices in this state only through a licensed wholesaler are not required to be licensed as an out-of-state manufacturer or wholesaler or have an out-of-state dangerous drug or dangerous device distributor's license.

(b) Applications for an out-of-state dangerous drug or dangerous device distributor's license shall be made on a form furnished by the board. The board may require any information as the board deems is reasonably necessary to carry out the purposes of the section. The license shall be renewed annually.

(c) The Legislature, by enacting this section, does not intend a license issued to any out-of-state manufacturer or wholesaler pursuant to this section to change or affect the tax liability imposed by Chapter 3 (commencing with Section 23501) of Part 11 of Division 2 of the Revenue and Taxation Code on any out-of-state manufacturer or wholesaler.

(d) The Legislature, by enacting this section, does not intend a license issued to any out-of-state manufacturer or wholesaler pursuant to this section to serve as any evidence that the out-of-state manufacturer or wholesaler is doing business within this state.

Add Section 4161 to the Business and Professions Code, to read:

4161. (a) Any wholesaler located outside this state that ships, mails, or delivers dangerous drugs or dangerous devices into this state shall be considered a nonresident wholesaler.

(b) All nonresident wholesalers shall be licensed by the board.

(c) A separate license shall be required for each place of business owned or operated by a nonresident wholesaler. Each license shall be renewed annually and shall not be transferable.

(d) A nonresident wholesaler shall disclose to the board the location, names, and titles of:

(1) Its agent for service of process in this state.

(2) Principal corporate officers as specified by the board.

(3) General partners as specified by the board.

(d) A report containing this information shall be made within 30 days of any change of office, corporate officer, or partner.

(e) All nonresident wholesalers shall comply with all lawful directions and requests for information from the regulatory or licensing agency of the state in which it is licensed as well as with all requests for information made by the board pursuant to this section.
(f) All nonresident wholesalers shall maintain records of dangerous drugs or dangerous devices sold, traded or transferred to persons in this state so that the records are in a readily retrievable form.

(g) The nonresident wholesaler shall maintain, at all times, a valid unexpired license, permit, or registration to conduct the wholesaler in compliance with the laws of the state in which it is a resident. Applications for a nonresident wholesaler license shall include a license verification from the licensing authority in the applicant’s state of residence.

(h) The board shall not issue or renew a nonresident wholesaler license until the nonresident wholesaler designates an exemptee-in-charge and notifies the board in writing of the identity and license number of that exemptee.

(i) The exemptee-in-charge shall be responsible for the nonresident wholesaler's compliance with state and federal laws governing wholesalers. Each nonresident wholesaler shall designate, and notify the board of, a new exemptee-in-charge within 30 days of the date that the prior exemptee-in-charge ceases to be exemptee-in-charge.

(j) For purposes of this section, "exemptee-in-charge" means a person granted a certificate of exemption pursuant to Section 4053 or a registered pharmacist who is the supervisor or manager of the facility.

(k) The registration fee shall be the fee specified in subdivision (f) of Section 4400.

(l) A prescription drug wholesaler that applies to the board for a wholesaler license or the renewal of a wholesaler license must submit a surety bond of $100,000, or other equivalent means of security acceptable to the board, such as an irrevocable letter of credit, or a deposit in a trust account or financial institution, payable to the Pharmacy Board Contingent Fund. The purpose of the surety bond is to secure payment of any administrative fine imposed by the board and any cost recovery ordered pursuant to Section 125.3. The board may make a claim against the bond if the licensee fails to pay a fine within 30 days of the issuance of the fine or costs become final. The board may make a claim against such bond or security until 1 year after the license ceases to be valid or until 60 days after any administrative or legal proceeding authorized which involves the permittee is concluded, including any appeal, whichever occurs later.

Repeal Section 4162 of the Business and Professions Code:

4162. (a) No person acting as principal or agent for any out-of-state manufacturer, wholesaler, or pharmacy who has not obtained a license from the board, and who sells or distributes dangerous drugs or dangerous devices in this state that are not obtained through a wholesaler who has obtained a license, pursuant to this chapter, or that are not obtained through a selling or distribution outlet of an out-of-state manufacturer that is licensed as a wholesaler, pursuant to this chapter, shall conduct the business of selling or distributing dangerous drugs or dangerous devices within this state without registering with the board.

(b) Registration of persons under this section shall be made on a form furnished by the board. The board may require any information as the board deems reasonably necessary to carry out the purposes of this section, including, but not limited to, the name and address of the registrant and the name and address of the manufacturer whose dangerous drugs or dangerous devices he or she is selling or distributing.

(c) The board may deny, revoke, or suspend the person's registration for any violation of this chapter or for any violation of Part 5 (commencing with Section 109875) of Division 104 of the Health and Safety Code. The board may deny, revoke, or suspend the person's registration if the manufacturer, whose dangerous drugs or dangerous devices he or she is selling or distributing, violates any provision of this chapter or any provision of Part 5 (commencing with Section 109875) of Division 104 of the Health and Safety Code. The registration shall be renewed annually.
Amend Section 4163 of the Business and Professions Code, to read:

4163. (a) No manufacturer or wholesaler shall furnish any dangerous drugs or dangerous devices to any unauthorized persons.
(b) Dangerous drugs or dangerous devices shall be acquired from a person authorized by law to possess or furnish dangerous drugs or dangerous devices.
(c) No wholesaler or pharmacy shall sell, trade, or transfer a dangerous drug or dangerous device without providing a pedigree.
(d) No wholesaler or pharmacy shall acquire a dangerous drug or dangerous device without receiving a pedigree.
(e) This section shall become operative on January 1, 2007.

Amend Section 4164 of the Business and Professions Code, to read:

4164. All wholesalers licensed by the board and all manufacturers who distribute controlled substances, dangerous drugs, or dangerous devices within or into this state shall report to the board all sales of dangerous drugs and controlled substances that are subject to abuse, as determined by the board.

Amend Section 4165 of the Business and Professions Code, to read:

4165. (a) Any wholesaler licensed by the board who sells or transfers any dangerous drug or dangerous device into this state or who receives, by sale or otherwise, any dangerous drug or dangerous device from any person in this state shall, on request, furnish an authorized officer of the law with all records or other documentation of that sale or transfer.
(b) Any manufacturer who fails within a reasonable time, or refuses, to comply with subdivision (a), shall be subject to citation and a fine, an order of abatement, or both, pursuant to Section 125.9 and any regulations adopted by the board, in addition to any other remedy provided by law.

Amend Section 4166 of the Business and Professions Code, to read:

4166. (a) Any wholesaler or other distributor that uses the services of any carrier, including, but not limited to, the United States Postal Service or any common carrier, shall be liable for the security and integrity of any dangerous drugs or dangerous devices through that carrier until the drugs or devices are delivered to the transferee at its board-licensed premises.
(b) Nothing in this section is intended to affect the liability of a wholesaler or other distributor for dangerous drugs or dangerous devices after their delivery to the transferee.

Add section 4168 to the Business and Professions Code, to read:

4168. A county or municipality shall not issue a business license for any establishment that requires a wholesaler license unless the establishment possesses a current wholesaler license issued by the board. For the purposes of this section, an “establishment” is defined as the licensee’s physical location in the state of California.

Add Section 4169 to the Business and Professions Code, to read:

4169. (a) No person or entity shall:
(1) Purchase, trade, sell or transfer dangerous drugs or dangerous devices at wholesale with a person or entity that is not licensed with the board as a wholesaler or pharmacy.
(2) Purchase, trade, sell or transfer dangerous drugs that the person knew or reasonably should have known were adulterated as defined in Health and Safety Code Division 104, Part 5, Chapter 6, Article 2.
(3) Purchase, trade, sell or transfer dangerous drugs that the person knew or reasonably should have known were misbranded as defined in Health and Safety Code Division 104, Part 5, Chapter 6, Article 3.
(3) Purchase, trade, sell or transfer dangerous drugs or dangerous devices after the beyond use date on the label.
(4) Fail to maintain records of the acquisition or disposition of dangerous drugs or dangerous devices for at least three years.

(b) Notwithstanding any other provision of law, a violation of this section or of Section 4163 subdivisions (c) and (d) may subject the person or entity that has committed the violation to a fine not to exceed the amount specified in Section 125.9 for each occurrence pursuant to a citation issued by the board.

(c) For notifications made on and after January 1, 2005, the Franchise Tax Board, upon notification by the board of a final judgment in an action brought under this section, shall subtract the amount of the fine from any tax refunds or lottery winnings due to the person who is a defendant in the action using the offset authority under Section 12419.5 of the Government Code, as delegated by the Controller, and the processes as established by the Franchise Tax Board for this purpose. That amount shall be forwarded to the board for deposit in the Pharmacy Board Contingent Fund.
Add Section 4021.5 to the Business and Professions Code, to read:

4021.5. “Closed Door Pharmacy” means a pharmacy that only serves patients in a skilled nursing or intermediate care facility. A closed door pharmacy may not dispense dangerous drugs or dangerous devices to a person not receiving care in either a skilled nursing or intermediate care facility.

Add Section 4034 to the Business and Professions Code, to read:

4034. “Pedigree” means a document containing information that records each distribution of any given dangerous drug or dangerous device, from sale by a manufacturer, through acquisition and sale by any wholesaler, until final sale to a pharmacy or other person administering or dispensing the drug. A pedigree shall include:
(a) quantity
(b) dosage form and strength
(c) lot numbers
(d) the name, address, signature, and California license number of each licensee possessing the dangerous drugs or dangerous devices
(e) shipping information, including the name and address of each person certifying delivery or receipt of the dangerous drug or dangerous device,
(f) a certification that the recipient has authenticated the pedigree papers,
(g) the name, address, California license number, and telephone number for each wholesaler involved in the chain of custody for the dangerous drug or dangerous device.

Add Section 4126.5 to the Business and Professions Code, to read:

4126.5. (a) A pharmacy may only furnish dangerous drugs or dangerous devices as follows:
(1) To the wholesaler or manufacturer from whom the dangerous drugs or dangerous devices were acquired.
(2) To a licensed reverse distributor.
(3) To another pharmacy or wholesaler to alleviate temporary shortages that could result in the denial of healthcare.
(4) To a patient or a provider of health care, other than a pharmacy, authorized to purchase dangerous drugs and dangerous devices.

Amend Section 4160 of the Business and Professions Code, to read:

4160. (a) No person shall act as a wholesaler of any dangerous drug or dangerous device unless he or she has obtained a license from the board.
(b) Upon approval by the board and the payment of the required fee, the board shall issue a license to the applicant.
(b) No selling or distribution outlet, located in this state, of any out-of-state manufacturer, that has not obtained a license from the board, that sells or distributes only the dangerous drugs or the dangerous devices of that manufacturer, shall sell or distribute any dangerous drug or dangerous device in this state without obtaining a wholesaler's license from the board.
(c) A separate license shall be required for each place of business owned or operated by a wholesaler. Each license shall be renewed annually and shall not be transferable.
(d) The board shall not issue or renew a wholesaler license until the wholesaler designates an exemptee-in-charge and notifies the board in writing of the identity and license number of that exemptee. The exemptee-in-charge shall be responsible for the wholesaler's compliance with state and federal laws governing wholesalers. Each wholesaler shall designate, and notify the board of, a new exemptee-in-charge within 30 days of the date that the prior exemptee-in-charge ceases to be exemptee-in-charge. A pharmacist may be designated as the exemptee-in-charge.

(e) For purposes of this section, "exemptee-in-charge" means a person granted a certificate of exemption pursuant to Section 4053, or a registered pharmacist, who is the supervisor or manager of the facility.

(f) Notwithstanding any other provision of law, the board shall not issue or renew a wholesaler license if the applicant is a person beneficially interested, as defined in Section 4201, in a closed door pharmacy.

(g) An applicant for a wholesaler license or an applicant for the renewal of a wholesaler license must submit a bond of $100,000 payable to the Pharmacy Board Contingent Fund. A separate bond shall be provided for each location. The purpose of the bond is to secure payment of any administrative fine imposed by the board and any cost recovery ordered pursuant to Section 125.3. The board may make a claim against the bond if the licensee fails to pay a fine within 30 days of the issuance of the fine or costs become final.

(h) A drug manufacturer licensed pursuant to Section 111615 of the Health and Safety Code that only ships drugs of its own manufacture is exempt from this section.

Repeal Section 4161 of the Business and Professions Code:

4161. (a) No person shall act as an out-of-state manufacturer or wholesaler of dangerous drugs or dangerous devices doing business in this state who has not obtained an out-of-state dangerous drug or dangerous device distributor's license from the board. Persons not located in this state selling or distributing dangerous drugs or dangerous devices in this state only through a licensed wholesaler are not required to be licensed as an out-of-state manufacturer or wholesaler or have an out of state dangerous drug or dangerous device distributor's license.

(b) Applications for an out-of-state dangerous drug or dangerous device distributor's license shall be made on a form furnished by the board. The board may require any information as the board deems is reasonably necessary to carry out the purposes of the section. The license shall be renewed annually.

(c) The Legislature, by enacting this section, does not intend a license issued to any out-of-state manufacturer or wholesaler pursuant to this section to change or affect the tax liability imposed by Chapter 3 (commencing with Section 23501) of Part 11 of Division 2 of the Revenue and Taxation Code on any out-of-state manufacturer or wholesaler.

(d) The Legislature, by enacting this section, does not intend a license issued to any out-of-state manufacturer or wholesaler pursuant to this section to serve as any evidence that the out-of-state manufacturer or wholesaler is doing business within this state.

Add Section 4161 to the Business and Professions Code, to read:

4161. (a) No person shall act as a non-resident wholesaler without possessing a nonresident wholesaler license from the board.

(b) Any person located outside this state that ships, mails, or delivers dangerous drugs or dangerous devices into this state shall be considered a nonresident wholesaler.

(c) A separate license shall be required for each place of business owned or operated by a nonresident wholesaler. Each license shall be renewed annually and shall not be transferable.

(d) An applicant for a nonresident wholesaler license shall disclose to the board the location, names, and titles of:
(1) Its agent for service of process in this state.
(2) Principal corporate officers as specified by the board.
(3) General partners as specified by the board.

(e) A report containing the information required in subdivision (d) shall be made to the board within 30 days of any change of office, corporate officer, or partner.

(f) All nonresident wholesalers shall comply with all lawful directions and requests for information from the regulatory or licensing agency of the state in which it is located as well as with all requests for information made by the board.

(g) All nonresident wholesalers shall maintain records of dangerous drugs or dangerous devices sold, traded or transferred to persons in this state so that the records are in a readily retrievable form.

(h) The nonresident wholesaler shall maintain, at all times, a valid unexpired license, permit, or registration to conduct the wholesaler in compliance with the laws of the state in which it is a resident. Applications for a nonresident wholesaler license shall include a license verification from the licensing authority in the applicant’s state of residence.

(i) The board shall not issue or renew a nonresident wholesaler license until an exemptee-in-charge is designated and the board is notified in writing of the identity and license number of that exemptee.

(j) The exemptee-in-charge shall be responsible for the nonresident wholesaler's compliance with state and federal laws governing wholesalers. Each nonresident wholesaler shall designate, and notify the board of, a new exemptee-in-charge within 30 days of the date that the prior exemptee-in-charge ceases to be exemptee-in-charge.

(k) For purposes of this section, "exemptee-in-charge" means a person granted a certificate of exemption pursuant to Section 4053 or a registered pharmacist who is the supervisor or manager of the facility.

(l) The registration fee shall be the fee specified in subdivision (f) of Section 4400.

(m) An applicant for a nonresident wholesaler license or an applicant for the renewal of a nonresident wholesaler license must submit a bond of $100,000 payable to the Pharmacy Board Contingent Fund. A separate bond shall be provided for each location. The purpose of the bond is to secure payment of any administrative fine imposed by the board and any cost recovery ordered pursuant to Section 125.3. The board may make a claim against the bond if the licensee fails to pay a fine within 30 days of the issuance of the fine or costs become final.

Repeal Section 4162 of the Business and Professions Code:

4162. (a) No person acting as principal or agent for any out-of-state manufacturer, wholesaler, or pharmacy who has not obtained a license from the board, and who sells or distributes dangerous drugs or dangerous devices in this state that are not obtained through a wholesaler who has obtained a license, pursuant to this chapter, or that are not obtained through a selling or distribution outlet of an out-of-state manufacturer that is licensed as a wholesaler, pursuant to this chapter, shall conduct the business of selling or distributing dangerous drugs or dangerous devices within this state without registering with the board.

(b) Registration of persons under this section shall be made on a form furnished by the board. The board may require any information as the board deems reasonably necessary to carry out the purposes of this section, including, but not limited to, the name and address of the registrant and the name and address of the manufacturer whose dangerous drugs or dangerous devices he or she is selling or distributing.

(c) The board may deny, revoke, or suspend the person's registration for any violation of this chapter or for any violation of Part 5 (commencing with Section 109875) of Division 104 of the Health and Safety Code. The board may deny, revoke, or suspend the person's registration if the manufacturer, whose dangerous drugs or dangerous devices he or she is selling or distributing,
Amend Section 4163 of the Business and Professions Code, to read:

4163. (a) Dangerous drugs or dangerous devices shall only be acquired from a person authorized by law to possess or furnish dangerous drugs or dangerous devices.
(b) No manufacturer or wholesaler shall furnish any dangerous drugs or dangerous devices to any unauthorized persons.
(c) On and after January 1, 2006, no wholesaler or pharmacy shall sell, trade, or transfer a dangerous drug or dangerous device without providing a pedigree.
(d) On and after January 1, 2006, no wholesaler or pharmacy shall acquire a dangerous drug or dangerous device without receiving a pedigree.

Amend Section 4165 of the Business and Professions Code, to read:

4165. (a) Any manufacturer or wholesaler licensed by the board who sells or transfers any dangerous drug or dangerous device into this state or who receives, by sale or otherwise, any dangerous drug or dangerous device from any person in this state shall, on request, furnish an authorized officer of the law with all records or other documentation of that sale or transfer.
(b) Any manufacturer who fails within a reasonable time, or refuses, to comply with subdivision (a), shall be subject to citation and a fine, an order of abatement, or both, pursuant to Section 125.9 and any regulations adopted by the board, in addition to any other remedy provided by law.

Amend Section 4166 of the Business and Professions Code, to read:

4166. (a) Any wholesaler or other distributor that uses the services of any carrier, including, but not limited to, the United States Postal Service or any common carrier, shall be liable for the security and integrity of any dangerous drugs or dangerous devices through that carrier until the drugs or devices are delivered to the transferee at its board-licensed premises.
(b) Nothing in this section is intended to affect the liability of a wholesaler or other distributor for dangerous drugs or dangerous devices after their delivery to the transferee.

Add section 4168 to the Business and Professions Code, to read:

4168. A county or municipality shall not issue a business license for any establishment that requires a wholesaler license unless the establishment possesses a current wholesaler license issued by the board.

Add Section 4169 to the Business and Professions Code, to read:

4169. (a) Notwithstanding any other provision of law, a the following violations may subject, in addition to any other remedy provided by law, the person or entity that has committed the violation to a fine not to exceed the amount specified in Section 125.9 for each occurrence pursuant to a citation issued by the board:
(1) Violation of Section 4126.5.
(2) Violation of Section 4163.
(3) Purchase, trade, sell or transfer drugs or devices that are adulterated as defined in Health and Safety Code Division 104, Part 5, Chapter 6, Article 2.
(4) Purchase, trade, sell or transfer dangerous drugs or dangerous devices after the beyond use date on the label.
(5) Fail to maintain records of the acquisition or disposition of dangerous drugs or dangerous devices for at least three years.

(b) For notifications made on and after January 1, 2005, the Franchise Tax Board, upon notification by the board of a final judgment in an action brought under this section, shall subtract the amount of the fine from any tax refunds or lottery winnings due to the person who is a defendant in the action using the offset authority under Section 12419.5 of the Government Code, as delegated by the Controller, and the processes as established by the Franchise Tax Board for this purpose. That amount shall be forwarded to the board for deposit in the Pharmacy Board Contingent Fund.
Attachment B
Drug Wholesalers Face State Efforts To Tighten Rules

By ANNA WILDE MATHEWS
Staff Reporter of THE WALL STREET JOURNAL

WASHINGTON -- A group of state regulators is preparing tough new guidelines to oversee pharmaceutical wholesalers, in a move designed to crack down on counterfeit and diverted medicines.

The National Association of Boards of Pharmacy, in a plan still being finalized, wants to require background checks for people seeking to be licensed as wholesalers, and stricter documentation on the origins of drugs. Wholesalers are largely regulated at the state level, and thus the new rules would have to be enacted by individual states in order to go into effect. State regulators, however, may face a battle with industry over some of the provisions.

The guidelines would "really weed out the legitimate wholesale distributors from those who shouldn't be in business," said Carmen Catizone, executive director of state pharmacy group. Its board is expected to vote on the guidelines late this month, but Mr. Catizone said he expects the final version to be similar to the current draft. The association is also likely to set up a national inspection service, which states could use if they lack the resources to do their own checks on wholesalers.

The effort is important, because investigators believe that the complicated network of drug distribution, which can involve medicines passing through multiple hands before they arrive on pharmacy shelves, has opened some windows for counterfeit medicines to get into the hands of consumers.

A number of high-profile cases, particularly last year's recall of as many as 200,000 counterfeit bottles of Lipitor, Pfizer Inc.'s huge-selling cholesterol drug, have raised concerns about the issue. Bogus medicines can contain too much or too little of a drug's active ingredient, or sometimes none at all.
If enacted by the states, the proposals would significantly tighten the rules for wholesalers, in ways that could cut many smaller operators out of the business, and could raise costs for others.

A spokeswoman for the Healthcare Distribution Management Association, which represents distributors, said the group's members hadn't yet formulated a response to the state regulators' guidelines. The group has come up with recommended industry guidelines. Its own proposals to the Food and Drug Administration mirrored some things included in the state regulators' draft, but also had some key differences, including how to define which wholesalers would be considered "authorized" by a drug company.

The FDA, which worked with the state regulators' association on its model rules, is expected to offer its own new anticounterfeiting measures soon. The agency has raised a number of possible options, including selling drugs in "unit of use" packaging, tamper-evident packaging and technologies that would track and trace medicines as they are distributed.

The state regulators' proposal includes several measures that would answer concerns that law-enforcement officials have raised, and follow some examples set by states, including Florida and Nevada. Under the guidelines, states would do in-depth background checks, including criminal checks. There would also be harsher penalties for wholesalers who break the rules, because several violations would become criminal offenses.

The proposal also would close a loophole that has long made it difficult to track counterfeits. Wholesalers that are "authorized distributors" would have to maintain paper "pedigrees," or documents that trace the origin of medicines. Starting in 2007, all distributors would have to have electronic versions. The model rules tighten the definition of an "authorized distributor," which has been loose, to include only distributors that have a written agreement with a drug manufacturer, or are listed by the manufacturer as authorized distributors.

For security purposes, the model rules would require wholesalers to possess "technology and equipment that allows the wholesale distributor to authenticate, track and trace drugs and devices," which would meet standards set by the state. Wholesalers would have to do random authentications of the origins of 10% of drugs and devices they bought from other wholesalers, and would have to check 90% of those that fall on a state list of the products most at risk for counterfeiting or diversion.

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URL for this article: http://online.wsj.com/article0,,SB107352058069387200,00.html

Updated January 8, 2004
Definitions:
Terms not herein defined shall have the definitions set forth in the Model Pharmacy Practice Act.

“Authorized Distributor” or “Authorized Distributor of Record” means a Wholesale Distributor with whom a manufacturer has established an ongoing relationship to Distribute the manufacturer's products. An ongoing relationship is deemed to exist between a Wholesale Distributor and a manufacturer when a Wholesale Distributor complies with any one of the following:

1. The Wholesale Distributor has a written agreement currently in effect with the manufacturer evidencing an ongoing relationship; or
2. The Wholesale Distributor is listed on the manufacturer's current list of Authorized Distributors of Record, which is updated by the manufacturer on no less than a monthly basis.

“Centralized Prescription Processing” means the processing by a Pharmacy of a request from another Pharmacy to fill or refill a Prescription Drug Order or to perform processing functions such as Dispensing, DUR, claims adjudication, refill authorizations, and therapeutic interventions.

“Closed Pharmacy” means a Pharmacy that purchases Drugs or Devices for a limited patient population and is not open for dispensing to the general patient population and cannot operate or be licensed as a Wholesale Distributor.

“Contraband Device” means a Device which is counterfeit, stolen, obtained by fraud, purchased by a non-profit institution for its own use and placed in commerce in violation of the Own Use agreement for that Drug or Device, or for which the documentation in existence has been forged, counterfeited, misbranded, falsely created, or contains any altered, false, or misrepresented information.

“Contraband Drug” means a Drug which is counterfeit, stolen, obtained by fraud, purchased by a non-profit institution for its own use and placed in commerce in violation of the own use agreement for that Drug, or for which a Pedigree (if required) does not exist, or for which the Pedigree Paper in existence has been forged, counterfeited, misbranded, falsely created, or contains any altered, false, or misrepresented information.

“Counterfeit Device” means a Device which, or the container, shipping container, seal, or labeling of which, without authorization, bears the trademark, trade name, or other identifying mark, imprint, or any likeness thereof, of a Manufacturer or Wholesale Distributor other than the Manufacturer or Wholesale Distributor that in fact Manufactured or Distributed that Device.

1 The NABP Model Act is constructed as a guide for states to assist the various jurisdictions in developing and implementing legislation and regulations. All definitions contained in the Model Rules are excerpted from the Act, Section 105 Definitions. The definitions also appear in the Model Rules to provide the reader with a quick reference to the key definitions used extensively or exclusively in the Model Rules. The definitions and provisions of the Model Rules shall be construed so that they are consistent with each other and interpreted in the context of the entire Model Act.
“Counterfeit Drug” means a Drug which, or the container, shipping container, seal, or labeling of which, without authorization, bears the trademark, trade name, or other identifying mark, imprint, or any likeness thereof, of a Drug manufacturer or Distributor other than the manufacturer or Distributor that in fact manufactured or Distributed that Drug.

“Designated Representative” means a person designated by the Wholesale Distributor who will serve as the designated representative of the Wholesale Distributor with the Board who is actively involved in and aware of the actual daily operation of the Wholesale Distributor.

“Distribute” or “Distribution” means to sell, offer to sell, broker, give away, transfer, whether by passage of title, physical movement, or both; deliver, or offer to deliver. The term does not mean to administer or dispense.

“Emergency Medical Reasons” include, but are not limited to, transfers of a prescription drug between a Wholesale Distributor or Pharmacy to alleviate a temporary shortage of a prescription drug arising from delays in or interruption of regular distribution schedules; sales to nearby emergency medical services, i.e., ambulance companies and fire fighting organizations in the same State or same marketing or service area, or nearby licensed practitioners, of drugs for use in the treatment of acutely ill or injured persons; provision of minimal emergency supplies of drugs to nearby nursing homes for use in emergencies or during hours of the day when necessary drugs cannot be obtained; and transfers of prescription drugs by a Retail Pharmacy or Pharmacy to another Retail Pharmacy or Pharmacy to alleviate a temporary shortage.

“Health Care Entity” means any Person that provides diagnostic, medical, surgical, dental treatment, or rehabilitative care but does not include any retail Pharmacy or Wholesale Distributor.

“Immediate Container” means a container and does not include package liners.

“Intracompany Transaction” means any transaction between a division, subsidiary, parent and/or affiliated or related company under the common ownership and control of a corporate entity.

“Label” means a display of written, printed, or graphic matter upon the immediate container of any drug or device.

“Pedigree” means a document in a form, written or electronic, approved by the Board that records each distribution of any given drug, from the sale by a pharmaceutical Manufacturer through acquisition and sale by any Wholesale Distributor or Repackager and includes the following information for each transaction:

1. The source of the Drug(s), including the name and principal address of the seller;
2. The amount of the Drug, its dosage form and strength, the date of the purchase, the sales invoice number, container size, number of containers, expiration date(s), and lot number(s) of the Drug;
3. The business name and address of each owner of the Drug, its shipping information, including the name and address of each person certifying delivery or receipt of the Drug;
4. Information that states the Wholesale Distributor has conducted Due Diligence of the Wholesale Distributor(s) from whom the Wholesale Distributor purchased, or may have purchased the Drug; and
A certification from the Designated Representative of the Wholesale Distributor that the information contained therein is true and accurate under penalty of perjury.

“Repackage” means changing the container, wrapper, quantity, or labeling of a Drug or Device to further the distribution of the Drug or Device.

‘Repackager’ means a Person who Repackages.

“Specified List of Susceptible Products” means a specific list of Drugs or Devices to be designated by the State, or a third party approved by the State, determined to be susceptible to adulteration, counterfeiting, or diversion and posing the potential for a greater public health risk.

“USP Standards” means current USP Standards.

“Wholesale Distribution” means the Distribution of Drugs or Devices by Wholesale Distributors to persons other than consumers or patients, and includes the transfer of Drugs by a Pharmacy to another Pharmacy if the value of the goods transferred exceeds five percent (5%) of total Drug sales revenue of either the transferor or transferee Pharmacy during any consecutive twelve (12) month period. Wholesale Distribution does not include:

1. The sale, purchase, or trade of a Drug, an offer to sell, purchase, or trade a Drug, or the Dispensing of a Drug pursuant to a Prescription;
2. The sale, purchase, or trade of a Drug or an offer to sell, purchase, or trade a Drug for Emergency medical reasons;
3. Intracompany sales, unless in violation of own use provisions;
4. The sale, purchase, or trade of a Drug or an offer to sell, purchase or trade a Drug among hospitals or other health care entities that are under common control;
5. The sale, purchase, or trade of a Drug or the offer to sell, purchase, or trade a Drug by a charitable organization described in 503(c)(3) of the Internal Revenue Code of 1954 to a nonprofit affiliate of the organization to the extent otherwise permitted by law;
6. The purchase or other acquisition by a hospital or other similar health care entity that is a member of a group purchasing organization of a Drug for its own use from the group purchasing organization or from other hospitals or similar health care entities that are members of these organizations; and
7. The transfer of Drugs between Pharmacies pursuant to a Centralized Prescription Processing agreement.

“Wholesale Distributor” means any Person engaged in Wholesale Distribution of Drugs in or into the State, including but not limited to manufacturers, repackagers, own-label distributors, private-label distributors, jobbers, brokers, warehouses, including manufacturers’ and distributors’ warehouses, chain drug warehouses, and wholesale drug warehouses, independent wholesale drug traders, and retail pharmacies that conduct wholesale distributions.

Section 1. Requirements for Licensure.

Wholesale Distributors that provide services within this State, whether the Wholesale Distributor is located within this State or outside this State, shall be licensed by the Board and shall annually renew their license with the Board using an application provided by the Board. Wholesale
Distributors cannot operate from a place of residence. Where Wholesale Distribution operations are conducted at more than one location, each such location shall be licensed by the Board of Pharmacy.

(A). Every Wholesale Distributor who engages in the Wholesale Distribution of Drugs or Devices shall license annually with the Board by application and provide information required by the Board on an application approved by the Board, including, but not limited to:

(1) All trade or business names used by the licensee, which cannot be identical to the name used by another Wholesale Distributor licensed to purchase Drugs or Devices in the State;
(2) Name(s) of the owner and operator of the licensee (if not the same person), including:
   a) if a person: the name, address, and social security number and date of birth;
   b) if a partnership: the name, address, and social security number, federal employer identification number, and date of birth of each partner, and the name of the partnership;
   c) if a corporation: the name, address, social security number and date of birth, and title of each corporate officer and director, the corporate names, the name of the State of incorporation, federal employer identification number, and the name of the parent company, if any; the name, address, and social security number of each shareholder owning ten percent (10%) or more of the voting stock of the corporation, including over-the-counter stock, unless the stock is traded on a major stock exchange and not over-the-counter;
   d) if a sole proprietorship: the full name, address, and social security number and date of birth of the sole proprietor and the name and federal employer identification number of the business entity;
   e) if a limited liability company, the name of each member, the name of each manager, the name of the limited liability company, and the name of the state in which the limited liability company was organized; and
   f) any other relevant information that the Board requires.

(3) Name(s), address(es), telephone number(s) of a person(s) to serve as the Designated Representative(s) of the Wholesale Distributor’s facility(ies) used by the licensee for storage, handling, and Distribution of Drugs; Also see Section 9: Personnel.

(B). A bond of not less than $100,000, or other equivalent means of security acceptable to the Board, or the Board’s agent, to secure payment of any administrative penalties imposed by the Board and any fees and costs incurred by the Board regarding that license which are authorized under state law and which the Wholesale Distributor fails to pay 30 days after the fine or costs become final. The Board may make a claim against such bond or security until one year after the Wholesale Distributor’s license ceases to be valid or until 60 days after any administrative or legal proceeding before or on behalf of the Board which involves the Wholesale Distributor is concluded, including any appeal, whichever occurs later.

(C). A fee to be determined by the Board.

(D). The Wholesale Distributor’s facility(ies) must also undergo an inspection by the Board or the Board’s agent for the purpose of inspecting the Wholesale Distribution operations prior
Section 2. Minimum Qualifications.

(A). The Board will use the following factors in determining the eligibility for licensure and renewal of Persons who engage in the Wholesale Distribution of Drugs:

(1) Any findings by the Board that the applicant has violated or been disciplined by a regulatory agency in any state for violating any Federal, State, or local laws relating to Drug or Device Distribution;
(2) Any criminal convictions of the applicant under Federal, State, or local laws;
(3) The applicant’s past experience in the Manufacture or Distribution of Drugs;
(4) The furnishing by the applicant of false or fraudulent material in any application made in connection with Drug or Device Manufacturing or Distribution;
(5) Suspension or Revocation by Federal, State, or local government of any license currently or previously held by the applicant for the Manufacture or Distribution of Drugs or Devices;
(6) Compliance with previously granted licenses of any kind;
(7) Compliance with the requirements to maintain and/or make available to the State licensing authority or to Federal, State, or local law enforcement officials those records required to be maintained by Wholesale Drug Distributors; and
(8) Any other factors or qualifications the Board considers relevant to and consistent with the public health and safety.

(B). The Board shall consider the results of a criminal background check of the applicant, all personnel involved in the operations of the Wholesale Distributor, all shareholders involved in operations, and anyone owning or being involved in operations to determine if an applicant or others associated with the ownership, management, or operations of the Wholesale Distributor has committed criminal acts that would constitute grounds for denial of licensure. The background check will be conducted in compliance with any applicable state laws, at the applicant’s expense, and will be sufficient to include all states of residence since the person has been an adult.

(C). The applicant shall provide, and attest to, a statement providing a complete disclosure of any past criminal convictions and violations of the state and federal laws regarding Drugs or Devices or an affirmation and attestation that the applicant has not been involved in, or convicted of, any criminal or prohibited acts.

Section 3. Personnel.

Each Person that is issued an initial or renewal license as a Wholesale Distributor, whether in or out-of-state, must designate in writing on a form required by the Board at least one person to serve as the Designated Representative of the Wholesale Distributor.

(A). To be certified as a Designated Representative, a person must
(1) Submit an application on a form furnished by the Board and provide information that includes, but is not limited to:
   a) A set of fingerprints for the person, under procedures specified by the Board, together with the payment of the an amount equal to the costs incurred by the Board for the criminal record check of the person;
   b) Date and place of birth;
   c) Occupations, positions of employment, and offices held during the past 7 years;
   d) Principal business and address of any business corporation, or other organization in which each such office of the person was held or in which each such occupation or position of employment was carried on;
   e) Whether the person, during the past 7 years, has been enjoined, either temporarily or permanently, by a court of competent jurisdiction from violating an federal or state law regulating the possession, control, or distribution of prescription drugs, together with details of such events;
   f) Description of any involvement by the person with any business, including any investments, other than the ownership of stock in publicly traded company or mutual fund, during the past 7 years, which manufactured, administered, prescribed, distributed, or stored pharmaceutical products and lawsuits in which such businesses were named as a party;
   g) Description of any criminal offense (not including minor traffic violations) of which the Person, as an adult, was found guilty, regardless of whether adjudication of guilt was withheld or whether the person pled guilty or nolo contendre. If the person indicates that a criminal conviction is under appeal and submits a copy of the notice of appeal of the criminal offense, the applicant must, within 15 days after the disposition of the appeal, submit to the Board a copy of the final written order of disposition;
   h) Photograph of the person taken within the previous 30 days under procedures specified by the Board;
   i) Name, address, occupation, and date and place of birth for each member of the person’s immediate family. As used in this subparagraph, the term “member of the immediate family” includes the person’s spouse(s), children, parents, siblings, the spouses of the person’s children, and the spouses of the person’s siblings; and
   j) Any other information the Board deems relevant.

(2) Have a minimum of two years of verifiable full-time managerial experience in a Pharmacy or Wholesale Distributor licensed in this State or another state, where the person’s responsibilities included but were not limited to recordkeeping, storage, and shipment for Prescription Drugs;

(3) May serve as the Designated Representative for only one Wholesale Distributor at any one time;

(4) Must be actively involved and aware of the actual daily operations of the Wholesale Distributor:
   a) Employed full time in a managerial position by the Wholesale Distributor;
   b) Physically present at the Wholesale Distributor during normal business hours, except for time periods when absent due to illness, family illness or death, scheduled vacation, or other authorized absence; and
c) Aware of, and knowledgeable about, all policies and procedures pertaining to the operations of the Wholesale Distributor.

(B). Each licensed Wholesale Distributor located outside of this State that Distributes Drugs in this State shall designate a registered agent in this State for service of process. Any licensed Wholesale Distributor that does not so designate a registered agent shall be deemed to have designated the Secretary of State of this state to be its true and lawful attorney, upon who may be served all legal process in any action or proceeding against such licensed Wholesale Distributor growing out of or arising from such Distribution. A copy of any such service of process shall be mailed to such Wholesale Distributor by the Board by certified mail, return receipt requested, postage prepaid, at the address such licensed Wholesale Distributor has designated on its application for licensure in this State. If any such Wholesale Distributor is not licensed in this State, service on the Secretary of State only shall be sufficient service.

(C). The licensed Wholesale Distributor shall employ additional personnel (engaged in the operation and handling of Drugs or Devices), following the appropriate criminal background check as indicated in Section 2, with the education and experience necessary to safely and lawfully engage in the Wholesale Distribution of Drugs.

(D). A Designated Representative must complete continuing education programs specified by the Board regarding federal and State laws in regard to the distribution, handling, and storage of Prescription Drugs.


The following are required for the shipping, transporting, storage and handling of Drugs, and for the establishment and maintenance of Drug Distribution records by Wholesale Distributors and their officers, agents, representatives, and employees:

(A). All facilities at which Drugs and Devices are received, stored, warehoused, handled, held, offered, marketed, displayed, or transported from shall:
   (1) be of suitable construction to ensure that all Drugs and Devices in the facilities are maintained in accordance with USP standards;
   (2) be of suitable size and construction to facilitate cleaning, maintenance, and proper Wholesale Distribution operations;
   (3) have adequate storage areas to provide adequate lighting, ventilation, temperature, sanitation, humidity, space, equipment, and security conditions;
   (4) have a quarantine area for storage of Drugs and Devices that are outdated, damaged, deteriorated, misbranded, or adulterated, or that are in immediate or sealed secondary containers that have been opened;
   (5) be maintained in a clean and orderly condition; and
   (6) be free from infestation of any kind.

(B). Shall be a commercial location and not a personal dwelling or residence.

(C). Shall provide for the secure and confidential storage of information with restricted access and policies and procedures to protect the integrity and confidentiality of the information.
Section 5. Security and Anti-Counterfeiting.

(A). All facilities used for Wholesale Drug Distribution shall be secure from unauthorized entry.
   (1) Access from outside the premises shall be kept to a minimum and be well-controlled;
   (2) The outside perimeter of the premises shall be well-lighted;
   (3) Entry into areas where Drugs or Devices are held shall be limited to authorized personnel;

(B). All facilities shall be equipped with an alarm system to detect entry after hours.

(C). All facilities shall be equipped with a security system that will provide suitable protection against theft and diversion. When appropriate, the security system shall provide protection against theft or diversion that is facilitated or hidden by tampering with computers or electronic records.

(D). All facilities shall be equipped with inventory management and control systems that protect against and detect and document any instances of theft, diversion, or counterfeiting.

(E). Wholesale Distributors should possess and maintain in good working order technology and equipment (when available) that allows the Wholesale Distributor to authenticate, track, and trace Drugs and Devices. The technology and equipment shall satisfy standards set by the Board for such technology and equipment. The technology and equipment shall be used, as required by the Board, to conduct “for cause” and random tracking, tracing, and authentication of Drugs and Devices. Wholesale Distributors shall employ, train, and document the training of personnel in the proper use of such technology and equipment.

(F). All facilities shall be equipped with security systems to protect the integrity and confidentiality of data and makes such data and documents readily available to the Board and other state and federal law enforcement officials.

Section 6. Storage.

All Drugs and Devices shall be stored at appropriate temperatures and under appropriate conditions in accordance with requirements, if any, in the Labeling of such Drugs and Devices, or with requirements in the current edition of an official compendium such as the USP/NF.

(A). If no storage requirements are established for a Drug, the Drug may be held at “controlled” room temperature, as defined in an official compendium (USP), to help ensure that its identity, strength, quality, and purity are not adversely affected.

(B). Appropriate manual, electromechanical, or electronic temperature and humidity recording equipment, Devices, and/or logs shall be utilized to document proper storage of Drugs.
(C). Packaging of the Drugs should be in accordance with USP standards and identify any compromise in the integrity of the Drugs due to tampering or adverse storage conditions.

(D). Controlled substance Drugs should be isolated from non-controlled substance Drugs and stored in a secure area in accordance with DEA security requirements and standards.

(E). The record-keeping requirements in Section 10 shall be followed for all Drugs.

Section 7. Examination of Materials.

(A). Upon receipt, each shipping container shall be visually examined for identity and to determine if it may contain contaminated, contraband, counterfeit, or damaged Drugs or Devices, or Drugs or Devices that are otherwise unfit for Distribution. This examination shall be adequate to reveal container damage that would suggest possible contamination, adulteration, misbranding, counterfeiting, suspected counterfeiting, or other damage to the contents.

(B). The Drugs or Devices found to be unacceptable under paragraph (A) should be quarantined from the rest of stock until the examination and determination that the Drugs and Devices are not outdated, damaged, deteriorated, misbranded, counterfeited, suspected of being counterfeit, or adulterated is completed and determined to be fit for human use.

(C). Each outgoing shipment shall be carefully inspected for identity of the Drugs or Devices and to ensure that there is no Delivery of Drugs or Devices that have been damaged in storage or held under improper conditions.

(D). Upon receipt, a Wholesale Distributor must review records for the acquisition of Drugs or Devices for accuracy and completeness, considering the total facts and circumstances surrounding the transactions and the Wholesale Distributors involved. This includes authenticating the Pedigree as defined in Section 10.

(E). The record-keeping requirements in Section 9 shall be followed for all incoming and outgoing Drugs and Devices.

Section 8. Returned, Damaged, and Outdated Drugs.

(A). Any Drug or Device that was ordered in error by the Wholesale Distributor, identified as such within three (3) business days, and the integrity has been maintained shall be returned to the Manufacturer or Wholesale Distributor from which it was acquired, provided the appropriate documentation is completed and any necessary notations made to the Pedigree.

(B). Any Drug or Device received in excess of need (overstock) may be returned to the Wholesale Distributor or Manufacturer from which acquired, provided the appropriate documentation is completed and any necessary notations made to the Pedigree.

(C). Any Drug or Device that is outdated, damaged, deteriorated, misbranded, counterfeited, suspected of being counterfeited, adulterated, or otherwise deemed unfit for human consumption shall be quarantined and physically separated from other Drugs and Devices until they are returned to either the Manufacturer or Wholesale Distributor from which it
was acquired. When Drugs and Devices are adulterated, misbranded, counterfeited, or suspect of being counterfeited notice of the adulteration, misbranding, counterfeiting, or suspected counterfeiting shall be provided to the Board and Manufacturer or Wholesale Distributor from which it was acquired within three (3) business days. Any Drug or Device returned to a Manufacturer or Wholesale Distributor shall be kept under proper conditions for storage, handling, and shipping, transporting, and documentation showing that proper conditions were maintained is provided to the Manufacturer or Wholesale Distributor to which the drugs are returned. No Drug or Device, and accompanying documentation, shall be destroyed until disposition by the appropriate state and federal authorities.

(D). Any Drug or Device whose immediate or sealed outer or secondary containers or Labeling are adulterated, misbranded, counterfeited, or suspect of being counterfeited shall be quarantined and physically separated from other Drugs or Devices until they are returned to either the Manufacturer or Wholesale Distributor from which it was acquired or destroyed. When the immediate or sealed outer or secondary containers or Labeling of any Drug and Device are adulterated, misbranded, counterfeited, or suspect of being counterfeited notice of the adulteration, misbranding, counterfeiting, or suspected counterfeiting shall be provided to the Board and Manufacturer or Wholesale Distributor from which it was acquired within three (3) business days. No immediate or sealed outer or secondary container or Labeling, and accompanying documentation, shall be destroyed until disposition by the appropriate state and federal authorities is authorized.

(E). Any Drug or Device that has been opened or used, shall be identified as such, and shall be quarantined and physically separated from other Drugs or Devices until they are either destroyed or returned to the Manufacturer or Wholesale Distributor who supplied the Drugs or Devices and notice provided to the Board and Manufacturer or Wholesale Distributor who supplied the Drugs or Devices.

(F). If the conditions under which a Drug or Device has been returned cast doubt on the Drug’s or Device’s safety, identity, strength, quality, or purity, then the Drug or Device shall be destroyed, or returned to the supplier, unless examination, testing, or other investigation proves that the Drug or Device meets appropriate standards of safety, identity, strength, quality, and purity. In determining whether the conditions under which a Drug or Device has been returned cast doubt on the Drug’s or Device’s safety, identity, strength, quality, or purity, the Wholesale Drug Distributor shall consider, among other things, the conditions under which the Drug or Device has been held, stored, or shipped before or during its return and the condition of the Drug and its container, carton, or Labeling, as a result of storage or shipping.

(G). Contraband, counterfeit, or suspected to be counterfeit Drugs and Devices, other evidence of criminal activity, and accompanying documentation shall be retained and not destroyed until its disposition is authorized by state and federal authorities.

(H). The shipping, immediate or sealed outer or secondary container or Labeling, and accompanying documentation, suspected of or determined to be counterfeit or fraudulent shall not be destroyed until its disposition is authorized by the appropriate state and federal authorities.

(I). The record-keeping requirements in Section 10 of this rule shall be followed for all outdated, damaged, deteriorated, misbranded, or adulterated Drugs.
Section 9. Due Diligence

If a Wholesale Distributor is licensed in accordance with these Model Rules, then the following Due Diligence shall not need to be performed:

(A). Prior to the initial purchase of Drugs or Devices from another Wholesale Distributor, a Wholesale Distributor shall obtain the following information from the selling Wholesale Distributor:

1. A list of states the Wholesale Distributor is licensed in, and into which it ships Drugs;
2. Copies of all state and federal regulatory licenses and registrations;
3. The Wholesale Distributor’s most recent facility inspection reports;
4. Information regarding general and product liability insurance, including copies of relevant policies;
5. A list of other names under which the Wholesale Distributor is doing business, or was formerly known as;
6. A list of corporate officers and managerial employees;
7. A list of all owners of the Wholesale Distributor that own more than ten percent (10%) of the Wholesale Distributor, unless the Wholesale Distributor is publicly traded;
8. A list of all disciplinary actions by state and federal agencies;
9. A description, including the address, dimensions, and other relevant information, of each facility or warehouse used for Drug storage and distribution;
10. A description of Drug import and export activities of the Wholesale Distributor;
11. A description of the Wholesale Distributor’s process to comply with this Act; and
12. A statement as to whether and for whom the Wholesale Distributor is an Authorized Distributor of Record.

(B). Prior to the first purchase of Drugs from another Wholesale Distributor, the purchasing Wholesale Distributor shall:

1. Conduct a criminal background check of all of the Wholesale Distributor’s owners, officers and key management;
2. Conduct a credit check of the Wholesale Distributor and members of the Wholesale Distributor’s Affiliated Group; and
3. Verify the Wholesale Distributor’s status as an Authorized Distributor of Record, if applicable.

(C). If the selling Wholesale Distributor’s facility has not been inspected by the Board or the Board’s agent within two years of the contemplated purchase, the purchasing Wholesale Distributor shall conduct an inspection of the Wholesale Distributor’s facility prior to the first purchase of Drugs or Devices from another Wholesale Distributor, to ensure compliance with applicable laws and regulations relating to current good manufacturing practices for storage and handling of Drugs or Devices. A third party may be engaged to conduct the site inspection on behalf of the purchasing Wholesale Distributor.

(D). At least annually, a Wholesale Distributor that purchases Drugs from another Wholesale Distributor shall update the information set forth in Section 9, (A).

(E). At least once every two years, a Wholesale Distributor that purchases Drugs from another Wholesale Distributor shall inspect, or engage a third party to inspect, the premises of the facility or facilities of the Wholesale Distributor from whom it is purchasing Drugs, as set
forth in Section 9, (C). If the selling Wholesale Distributor’s facility has been inspected by the Board, or the Board’s agent, within the two year time period, the inspection report of the Board is sufficient to meet the requirements of this subsection.

(F). For Cause Authentications:
   (1) If a Wholesale Distributor that purchases Drugs or Devices from another Wholesale Distributor has reason to believe, based on the totality of the facts and circumstances, that any Drug or Device purchased from the Wholesale Distributor is Counterfeit or otherwise adulterated, the purchasing Wholesale Distributor must Authenticate every Distribution of the Drug or Device back to the Authorized Distributor;
   (2) Each Wholesale Distributor that has engaged in the Distribution of a Drug or Device, for which a purchasing Wholesale Distributor is conducting a for cause Authentication shall provide, upon request, detailed information regarding the Distribution of the Drug or Device, including:
      (a) Date of purchase;
      (b) Lot number;
      (c) Sales invoice number; and
      (d) Contact information, including name, address, telephone number, and e-mail address (if available) for the Wholesale Distributor that sold the Drug or Device, the Distribution of which is being Authenticated.
   (3) If the Wholesale Distributor that is attempting to Authenticate the Distribution of the Drug or Device back to an Authorized Distributor is unable to Authenticate each Distribution of the Drug or Device, the Wholesale Distributor shall report this to the Board within ten (10) business days after completing the attempted Authentication; and
   (4) If the Wholesale Distributor that is attempting to Authenticate the Distribution of the Drug or Device back to an Authorized Distributor satisfactorily completes the Authentication, the Wholesale Distributor shall maintain records of the Authentication for three (3) years, and shall produce them to the Board upon request.

(G). Random Authentications:
   (1) Wholesale Distributors that purchase Drugs or Devices from other Wholesale Distributors, shall, at least annually, conduct random Authentications of Pedigree Papers on at least ten percent (10%) of Distributions of Drugs or Devices that were purchased from other Wholesale Distributors;
   (2) If a Wholesale Distributor has purchased a Drug or Device that is on the State’s Specified List of Susceptible Products, the Wholesale Distributor shall, at least quarterly, conduct random Authentications of Pedigree Papers on at least ninety percent (90%) of Distributions of Drugs or Devices that are on the Board’s Specified List of Susceptible Products that were purchased from other Wholesale Distributors; and
   (3) Wholesale Distributors from whom other Wholesale Distributors have purchased Drugs or Devices shall cooperate with the random Authentications of the Pedigree Papers and provide the requested information in a timely manner.

Section 10: Recordkeeping.
(A). Wholesale Distributors shall establish and maintain inventories and records of all transactions regarding the receipt and distribution or other disposition of Drugs and Devices. These records shall include:

   (1) If an Authorized Distributor, Paper Pedigrees for Drugs and Devices distributed that are included on the list of Specified Drugs and Devices;

   (2) If an Authorized Distributor, Paper Pedigrees for all Drugs and Devices that are distributed; and

   (3) Effective January 1, 2007\(^2\), all Wholesale Distributors, whether located in or out of State, whether an Authorized Distributor or not, must provide and maintain an electronic Pedigree developed in accordance with standards and requirements of the Board, for all Drugs and Devices received and distributed.

(B). Wholesale Distributors shall establish and maintain inventories and records of all transactions regarding the receipt and distribution, or other disposition of all Drugs and Devices. Such records shall include the dates of receipt and distribution or other disposition of the Drugs and Devices. Inventories and records shall be made available for inspection and photocopying by any authorized official of any State, federal, or local governmental agency for a period of 3 (three) years following their creation date.

(C). Records described in this section that are kept at the inspection site or that can be immediately retrieved by computer or other electronic means shall be readily available for authorized inspection during the retention period. Records kept at a central location apart from the inspection site and not electronically retrievable shall be made available for inspection within two working days of a request by an authorized official of any State and federal governmental agency charged with enforcement of these rules.

(D). Should maintain an ongoing list of Persons with whom they do business.

(E). All facilities shall establish and maintain procedures for reporting counterfeit or suspected counterfeit Drugs or Devices or counterfeiting or suspected counterfeiting activities to the Board.

(F). Should maintain a system for the mandatory reporting of significant shortages or losses of Drugs and Devices.

Section 11. Prohibited Acts.

It is unlawful for a Person to perform or cause the performance of or aid and abet any of the following acts in this State:

(A). The manufacture, repackaging, sale, delivery, or holding or offering for sale any drug or device that is adulterated, misbranded, counterfeit, suspected of being counterfeit, or has otherwise been rendered unfit for human or animal use;

(B). The adulteration, misbranding, or counterfeiting of any drug or device;

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\(^2\) NABP recognizes that technology must be available that allows for such systems to be put in place. Language must reflect the current availability of such technology and not require compliance if such technology is not operable.
(C). The receipt of any drug or device that is adulterated, misbranded, stolen, obtained by fraud or deceit, and the delivery or proffered delivery of such drug or device for pay or otherwise;

(D). The alteration, mutilation, destruction, obliteration, or removal of the whole or any part of the Labeling of a Drug or Device or the commission of any other act with respect to a Drug or Device that results in the Drug or Device being misbranded;

(E). Forging, counterfeiting, simulating, falsely representing any Drug or Device without the authority of the manufacturer, using any mark, stamp, tag, label, or other identification device without the authorization of the manufacturer;

(F). The purchase or receipt of a Drug or Device from a Person that is not licensed to distribute Drugs or Devices to that purchaser or recipient;

(G). The sale or transfer of Drug or Device to a Person that is not authorized under the law of the jurisdiction in which the Person receives the Drug or Device to purchase or possess Drugs or Devices from the Person selling or transferring the Drug or Device;

(H). Failure to maintain or provide records as required by this Act;

(I). Providing the Board or any of its representatives or any state or federal official with false or fraudulent records or making false or fraudulent statements regarding any matter within the provisions of this Act;

(J). The Wholesale Distribution of any Drug or Device that was:
   (1) Purchased by a public or private hospital or other health care entity; or
   (2) Donated or supplied at a reduced price to a charitable organization.
   (3) Stolen or obtained by fraud or deceit.

(K). Failure to obtain a license or operating without a valid license when a license is required;

(L). Obtaining or attempting to obtain a Drug or Device by fraud, deceit, misrepresentation or engaging in misrepresentation or fraud in the distribution of a Drug or Device;

(M). Distributing a Drug or Device to the patient without a Prescription or Prescription Order from a Practitioner licensed by law to use or prescribe the Drug or Device;

(N). Failure to obtain, authenticate when required under Section 10 of these Rules, or pass on a Pedigree;

(O). The receipt of a Drug or Device pursuant to a Wholesale Distribution without first receiving a Pedigree, when required, that was attested to as accurate and complete by the Wholesale Distributor; or

(P). Distributing a Drug or Device that was previously dispensed by a Pharmacy or distributed by a Practitioner.

(Q). Failure to report any Prohibited Act.

**Section 12: Criminal Acts**
(A). A Person who engages in the Wholesale Distribution of Drugs or Devices who knowingly fails to deliver to another Person complete and accurate Pedigree concerning a Drug or Device prior to transferring the Drug or Device to another Person commits a felony of the third degree;

(B). A Person who engages in the Wholesale Distribution of Drugs or Devices who knowingly fails to acquire complete and accurate Pedigree concerning a Drug or Device prior to obtaining the Drug or Device from another Person commits a felony of the third degree;

(C). A Person who engages in the Wholesale Distribution of Drugs and Devices and knowingly destroys, alters, conceals, or fails to maintain complete and accurate Pedigree concerning any Drug or Device in his possession commits a felony of the third degree;

(D). A Person who engages in the Wholesale Distribution of Drugs or Devices who is knowingly in possession of documents and who knowingly fails to authenticate the matters contained in the documents and who nevertheless attempts to further distribute Drugs or Devices commits a felony of the third degree;

(E). A Person who engages in the Wholesale Distribution of Drugs or Devices and is knowingly in possession of documents related to the Wholesale Distribution of Drugs or Devices who falsely swears or certifies that he has authenticated the matters contained in the documents commits a felony of the third degree;

(F). A Person who engages in the Wholesale Distribution of Drugs or Devices who knowingly is in possession of Pedigree concerning Drugs or Devices and who fails to authenticate the matters contained in the Pedigree and who nevertheless attempts to further distribute Drugs or Devices commits a felony of the third degree;

(G). A Person who engages in the Wholesale Distribution of Drugs or Devices and knowingly is in possession of Pedigree concerning Drugs or Devices who falsely swears or certifies that he has authenticated the matters in the Pedigree Papers commits a felony of the third degree;

(H). A Person who engages in the Wholesale Distribution of Drugs or Devices and knowingly forges, counterfeits, or falsely creates any Pedigree, who falsely represents any factual matter contained on any Pedigree Paper, or who knowingly omits to record material information required to be recorded in a Pedigree commits a second degree felony;

(I). A Person who engages in the Wholesale Distribution of Drugs or Devices and knowingly purchases or receives from a Person, not authorized to distribute Drugs or Devices, in Wholesale Distribution commits a felony of the second degree;

(J). A Person who engages in the Wholesale Distribution of Drugs or Devices and knowingly sells or transfers to a Person not authorized to purchase Drugs or Devices, under the jurisdiction in which the Person receives the Drug(s) or Device(s) in a Wholesale Distribution commits a second degree felony;

(K). A Person who knowingly possesses, actually or constructively, any amount of a contraband Drug(s) or Device(s), who knowingly sells or delivers, or who possesses with intent to sell
or deliver any amount of a contraband Drug(s) or Device(s) commits a felony of the second degree;

(L). A Person who knowingly forges, counterfeits, or falsely creates any Label for a Drug(s) or Device(s) or who falsely represents any factual matter contained in any Label of a Drug(s) or Device(s) commits a felony of the first degree;

(M). A Person who knowingly manufactures, purchases, sells, delivers or brings into the State, or who is knowingly in actual or constructive possession of any amount of contraband Drug(s) or Device(s) commits a felony of the first degree; and

(N). A Person who knowingly manufactures, purchases, sells, delivers, or brings into the State, or who is knowingly in actual or constructive possession of any amount of contraband Drug(s) or Device(s), and whose acts result in the death of a person, commits a felony in the first degree.

(O). A Person found guilty of any offense under this section, under the authority of the Court convicting and sentencing the Person, shall order that the Person forfeit to the State any real or personal property:

1. Used or intended to be used to commit, to facilitate or to promote the commission of such offense;
2. Constituting, derived from, or traceable to the gross proceeds that the defendant obtained direction or indirectly as a result of the offense. Any property or assets subject to forfeiture under this section may be seized pursuant to a warrant obtained in the same manner as a search warrant or as otherwise permitted by law, and held until the case against a defendant is adjudicated. Monies ordered forfeited, or proceeds from the sale of other assets ordered forfeited shall be equitably divided between the Board and other agencies involved in the investigation and prosecution which led to the conviction. Other property ordered forfeited after conviction of a defendant may, at the discretion of the investigating agencies, be placed into official use by the Board or the agencies involved in the investigation and prosecution which led to the conviction.

Section 13: Policies and Procedures

Wholesale Distributors shall establish, maintain, and adhere to written policies and procedures, which shall be followed for the receipt, security, storage, inventory, transport, and shipping and Distribution of Drugs, including policies and procedures for identifying, recording, and reporting losses or thefts, for correcting all errors and inaccuracies in inventories, and implementing and maintaining a continuous quality improvement system. Wholesale Distributors shall include in their written policies and procedures the following:

(A). A procedure to be followed for handling recalls and withdrawals of Drugs and Devices. Such procedure shall be adequate to deal with recalls and withdrawals due to:

1. any action initiated at the request of the Food and Drug Administration or other Federal, State, or local law enforcement or other government agency, including the Board of Pharmacy;
2. any volunteer action by the Manufacturer to remove defective or potentially defective Drugs or Devices from the market; or
(3) any action undertaken to promote public health and safety by the replacing of existing merchandise with an improved product or new package design.

(B). A procedure to ensure that Wholesale Distributors prepare for, protect against, and handle any crisis that affects security or operation of any facility in the event of a strike, fire, flood, or other natural disaster, or other situations of local, State, or national emergency.

(C). A procedure to ensure that any outdated Drugs shall be segregated from other Drugs and either returned to the Manufacturer or destroyed in accordance with federal and State laws, including all necessary documentation and the appropriate witnessing. This procedure shall provide for written documentation of the disposition of outdated Drugs. This documentation shall be maintained for two years after disposition of the outdated Drugs.

(D). A procedure for the destruction in accordance with federal and State laws, including all necessary documentation, maintaining for a minimum of two years, and the appropriate witnessing of the destruction of outdated or expired Drugs in accordance with all applicable federal and State requirements.

(E). A procedure for disposing and destruction of containers, labels, and packaging to ensure that the containers, labels, and packaging cannot be used in counterfeiting activities including all necessary documentation, maintained for a minimum of two years, and the appropriate witnessing of the destruction of any Labels, packaging, Immediate Containers, or containers in accordance with all applicable federal and State requirements.

(F). A procedure for investigating discrepancies in the inventory and reporting such discrepancies within three (3) business days to the Board and/or appropriate federal or State agency.

(G). A procedure for reporting criminal or suspected criminal activities involving the inventory of Drug(s) and Device(s) to the Board within the three (3) business days.

Definitions

“Authorized Distributor” the definition of “Authorized Distributor” when involving a multi-facility corporation would not require a separate approval for each individual facility. The “Authorized Distributor” status would apply across all product lines of the manufacturer and would not be segregated by individual products.

Section 1
The application and screening process for licensing Wholesale Distributors represents a critical point in efforts to prevent the introduction of Counterfeit Drugs into the medication distribution system. An application that requires detailed information about the applicant and every individual involved in the operations of the Wholesale Distributor is critical. A sample application that has proved successful in the State of Nevada is appended to these Model Rules.

Section 1: (D)
The Board may designate a third party to conduct inspections and ensure that all requirements for licensure established by the legislature and Board are fulfilled. The National Association of
Boards of Pharmacy (NABP) Wholesale Distributor Accreditation and Clearinghouse Service is a service available to the Board.

Section 3 (A) (1) (a)
Fingerprints represent one of the current means of authenticating the identity of the person as well as providing a reliable means to conduct criminal background checks. As technology changes and other means become available to the Board such as retina scanning or DNA sampling, the Board must stay current with such technologies and amend rules as necessary and appropriate.

Section 5: (D)
Standards for technology

Section 13:
Reference the HDMA Guidelines.
Attachment C
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EXECUTIVE SUMMARY

The U.S. Food and Drug Administration (FDA) is examining the drug wholesaling and distribution industry as it reviews policies applying to the distribution of prescription drugs. This study profiles drug wholesalers and drug distribution patterns. It also characterizes the pharmaceutical purchasing organizations and their impact on prescription drug prices and distribution.

Drug wholesalers consist of the Big Five full-line wholesalers (including McKesson HBOC, Inc., Bergen Brunswig Drug Company, and Cardinal Health, Inc.), regional wholesalers, and numerous smaller sub-regional/specialty wholesalers. In addition, there are “secondary wholesalers” that take advantage of manufacturers’ sales on drugs to purchase discounted products and then resell these products throughout the distribution chain.

ERG identified several models that apply to the distribution of pharmaceuticals. In the most common model, covering a majority of drugs, manufacturers sell drugs to the Big Five drug wholesalers, who then sell them to dispensing organizations, such as retail chain stores, independent drug stores, and health care facilities. These drugs reach the ultimate consumer with a minimum number of transactions or physical shipments. In some cases, manufacturers sell directly to health care facilities or drug stores, eliminating any role for wholesalers. According to a compilation by PhRMA, 20 percent of all pharmaceutical drug sales went directly to dispensing organizations.

A more complex model of distribution is initiated, however, when manufacturers offer price discounts on various prescription drugs. Frequently, manufacturers hold short-term sales for individual drugs in order to reduce inventories or to meet quarterly sales targets. Large distributors, and especially secondary wholesalers, who are willing to risk substantial capital to acquire the discounted goods, purchase these sale drugs. These purchasers then turn the product over quickly by selling it to their networks of customers, which might include both larger and smaller distributors, and some drug dispensing organizations. In this model of drug dispersion, however, the sale drugs might change hands more than one-half dozen times before reaching a drug dispenser (i.e., a retail pharmacy or a hospital).
SECTION ONE

PROFILE OF THE PRESCRIPTION DRUG WHOLESALING INDUSTRY—
THE SUPPLY OF WHOLESALE DRUG PRODUCTS

This section examines the market characteristics of the prescription drug wholesaling
and distribution industry. Section 1.1 outlines the applicable Federal and State regulations
governing the distribution of prescription drugs. Subsequent sections describe the components
and characteristics of the entities that distribute wholesale drug products. Section Two
examines the organization of purchasers of wholesale drugs. These sections also provide data
on the number of companies and distribution of sales for each of the market players addressed.

This report generally refers to the companies being profiled as “wholesalers,” in keeping
with the terminology most commonly used in the industry. In fact, it is recognized that most
wholesalers also perform substantial distribution functions and, therefore, can also be called
“distributors.” This report, however, will generally use the term wholesalers to refer to the larger
companies that engage in wholesale purchasing and reselling of pharmaceutical products.
While most of these wholesalers also perform distribution functions, their activities do not
always primarily involve distribution in the sense of moving products closer to their eventual
point of consumption. For example, some discount wholesalers could theoretically purchase an
entire lot of distressed product and resell it, in its entirety, to another company, without
“distributing” the product to smaller companies. The term “distribution” will be used to refer to
the physical activity that generally is one of the primary functions of the wholesalers, namely, to
divide large-volume purchases among customers for them to eventually resell to retail
customers or to smaller wholesalers.

Much of the material collected for this report is derived from conversations with industry
sources that did not wish to be quoted or for whom their identification posed a possibility of
revealing sensitive material. Thus, some statements about the operation of the drug distribution
industry are not attributable to specific sources.
1.1 Regulatory Framework for the Distribution of Prescription Drugs

Federal regulations define distributor requirements for reporting on the source of their drug purchases to their customers. States impose basic licensing requirements on drug distributors.

1.1.1 Federal Regulations

At the Federal level, the Prescription Drug Marketing Act (PDMA) of 1988, as modified by the Prescription Drug Amendments of 1992, establishes requirements for the distribution of prescription drugs. Section 503[e][1][A] of the Act requires each person, who is engaged in the wholesale distribution of a prescription drug and who is not the manufacturer or an authorized distributor of record for the drug, to provide the person receiving the drug a statement identifying each prior sale, purchase, or trade of the drug, including the date of the transaction and the names and addresses of all parties to the transaction before each wholesale distribution. Further Section 503[e][4][A] of the Act defines the term “authorized distributors of record” as those distributors with whom a manufacturer has established an “ongoing relationship” to distribute the manufacturer’s products. In a 1988 Guidance, FDA indicated that:

“Ongoing relationship” as used in the definition of “authorized distributors of record,” 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 (FDA, 1988).

On December 3, 1999, the Agency published final regulations in 21 CFR Part 203 implementing these and other provisions of the PDMA as amended by the Prescription Drug Amendments of 1992 (64 FR 67720). Section 203.50 of these final regulations requires that, before the completion of any wholesale distribution transaction where the seller is not an authorized distributor of record, the seller must provide the purchaser with a statement...
identifying each prior sale, purchase, or trade of the drug. The identifying statement, also known as the drug product's pedigree, must include the proprietary and established name of the drug, its dosage, the container size, the number of containers, lot or control numbers of the drug being distributed, the business name and address of all parties to each prior transaction involving the drug, starting with the manufacturer, and the date of each previous transaction.

The Agency further refined its definition of "ongoing relationship" in Section 203.3 [u] of the final regulation to mean

"... 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 products for a period of time or for a number of shipments. If the distributor is not authorized to distribute a manufacturer's entire product line, the agreement must identify the specific drug products that the distributor is authorized to distribute."

Based on concerns expressed by the industry and the Small Business Administration (SDA), FDA decided to delay the effective date for the above sections of the final rule (21 CFR Part 203) until October 1, 2001. At present, the prescription drug wholesale industry operates on the basis of its interpretation of the 1988 FDA Guidance regarding drug product pedigrees. Specifically, the wholesale distribution industry has interpreted the last sentence of the "ongoing relationship" definition (see p. 1-2) as indicating that it is sufficient for a wholesaler to have had two transactions within a 24-month period in order to be considered authorized. Figure 1-1 compares the distribution chain and the associated drug pedigrees under current industry practice and the final rule.

1.1.2 State Regulations

All drug wholesalers must be licensed under state licensing systems, which must in turn meet the FDA guidelines under State Licensing of Wholesale Prescription Drug Distributors (21 CFR Part 205). The regulations set forth minimum requirements for prescription drug storage (21 CFR Part 205.50 [a] and [c]) and security (21 CFR Part 205.50 [b]), as well as for the treatment of returned, damaged, and outdated prescription drugs (21 CFR Part 205.50 [e]). Further, under 21 CFR Part 205.50 [f], wholesale drug distributors must establish and maintain inventories and records of all transactions regarding the receipt and distribution of prescription...
Figure 1-1
Views of the Distribution Chain and Drug Pedigrees Under Current Industry Practice and the Final Rule

Current Industry Practice

Pharmaceutical Manufacturer X

Invoice

Distributor A

Invoice

Distributor B

Invoice

Bought from Dist. B on __

Distributor C

Invoice

Bought from Dist. B on __

Pharmacy

Final Rule 21 CFR Part 203

Pharmaceutical Manufacturer X

Invoice

Distributor A

Invoice

Distributor B

Invoice

Bought from Dist. A on __

Bought from Mfr. X on __

Distributor C

Invoice

Bought from Dist. B on __

Bought from Dist. A on __

Bought from Mfr. X on __

Pharmacy

Notes:
Distributor A has a written distribution agreement with Manufacturer X.
Distributor B has no written distribution agreement but has at least two transactions with Manufacturer X in any 24-month period.
Distributor C has neither a written distribution agreement nor at least 2 transactions with Manufacturer X in any 24-month period.
drugs and make these available for inspection and copying by authorized federal, state, or local law enforcement officials.

In most states, wholesale distributor licenses are issued by the State Boards of Pharmacy and require periodic renewal. The majority of states (approximately 80 percent) also require out-of-state wholesalers that distribute drugs within their borders to be licensed as well. Table 1-1 presents the available data on wholesale distributor licensure requirements, license renewal schedules, and the number of in-state and out-of-state licenses issued, by state.

1.2 Role and Functions of Wholesalers

Drug wholesalers serve as middlemen between drug manufacturers and prescription drug dispensers (i.e., retail outlets and institutions). Wholesalers provide a cost-effective means for the purchase, delivery, and sale of prescription drugs. They improve purchasing economies and lower manufacturer costs by reducing the number of small volume sales by drug manufacturers. They also relieve retailers and institutions from the burden of dealing with each individual manufacturer for drug purchases.

Typically, major wholesalers have sophisticated ordering systems that allow customers to place and confirm orders electronically and to determine the availability and prices of wholesalers' stock. Wholesalers' inventory management systems help customers minimize carrying costs while maintaining adequate supplies to meet patients' needs. In most cases, wholesalers can also provide products within 24 hours. In addition to the delivery of drugs, wholesalers also provide a broad range of value-added services to pharmaceutical manufacturers, dispensers, and other customers, such as pharmacy benefit management companies (PBMs), clinical research organizations (CROs), group purchasing organizations (GPOs), and integrated delivery networks (IDNs). The major supplemental services offered by wholesalers include the following:

- **Private label/Control label programs**—Number of wholesalers offer packaging and labeling operations in accordance with current Good Manufacturing Practices (CGMPs). The services offered typically include package configuration and product label design, filling and capping, labeling, and printing of bar coded product identification stickers.
<table>
<thead>
<tr>
<th>State</th>
<th>Does State License Out-of-State Wholesalers?</th>
<th>License Renewal Schedule</th>
<th>Number of Wholesale Licenses</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td>In-State</td>
</tr>
<tr>
<td>Alabama</td>
<td>Yes</td>
<td>1 year</td>
<td>NA</td>
</tr>
<tr>
<td>Alaska</td>
<td>No</td>
<td>2 years</td>
<td>9</td>
</tr>
<tr>
<td>Arizona</td>
<td>No [a]</td>
<td>2 years</td>
<td>15</td>
</tr>
<tr>
<td>Arkansas</td>
<td>Yes</td>
<td>1 year</td>
<td>NA</td>
</tr>
<tr>
<td>California</td>
<td>Yes</td>
<td>1 year</td>
<td>427</td>
</tr>
<tr>
<td>Colorado</td>
<td>Yes [b]</td>
<td>1 year</td>
<td>NA</td>
</tr>
<tr>
<td>Connecticut</td>
<td>Yes</td>
<td>1 year</td>
<td>NA</td>
</tr>
<tr>
<td>Delaware</td>
<td>Yes</td>
<td>2 years</td>
<td>32</td>
</tr>
<tr>
<td>District of Columbia</td>
<td>Yes</td>
<td>1 year</td>
<td>NA</td>
</tr>
<tr>
<td>Florida</td>
<td>Yes</td>
<td>2 years</td>
<td>530</td>
</tr>
<tr>
<td>Georgia</td>
<td>Yes</td>
<td>2 years</td>
<td>NA</td>
</tr>
<tr>
<td>Hawaii</td>
<td>No [c]</td>
<td>2 years</td>
<td>NA</td>
</tr>
<tr>
<td>Idaho</td>
<td>Yes</td>
<td>1 year</td>
<td>NA</td>
</tr>
<tr>
<td>Illinois</td>
<td>Yes</td>
<td>2 years</td>
<td>NA</td>
</tr>
<tr>
<td>Indiana</td>
<td>Yes</td>
<td>2 years</td>
<td>192</td>
</tr>
<tr>
<td>Iowa</td>
<td>Yes</td>
<td>1 year</td>
<td>NA</td>
</tr>
<tr>
<td>Kansas</td>
<td>Yes</td>
<td>1 year</td>
<td>NA</td>
</tr>
<tr>
<td>Kentucky</td>
<td>Yes</td>
<td>1 year</td>
<td>NA</td>
</tr>
<tr>
<td>Louisiana</td>
<td>Yes</td>
<td>1 year</td>
<td>180</td>
</tr>
<tr>
<td>Maine</td>
<td>Yes</td>
<td>1 year</td>
<td>5</td>
</tr>
<tr>
<td>Maryland</td>
<td>Yes</td>
<td>1 year</td>
<td>NA</td>
</tr>
<tr>
<td>Massachusetts</td>
<td>No</td>
<td>1 year</td>
<td>0</td>
</tr>
<tr>
<td>Michigan</td>
<td>Yes</td>
<td>2 years</td>
<td>NA</td>
</tr>
<tr>
<td>Minnesota</td>
<td>Yes</td>
<td>1 year</td>
<td>NA</td>
</tr>
<tr>
<td>Mississippi</td>
<td>Yes</td>
<td>2 years</td>
<td>NA</td>
</tr>
<tr>
<td>Missouri</td>
<td>Yes</td>
<td>1 year</td>
<td>NA</td>
</tr>
<tr>
<td>Montana</td>
<td>Yes</td>
<td>1 year</td>
<td>NA</td>
</tr>
<tr>
<td>Nebraska</td>
<td>No</td>
<td>1 year</td>
<td>NA</td>
</tr>
<tr>
<td>Nevada</td>
<td>Yes</td>
<td>2 years</td>
<td>83</td>
</tr>
<tr>
<td>New Hampshire</td>
<td>Yes</td>
<td>1 year</td>
<td>8</td>
</tr>
<tr>
<td>New Jersey</td>
<td>No</td>
<td>NA</td>
<td>NA</td>
</tr>
<tr>
<td>New Mexico</td>
<td>Yes</td>
<td>1 year</td>
<td>NA</td>
</tr>
<tr>
<td>New York</td>
<td>No</td>
<td>3 years</td>
<td>349</td>
</tr>
<tr>
<td>North Carolina</td>
<td>Yes</td>
<td>1 year</td>
<td>154</td>
</tr>
<tr>
<td>North Dakota</td>
<td>Yes</td>
<td>1 year</td>
<td>6</td>
</tr>
<tr>
<td>Ohio</td>
<td>Yes</td>
<td>1 year</td>
<td>491</td>
</tr>
<tr>
<td>Oklahoma</td>
<td>Yes</td>
<td>1 year</td>
<td>34</td>
</tr>
<tr>
<td>Oregon</td>
<td>Yes</td>
<td>1 year</td>
<td>825</td>
</tr>
<tr>
<td>Pennsylvania</td>
<td>NA [d]</td>
<td>1 year</td>
<td>525</td>
</tr>
<tr>
<td>Rhode Island</td>
<td>Yes</td>
<td>1 year</td>
<td>46</td>
</tr>
<tr>
<td>South Carolina</td>
<td>No</td>
<td>1 year</td>
<td>NA</td>
</tr>
</tbody>
</table>
## Table 1-1

**State Wholesale Distributor Licensure Requirements, Renewal Schedules, And the Number of In-State and Out-of-State Wholesale Distributor Licenses Issued by State**

<table>
<thead>
<tr>
<th>State</th>
<th>Does State License Out-of-State Wholesalers?</th>
<th>License Renewal Schedule</th>
<th>Number of Wholesale Licenses</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td>In-State</td>
</tr>
<tr>
<td>South Dakota</td>
<td>Yes</td>
<td>1 year</td>
<td>29</td>
</tr>
<tr>
<td>Tennessee</td>
<td>Yes</td>
<td>Cyclical</td>
<td>350</td>
</tr>
<tr>
<td>Texas</td>
<td>Yes [d]</td>
<td>1 year</td>
<td>1,832</td>
</tr>
<tr>
<td>Utah</td>
<td>No</td>
<td>2 years</td>
<td>52</td>
</tr>
<tr>
<td>Vermont</td>
<td>Yes</td>
<td>2 years</td>
<td>3</td>
</tr>
<tr>
<td>Virginia</td>
<td>Yes</td>
<td>1 year</td>
<td>238</td>
</tr>
<tr>
<td>Washington</td>
<td>Yes</td>
<td>1 year</td>
<td>72</td>
</tr>
<tr>
<td>West Virginia</td>
<td>Yes</td>
<td>1 year</td>
<td>NA</td>
</tr>
<tr>
<td>Wisconsin</td>
<td>Yes</td>
<td>2 years</td>
<td>194</td>
</tr>
<tr>
<td>Wyoming</td>
<td>Yes</td>
<td>1 year</td>
<td>50</td>
</tr>
<tr>
<td>Total</td>
<td>NA</td>
<td>NA</td>
<td>6,733</td>
</tr>
</tbody>
</table>


"NA" = Not available

[a] Will begin licensing (permitting) non-resident wholesale drug distributors in the year 2000 pursuant to methamphetamine legislation requirement.

[b] For controlled substances only.

[c] However, per Board’s informal interpretation, if the out-of-state wholesaler has a vendor-managed inventory system within the State, a wholesale distributor license is required.

[d] Wholesalers are regulated and licensed by Department of Health.

[e] Indicates that the figure is approximate.

[f] The figure represents the number of wholesale distributor licenses that are current as of January 17, 2001 (Texas Department of Health, 2001).

[g] The figure represents the total number of licenses for wholesale operation. Multi-state wholesalers presumably hold licenses in all states where they operate and are required. The total number of licenses does not represent an estimate of the number of unique wholesalers.
Voluntary and/or co-op advertising programs—The cooperative advertising program is one in which the wholesaler provides marketing materials (i.e., store displays, flyers, etc.) to and reimburses the retail pharmacy for part or all of the retail pharmacy’s advertising expenditures on selected products purchased from the wholesaler.

Special handling services for vaccines, frozen products, and orphan drugs.

Generic source programs—The program enables a wholesaler to combine the purchase volumes of its customers and negotiate prices with generic manufacturers. This results in competitive pricing of generic pharmaceuticals for the customers of the wholesaler.

Pharmacy computer systems—The pharmacy computer system facilitates the processing of prescriptions, drug interactions monitoring and claims processing.

Third-party claims processing—The claims processing system, which is integrated into the pharmacy computer system, facilitates real-time review and adjudication of prescriptions by third-party payers (i.e., health insurance companies). The system allows the pharmacist to establish patient eligibility, perform prospective drug utilization review (DUR), and notify the patient of any formulary requirements or prior authorization restrictions.

Retail-zone pricing systems—The products are delivered to the retail pharmacy with price labels already affixed to the individual containers so that the products can be immediately shelved.

Point-of-sale (POS) systems—The information technology (IT) system allows pharmacies to manage their inventory and ensure drug pricing accuracy. Typically, the POS systems feature bar code scanning and electronic credit card processing capabilities, which promote faster checkout at the cash register. The system also tracks product movement, identifying best and worst sellers, and facilitates better utilization of product shelf space. The system can generate a multitude of customized business management reports, including hourly product sales, monthly profit trends, and various cashier activities.

Table 1-2 describes the percentage of wholesalers providing each common type of value-added service discussed above.

Despite the broad range of services available from a full-line wholesaler, most dispensing customers of wholesalers use both a primary, usually a major full-line wholesaler and a backup wholesaler. The backup wholesaler provides products when the primary wholesaler cannot fill the order (U.S. District Court for the District of Columbia, 1998).
Table 1-2
Percent of Wholesalers Offering Each Type of Value-Added Service

<table>
<thead>
<tr>
<th>Type of Service</th>
<th>Percent of Wholesalers (1998)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Private Label/Control Label Program</td>
<td>71%</td>
</tr>
<tr>
<td>Voluntary and/or Co-op Advertising Program</td>
<td>62%</td>
</tr>
<tr>
<td>Special Handling Services</td>
<td></td>
</tr>
<tr>
<td>Vaccines</td>
<td>100%</td>
</tr>
<tr>
<td>Frozen Products</td>
<td>100%</td>
</tr>
<tr>
<td>Orphan Drugs</td>
<td>35%</td>
</tr>
<tr>
<td>Generic Source Programs</td>
<td>84%</td>
</tr>
<tr>
<td>Pharmacy Computer Systems</td>
<td>34%</td>
</tr>
<tr>
<td>Third Party Claims Processing</td>
<td></td>
</tr>
<tr>
<td>Print Universal and Other Claim Forms</td>
<td>32%</td>
</tr>
<tr>
<td>Electronic Transmission</td>
<td>33%</td>
</tr>
<tr>
<td>Tape-to-tape Transmission</td>
<td>100%</td>
</tr>
<tr>
<td>On-line Adjudication</td>
<td>92%</td>
</tr>
<tr>
<td>Connectivity (Customer-to-customer communication)</td>
<td>33%</td>
</tr>
<tr>
<td>Retail Zone Pricing Systems</td>
<td>63%</td>
</tr>
<tr>
<td>Rx Drugs - Branded</td>
<td>38%</td>
</tr>
<tr>
<td>Rx Drugs - Generic</td>
<td>46%</td>
</tr>
<tr>
<td>OTC Drugs</td>
<td>96%</td>
</tr>
<tr>
<td>Health and Personal Care</td>
<td>96%</td>
</tr>
<tr>
<td>General Merchandise</td>
<td>54%</td>
</tr>
<tr>
<td>Durable Medical Equipment/Home Health Care</td>
<td>52%</td>
</tr>
<tr>
<td>Point-of-Sale (POS) Systems</td>
<td>34%</td>
</tr>
</tbody>
</table>

Source: NWDA, 1999
Notes:
[1] Based on a survey of NWDA member wholesalers.
[2] The total number of responses received is 39.
1.3 Major Categories of Wholesalers

Wholesalers can be classified into several categories based on their size, breadth of coverage and activity, and principal function. The following sections profile the "Big Five" wholesalers, regional wholesalers, smaller (i.e., sub-regional and/or specialty) wholesalers, and secondary wholesalers.

1.3.1 The Big Five Wholesalers

The prescription drug wholesaling industry in the United States is highly concentrated, with 90 percent of sales made by five major full-line companies, referred to as the "Big Five." This group consists of McKesson HBOC, Inc., Bergen Brunswig Drug Company, Cardinal Health, Inc., AmeriSource Corporation, and Bindley Western Drug Company (see Table 1-3) (NWDA, 1999 and U.S. District Court for the District of Columbia, 1998). These companies generate from $7.6 billion to $21.5 billion per year in revenue, and represent the principal pipeline of drug distribution from manufacturers to dispensers (NWDA, 1999). The Big Five sell to regional distributors but also supply some health care institutions and independent drug stores (i.e., those with no more than three pharmacies). The Big Five distribute a full-line of drug products.

Traditionally, these wholesalers purchased the prescription drugs in large quantities from drug manufacturers, took ownership of the drugs in their own warehouses, and then resold them directly to the retail chains or hospitals (i.e., large dispensers) in desired allotments. This traditional service is referred to as "direct store delivery." Increasingly, however, large purchasers (especially retail chains) prefer self-warehousing, where the retailer buys direct from the manufacturer, stores the drugs in one or more of its own warehouses, and then delivers them to its retail stores and hospitals as needed. Accordingly, the Big Five and various regional wholesalers now also offer "dock-to-dock" delivery and "drop shipment" charging, which are also known as "brokerage" services in the wholesale industry (U.S. District Court for the District
# Table 1-3

## Sales and Market Shares of the Big Five Wholesalers

<table>
<thead>
<tr>
<th>Company</th>
<th>1998 Annual Sales ($ Million)</th>
<th>1998 Market Share</th>
<th>1998 Sales Ranking</th>
<th>Number of Distribution Centers</th>
<th>Types of Customers</th>
</tr>
</thead>
</table>
| McKesson HBC, Inc.             | $21,484                       | 28%               | 1                 | 35                            | Health care institutions - 32%  
Independent pharmacies - 37%  
Retail chain pharmacies - 31% |
| Bergen Brunswig Drug Company   | $16,698                       | 22%               | 2                 | 31 [a]                        | Health care institutions - 50%  
Independent pharmacies - 27%  
Retail chain pharmacies - 16% |
| Cardinal Health, Inc.          | $14,828                       | 19%               | 3                 | 26 [b]                        | Health care institutions - 52%  
Independent pharmacies - 16%  
Retail chain pharmacies (non-warehousing) - 29%  
Retail chain pharmacies (warehouse) - 3% |
| Amerisource Corporation        | $8,669                        | 11%               | 4                 | 19 [c]                        | Health care institutions - 47%  
Independent pharmacies - 33%  
Retail chain pharmacies - 20% |
| Bindley Western Drug Company   | $7,623                        | 10%               | 5                 | 18                            | Direct store delivery - 58% [d]  
Retail chain pharmacies (warehouse) - 42% |
| Big Five Total                 | $69,402                       | 90.0%             | NA                | 129                           | NA                                                                                 |


[a] Additionally, the company has alternate site and depot facilities.

[b] Additionally, the company has 4 specialty distribution centers, 1 medical/surgical distribution facility, 6 packaging facilities, and 4 specialty centers.

[c] The company also has 3 specialty products distribution facilities.

[d] The annual report of the company did not provide figures for the different types of direct store deliveries.
of Columbia, 1998). In dock-to-dock delivery, the wholesaler obtains drugs in large quantities from the manufacturer for direct delivery to retail chain or hospital warehouses and does not bring the drugs into its own inventory. In drop shipments, the manufacturer ships the product directly to the customer, but with the order and payment submitted through the wholesaler. In these brokerage operations, the wholesaler does not take ownership of the drugs in its own warehouse at any time. In 1998, these non-stock sales of the Big Five and regional wholesalers amounted to 17 percent ($12.7 billion) of total sales by wholesalers ($73.8 billion) (NWDA, 1999).

Wholesalers generate revenues from both ends of the wholesale transaction. From dispensers, they receive the “upcharge,” which is the percentage fee paid by dispensers for the cost of distribution, and other brokerage fees. These revenues are generally described as the “sell-side” margins. From manufacturers they receive “buy-side” margins, consisting of cash rebates and discounts for prompt and/or early payment. Distributors also might generate revenues by using the time differential, known as the “float,” between when they receive payment from the drug purchaser and when they pay their supplier.

While the Big Five are very large business entities, price and competitive conditions dictate that they operate on narrow profit margins. In general, the wholesale markup is modest. According to data generated during a recent U.S. court case, for every dollar of prescription drugs sold in 1997, 76 cents went to the manufacturer, 20 cents to the dispenser (i.e., pharmacy), and only 4 cents to the wholesale distributor (U.S. District Court for the District of Columbia, 1998). The NWDA reported the after-tax net profit expressed as a percent of sales, was only 0.62 percent for 1998 (NWDA, 1999).

The Big Five purchase the large majority of their drugs directly from the drug manufacturers. Because the Big Five have formal, written distribution contracts and conduct more than 2 transactions in any 24-month period with the drug manufacturers, they are clearly considered authorized distributors as the Agency has defined the term. The Big Five also

1Based on the context of the discussion in the source, this estimate of the division of the average prescription dollar among manufacturers, wholesalers, and dispensers, reflects all rebates and markups applicable to the industry.
purchase drugs from other distributors who can occasionally offer lower prices. The role of price
discounting in the industry is described in more detail below.

1.3.2 Regional Wholesalers

The next largest distributors after the Big Five are the regional wholesalers. While at
least an order of magnitude smaller than the Big Five, these companies generate revenues of
approximately $500 million to $900 million per year (NWDA, 1999). ERG estimates that there
are approximately 70 regional prescription drug wholesalers, based on the membership roster
of the National Wholesale Druggist Association (NWDA), an industry trade association, and
comments submitted to the FDA docket by Purity Distributors (Riccardi, 2000). Table 1-4
presents the 1998 sales volumes and rankings of the top regional wholesalers.

Regional distributors are distinguished from the Big Five by a smaller volume throughput
of drugs. Many regional distributors, however, offer a complete or nearly complete line of drugs.
Unlike the Big Five, most regional wholesalers do not have formal written distribution contracts
with the pharmaceutical manufacturers, although many conduct business with them on a
regular basis. Thus, while these wholesalers could be considered authorized distributors under
industry's interpretation of the 1988 FDA Guidance, they are not authorized according to the
final rule, 21 CFR Part 203.

Regional distributors and the Big Five sell to the same industry sectors. The regional
distributors can compete with the Big Five because they can provide better service to some of
the areas in their region and because many of their drug purchases from manufacturers are on
terms as or nearly as favorable as those offered to the Big Five. The main customers for the
two groups combined include: (1) health care institutions (36.6 percent of total sales), (2)
independent (non-chain) drug stores (31.6 percent of sales), (3) retail chains (25.7 percent of
sales), and (4) other entities, such as surgical or dialysis centers and physicians’ offices (6.1
percent) (Casteuble, 2000a). Table 1-5 summarizes the distribution of drug sales by type of
customer.
Table 1-4

Top Regional Drug Wholesalers in the U.S.,
by 1996 Sales Volume and Market Share

<table>
<thead>
<tr>
<th>Company</th>
<th>Sales ($ Million)</th>
<th>Market Share</th>
<th>Sales Ranking</th>
</tr>
</thead>
<tbody>
<tr>
<td>Neuman Distributors, Inc.</td>
<td>$1,668</td>
<td>2%</td>
<td>6</td>
</tr>
<tr>
<td>Kinray, Inc.</td>
<td>$905</td>
<td>1%</td>
<td>7</td>
</tr>
<tr>
<td>C.D. Smith Healthcare Inc.</td>
<td>$798</td>
<td>1%</td>
<td>8</td>
</tr>
<tr>
<td>D &amp; K Healthcare Resources, Inc.</td>
<td>$703</td>
<td>1%</td>
<td>9</td>
</tr>
<tr>
<td>Remo Drug Corp.</td>
<td>$508</td>
<td>1%</td>
<td>10</td>
</tr>
<tr>
<td>N.C. Mutual Wholesale Drug Co.</td>
<td>$480</td>
<td></td>
<td>11</td>
</tr>
<tr>
<td>The F. Dohmen Co.</td>
<td>$423</td>
<td></td>
<td>12</td>
</tr>
<tr>
<td>Walsh Distribution, Inc.</td>
<td>$387</td>
<td></td>
<td>13</td>
</tr>
<tr>
<td>Harvard Drug Group</td>
<td>$347</td>
<td></td>
<td>14</td>
</tr>
<tr>
<td>H.D. Smith Wholesale Drug Co.</td>
<td>$306</td>
<td></td>
<td>15</td>
</tr>
<tr>
<td>Belico Drug Corporation</td>
<td>$300</td>
<td></td>
<td>16</td>
</tr>
<tr>
<td>Value Drug Company</td>
<td>$267</td>
<td></td>
<td>17</td>
</tr>
<tr>
<td>Smith/Smith/Texas</td>
<td>$235</td>
<td></td>
<td>18</td>
</tr>
<tr>
<td>FMC Distributors Inc.</td>
<td>$175</td>
<td></td>
<td>19</td>
</tr>
<tr>
<td>Rochester Drug Cooperative</td>
<td>$160</td>
<td></td>
<td>20</td>
</tr>
</tbody>
</table>

Source: NWDA, 1999
Table 1-5
1998 Net Sales of The Big Five and Regional Drug Wholesalers by Type of Customer

<table>
<thead>
<tr>
<th>Type of Customer</th>
<th>Net Sales [a] ($ million)</th>
<th>Percent of Total Stock Sales</th>
<th>Percent of Total Sales</th>
</tr>
</thead>
<tbody>
<tr>
<td>Institutional Dispensers</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Hospitals</td>
<td>$22,362</td>
<td>36.6%</td>
<td>30.3%</td>
</tr>
<tr>
<td>Clinics and Nursing Homes</td>
<td>$17,902</td>
<td>29.3%</td>
<td>24.3%</td>
</tr>
<tr>
<td></td>
<td>$4,460</td>
<td>7.3%</td>
<td>6.0%</td>
</tr>
<tr>
<td>Independent Drug Stores</td>
<td>$19,306</td>
<td>31.6%</td>
<td>26.2%</td>
</tr>
<tr>
<td>Retail Chains</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Chain Drug Stores</td>
<td>$15,716</td>
<td>25.7%</td>
<td>21.3%</td>
</tr>
<tr>
<td>Chain Drug Warehouses</td>
<td>$7,027</td>
<td>11.5%</td>
<td>9.5%</td>
</tr>
<tr>
<td>Mass Merchandisers and Food Stores</td>
<td>$1,528</td>
<td>2.5%</td>
<td>2.1%</td>
</tr>
<tr>
<td></td>
<td>$7,161</td>
<td>11.7%</td>
<td>9.7%</td>
</tr>
<tr>
<td>Other Customers</td>
<td>$3,715</td>
<td>6.1%</td>
<td>5.0%</td>
</tr>
<tr>
<td>Total Stock Sales</td>
<td>$61,101</td>
<td>100.0%</td>
<td>82.8%</td>
</tr>
<tr>
<td>Non-Stock Sales [b]</td>
<td>$12,700</td>
<td>NA</td>
<td>17.2%</td>
</tr>
<tr>
<td>Total Sales</td>
<td>$73,801</td>
<td>NA</td>
<td>100.0%</td>
</tr>
</tbody>
</table>

Source: NWDA, 1999

"NA" = Not available

[a] Includes sales of prescription drugs, OTC drugs, health and beauty aids, general merchandise, and other products.

[b] Non-stock sales include brokerage sales, dock-to-dock, drop shipments, and any other form of sales not placed in inventory that are generally sold at a significantly lower margin. Most non-stock sales are to chain drug store warehouses.
Combined, the Big Five and the regional distributors operate a total of 235 distribution centers across the continental United States and U.S. Territories (NWDA, 1999 and Pharmaceutical Distributors Association, [PDA], 2000a). Based on data provided by the NWDA Industry Performance and Trend Reporting Program, the average number of suppliers (whether manufacturer or other wholesaler) per wholesaler among the Big Five and regional companies is 913 in 1998. This represents an increase of around 47 percent from its 1994 level of 620 (NWDA, 1999). The increase is at least partly due to the significant growth in the variety of products offered in many pharmacies, and especially by the increase in herbal products and remedies now being offered (Casteuble, 2000b).

1.3.3 Smaller Wholesalers

Numerous additional, and generally smaller, wholesalers also distribute pharmaceutical products. This category captures wholesalers of varying characteristics. For example, some of these companies carry a relatively full line of drug products and provide distribution service to small independent pharmacies and physicians. Other wholesalers distribute partial lines of pharmaceutical products, such as injectables, that require special handling. Still other wholesalers team with medical supply companies to provide the combination lines of drug and medical devices dispensed from physician’s office, or supplies provided for veterinarians’ offices.

Many viable drug wholesalers are quite small. Some companies contacted for this study generated over $10 million in annual revenues with fewer than 10 staff dedicated to drug distribution.

Some of these wholesalers serve small drug dispensers, such as small, independent pharmacies, that are not part of buying groups or under contract to larger, full-line distributors. Smaller wholesalers generally are willing to deal in smaller volumes than regional wholesalers and serve the individual independent pharmacies and physicians offices. Figure 1-2 presents the distribution of prescription drug sales by dispensing outlet. In the figure, physician’s offices

\[2\] A small drug store’s contract with a distributor might require that they purchase all pharmaceuticals or a specified range of pharmaceuticals from that distributor.
Figure 1-2
1999 U.S. Prescription Drug Sales by Outlet

Chain Drug (37.6%)
Food Store (8.9%)
Staff Model HMO (1.1%)
Hospital (10.5%)
Home Health Care (1.1%)
Independent Pharmacy (17.1%)
Mass Merchandise (4.4%)
Long-Term Care (2.7%)
Others (0.3%)
Mall Order (10.2%)

Source: PhRMA, 2000
are included in the “Other” category, which represents 0.3 percent of total sales. Small dispensers of various types (e.g., small clinics) are also found in the other dispenser categories as well.

Based on discussions with industry personnel, ERG concluded that virtually none of these smaller wholesalers have formal distribution contracts with drug manufacturers and thus, are not considered authorized distributors. Further, many of these wholesalers probably do not purchase products directly from manufacturers on a regular basis. For example, one wholesaler reports that 83 percent of its purchases are from 3 major full-line wholesalers, 8 percent are from other distributors, and only 9 percent are from 11 different manufacturers (Ford and Everly, 2000). Thus, most smaller wholesalers probably do not meet the requirement for 2 transactions with most pharmaceutical manufacturers in any 24-month period.

The customers of smaller wholesalers do not purchase pharmaceuticals from the major wholesalers (the Big Five or the regional distributors) because:

- They do not meet the minimum volume purchase requirements set by major wholesalers to qualify potential customers; or
- Some wholesalers sell prescription drugs in packages that are inconveniently large for these customers, (Ford and Everly, 2000, Everly, 2000, and Clark, 2000).

1.3.4 Secondary Wholesalers

Secondary wholesalers generally do not offer a full line of pharmaceutical products but specialize in purchasing and selling selected discounted drug products. Pharmaceutical manufacturers occasionally offer drug products for sale, such as when they strive to meet a quarterly sales goal or wish to sell off inventory in advance of a price increase (Riccardi, 2000). At such times, manufacturers offer products for a limited time at a discounted price. Cash customers often receive an additional discount. In response to such sales, secondary wholesalers (and some full-line national or regional wholesalers) will purchase quantities of the sale products.
Secondary wholesalers in turn offer the discounted products for sale, principally to other wholesalers. They sell products to many other wholesalers, including the Big Five and regional wholesalers, because their discounted price undercuts the regular prices being offered by the manufacturer. Thus, a manufacturer’s special sale price for a given drug might undercut the price at which the drug is sold under contract to the Big Five and to regional wholesalers. The Big Five might then reduce their purchases under contract for selected drugs in order to take advantage of sale prices being offered by these secondary and other wholesalers.

While any distributor might be able to take advantage of manufacturer sale prices, secondary wholesalers are distinguished by their willingness to risk substantial capital in buying and trading discounted drugs. Their activities are built around the rapid turnover of discounted drugs in a fashion similar to that of discounters in other industries. One executive noted that his company will fax its inventory and current sale price list either daily or at least twice a week to potential customers. The companies do very little advertising or sales promotion work other than publishing and advertising their sale prices periodically. Industry contacts also noted that, while secondary wholesalers are able to build some customer loyalty, their relationships are built almost entirely on the competitiveness of their sale prices.

There is no formal definition or count of the number of secondary wholesalers. Like other wholesalers, some of these firms are very modest in size, with fewer than 10 staff handling drug orders. There are three prominent secondary wholesalers, each of which are fairly large companies, namely Supreme Distributors Company, Victory Wholesale Grocers Company, and Quality King Distributors, Inc. As their names indicate, these secondary wholesalers distribute other products, including food.

Additionally, a wide spectrum of wholesalers, including the Big Five companies, engage in trading of pharmaceutical products to take advantage of price differentials. Thus, even wholesalers that are primarily engaged in routine distribution services will sometimes trade in pharmaceuticals to take advantage of price differentials.

Like the majority of regional and smaller wholesalers, most secondary wholesalers do not have a written distribution agreement with drug manufacturers whose products they purchase and resell. Some of the reasons why drug manufacturers decline to enter into written
distribution agreements with the secondary wholesalers include (1) the inability of these wholesalers to carry the full line of manufacturers' products and maintain a required line of credit, and (2) manufacturers' unwillingness to open new accounts (PDA, 2000b). Furthermore, secondary wholesalers are only irregular customers of the manufacturers and thus do not represent an avenue for routine distribution of the manufacturers' products.

Many secondary wholesalers engage in numerous transactions with pharmaceutical manufacturers over the course of any 24-month period but usually lack formal written agreements with pharmaceutical manufacturers. Thus, while many secondary wholesalers have believed themselves to be authorized distributors under industry's interpretation of the 1988 FDA Guidance, they are not classified as such under the final rule (21 CFR Part 203).

There are believed to be numerous, smaller, secondary wholesalers as well as the large firms mentioned above. The small secondary wholesalers are entities that also engage substantially in trading of price discounted drugs. This group also resembles the smaller wholesalers described in the previous section, however, in that they service portions of the industry that are not supplied by the Big Five or by the larger regional wholesalers. Even these small secondary wholesalers participate in manufacturer sales of products and trade products aggressively to take advantage of price discounts. ERG lacks quantitative data or distinct industry statistics that allows it to characterize further the population of small secondary wholesalers.

1.4 Statistical Profile of Wholesalers

Government data sources address the drug wholesaling industry, but do little to differentiate drug distributors from other medical and consumer product distributors. According to the U.S. Standard Industrial Classification (SIC) system, businesses primarily engaged in the wholesale distribution of drugs and druggists's sundries, including over-the-counter (OTC) drugs, health and beauty products, vitamins, and in vitro and in-vivo diagnostics, are classified in SIC 5122, Drugs, Drug Proprietaries, and Druggists' Sundries (NAICS 42221, Drugs and Druggists' Sundries, Wholesalers). Based on 1997 data from the Small Business Administration (SBA) (see Table 1-6), there are a total of 6,500 wholesalers in SIC 5122, of which 83 percent
<table>
<thead>
<tr>
<th>Firm Employment Size</th>
<th>Firms</th>
<th>Establishments</th>
<th>Employment</th>
<th>Annual Payroll ($1,000)</th>
<th>Estimated Receipts ($1,000)</th>
<th>Estimated Receipts Per Employee ($)</th>
</tr>
</thead>
<tbody>
<tr>
<td>0 to 9 Employees</td>
<td>4,737</td>
<td>4,747</td>
<td>12,595</td>
<td>$500,975</td>
<td>$8,011,427</td>
<td>$636,080</td>
</tr>
<tr>
<td>10 to 19 Employees</td>
<td>670</td>
<td>689</td>
<td>8,798</td>
<td>$307,819</td>
<td>$3,898,071</td>
<td>$443,063</td>
</tr>
<tr>
<td>20 to 99 Employees</td>
<td>738</td>
<td>820</td>
<td>27,086</td>
<td>$957,207</td>
<td>$12,581,836</td>
<td>$464,514</td>
</tr>
<tr>
<td>100 to 499 Employees</td>
<td>201</td>
<td>354</td>
<td>26,851</td>
<td>$1,000,117</td>
<td>$15,208,338</td>
<td>$563,668</td>
</tr>
<tr>
<td>500 or More Employees</td>
<td>171</td>
<td>1,725</td>
<td>122,254</td>
<td>$6,047,119</td>
<td>$157,600,505</td>
<td>$1,289,124</td>
</tr>
<tr>
<td>[a] Small Entities - 0 to 100 Employees</td>
<td>6,145</td>
<td>6,256</td>
<td>48,479</td>
<td>$1,766,001</td>
<td>$24,491,334</td>
<td>$505,195</td>
</tr>
<tr>
<td>Total</td>
<td>6,517</td>
<td>6,335</td>
<td>197,714</td>
<td>$8,813,237</td>
<td>$197,300,177</td>
<td>$997,907</td>
</tr>
</tbody>
</table>

Source: SBA, 2000

[a] According to the SBA size standards, firms employing 100 or fewer employees are small.
are small (with less than 20 employees), 11 percent are medium-sized (with 20 to 99 employees), and the remaining 6 percent are large (with more than 100 employees). The average estimated revenues per firm ranges from $2.2 million for small to over $0.9 billion for very large wholesalers.

ERG judged that the estimate of 6,500 wholesalers is, at best, a rough approximation of the actual number of U.S. drug wholesalers because SIC 5122 (1) does not include firms that distribute drugs but generate the majority of their revenues from other activities, such as the distribution of groceries, distribution of medical and surgical equipment, and the operation of retail pharmacies, and (2) includes firms that may not distribute prescription drugs (i.e., firms that distribute druggists' sundries such as health and beauty products).

According to the Robert Morris Associates (RMA) Annual Statement Studies, the operating profits of wholesalers classified in SIC 5122 range from 3.4 percent to 4.9 percent of annual sales in 1999 (RMA, 2000).

1.5 Models of Prescription Drug Distribution

ERG identified four broadly defined models of drug distribution although numerous additional variations can be defined. The models are delineated according to the number of times the drug product is resold. Table 1-7 outlines the 1998 sales of prescription drugs by some of the distribution channels identified and by type of dispenser.

ERG did not consider mail-order distribution to be a separate and unique distribution model, but rather a separate dispensing model. Mail-order companies buy their drugs directly from manufacturers or, more commonly, from wholesalers. In either case, distribution occurs through a channel that is equivalent to Models 1 and 2 described below.

---

3 Data provided in Robert Morris Associates Annual Statement Studies is compiled from bank loan requests of companies and includes ratios and common size financial statement percentages segregated by sales size and quartile.
## Table 1-7

1998 Sales of Prescription Drugs to Dispensers, by Channel of Distribution

<table>
<thead>
<tr>
<th>Type of Dispenser</th>
<th>Total Sales</th>
<th>Manufacturer Direct</th>
<th>Chain Store Warehouse/Mail Order</th>
<th>Wholesaler</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>$ Million</td>
<td>$ Million</td>
<td>$ Million</td>
<td>$ Million</td>
</tr>
<tr>
<td>Health Care Institutions</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Hospitals</td>
<td>$24,959</td>
<td>$5,270</td>
<td>$22.4</td>
<td>$18,669</td>
</tr>
<tr>
<td>Clinics</td>
<td>$12,980</td>
<td>$2,622</td>
<td>$0.0</td>
<td>$10,358</td>
</tr>
<tr>
<td>Long Term Care/Home Health</td>
<td>$6,251</td>
<td>$2,494</td>
<td>$12.5</td>
<td>$3,744</td>
</tr>
<tr>
<td>Health Care Plans</td>
<td>$4,219</td>
<td>$447</td>
<td>$84</td>
<td>$3,763</td>
</tr>
<tr>
<td></td>
<td>$1,509</td>
<td>$706</td>
<td>$1.5</td>
<td>$803</td>
</tr>
<tr>
<td>Independent Drug Stores</td>
<td>$19,291</td>
<td>$714</td>
<td>$57.9</td>
<td>$18,519</td>
</tr>
<tr>
<td>Retail Chains</td>
<td>$46,171</td>
<td>$1,031</td>
<td>$29,245.7</td>
<td>$15,894</td>
</tr>
<tr>
<td>Chain Drug Stores</td>
<td>$30,288</td>
<td>$1,000</td>
<td>$22,292.0</td>
<td>$7,027</td>
</tr>
<tr>
<td>Mass Merchandisers</td>
<td>$7,573</td>
<td>$15</td>
<td>$4,543.8</td>
<td>$3,014</td>
</tr>
<tr>
<td>Food Stores</td>
<td>$8,310</td>
<td>$17</td>
<td>$2,409.9</td>
<td>$5,863</td>
</tr>
<tr>
<td>Mail-order Pharmacies</td>
<td>$10,972</td>
<td>$417</td>
<td>$7,153.7</td>
<td>$3,401</td>
</tr>
<tr>
<td>Others</td>
<td>$278</td>
<td>$225</td>
<td>$0.6</td>
<td>$52</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td><strong>$101,671</strong></td>
<td><strong>$8,657</strong></td>
<td><strong>$36,480.3</strong></td>
<td><strong>$56,566</strong></td>
</tr>
</tbody>
</table>

Source: NWDA, 1999
1.5.1 Model 1—Distribution Directly from Manufacturer to Dispensing Organization

Manufacturers sell a portion of their output directly to dispensing organizations, such as large retail pharmacy chains or healthcare organizations. Table 1-8 provides a breakdown of the drug purchases prescription drug sales of innovator drug companies (i.e., excluding generic drug manufacturers) by class of customer. According to a compilation by PhRMA, 20 percent of all pharmaceutical drug sales went directly to dispensing organizations. Specifically, 12.4 percent of manufacturer sales went to retailers, 2.1 percent to private hospitals, and 1.4 percent to healthcare practitioners. The data include sales of both branded and generic drugs, as sold by PhRMA members.

In the past decade, institutional consumers of pharmaceutical drugs, such as hospitals and retail pharmacy chains, as well as independent retail pharmacies, have significantly decreased the percentage of pharmaceuticals purchased directly from the manufacturer. For these institutions, the value-added services of the distributor are more valuable than the price savings from dealing directly with the manufacturer. Conversely, mail order pharmacies have increased the volume of pharmaceuticals they purchase directly from manufacturers. Mail order dispensing of pharmaceuticals is the fastest growing segment of the industry. From 1990 to 1997, the sale of pharmaceuticals by mail order increased from 5.1% to 9.7% of the total sales (U.S. District Court for the District of Columbia, 1998). Mail-order is often used to dispense "maintenance" drugs regularly used by patients over an extended period of time. There are approximately 63 mail-order pharmacies and 32 retail companies with mail-order pharmacy operations in the U.S. (NWDA, 1990).

Some large dispensing companies, especially chain drug stores, perform "self-warehousing" wherein they assume the task of distribution itself. Instead of relying upon an outside distributor, these retailers buy directly from the manufacturer; store the drugs in one or more of their own warehouses; and deliver the drugs to their retail stores as needed. Retail chains with four or more stores (including chain drug stores, mass merchandisers, and food stores) have increased the percentage of drugs they now self-warehouse to 66.1 percent of their total drug purchases (U.S. District Court for the District of Columbia, 1998).4 Thus, retail

4Defined in terms of the total dollar volume of pharmaceuticals purchased.
<table>
<thead>
<tr>
<th>Class of Customer</th>
<th>Sales ($ million)</th>
<th>Market Share</th>
</tr>
</thead>
<tbody>
<tr>
<td>Wholesalers</td>
<td>$64,015.1</td>
<td>80.0%</td>
</tr>
<tr>
<td>Retailers</td>
<td>$9,922.3</td>
<td>12.4%</td>
</tr>
<tr>
<td>Private Hospitals</td>
<td>$1,680.3</td>
<td>2.1%</td>
</tr>
<tr>
<td>Practitioners</td>
<td>$1,120.2</td>
<td>1.4%</td>
</tr>
<tr>
<td>Manufacturers, Repackers</td>
<td>$1,200.2</td>
<td>1.5%</td>
</tr>
<tr>
<td>Federal Hospitals</td>
<td>$640.1</td>
<td>0.8%</td>
</tr>
<tr>
<td>Other Federal Government</td>
<td>$880.2</td>
<td>1.1%</td>
</tr>
<tr>
<td>State and Local Government Hospitals</td>
<td>$560.1</td>
<td>0.7%</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td><strong>$80,018.9</strong></td>
<td><strong>100.0%</strong></td>
</tr>
</tbody>
</table>

Source: PhRMA, 2000

Note: Sales are reported net of rebates and discounts. Numbers and percents may not add to totals because of rounding.
chains self-warehouse a majority of purchases made either directly from manufacturers or through wholesalers.

### 1.5.2 Model 2—Distribution Through Major Wholesalers

The second model of drug distribution characterizes the movement of the large bulk of pharmaceutical products. Most drug shipments move from the drug manufacturer to several large wholesalers (i.e., the Big Five and regional wholesalers) and then on to dispensers (i.e., health care organizations, retail pharmacy chains, etc.). For these drugs, the number of transactions and the times that the drug product is handled and physically moved is the minimum necessary to reach an eventual consumer. Specifically, perhaps 2 transactions (manufacturer to wholesale distributor to pharmacy chain or other dispenser) are made before the product is consumed.

### 1.5.3 Model 3—Distribution from Large to Small Wholesalers to Dispensers

Additional tiers of distribution exist for drugs that are shipped to some of the smaller drug dispensers. As has been noted, the Big Five and even regional wholesalers often have volume requirements that exclude some small dispensers from using their services. In the case of physicians' offices or small healthcare facilities, their demand for drugs is also somewhat limited and/or specialized so that they do not require the services of a full-line distributor. Thus, a hypothetical small wholesaler might report that his customer base consists of several hundred physicians' offices, selected Federal health facilities, selected health care clinics, and miscellaneous other dispensers.

For this case, the number of drug transactions made from manufacturer to dispenser might be three or four (full-line to regional to small sub-regional to perhaps smaller wholesaler).
1.5.4 Model 4—Distribution of Discounted Drugs, Via Secondary Wholesalers

Discounted drugs are sometimes sold in substantial volumes and, in order to absorb the supply, dispersed widely throughout the distribution network. In these cases, the number of transactions made before the drug product reaches a dispenser can be quite large.

Discounted products are often sold to secondary wholesalers, although the Big Five or regional wholesalers also participate in such sales. The secondary wholesalers are notable, however, for their willingness to absorb the risk of large purchases of discounted products.

Representatives of secondary wholesalers described a considerably lengthy set of transactions for many of the drug products they handle. First, while manufacturers sell the bulk of their output to the Big Five wholesalers, they sometimes wish to sell additional products separately from these relationships. As noted earlier, manufacturers will often announce short-term sales of products for various reasons, such as to meet quarterly sales goals, or to reduce inventory before a price increase. Wholesalers might also hold drug sales to eliminate slow-moving inventory.

Such discounted drugs are then purchased by wholesalers, with many purchases by wholesalers other than the Big Five. In making these sometimes large purchases of sale merchandise, the wholesalers incur a substantial capital investment and, less significantly, also use warehouse space to hold the drugs. Furthermore, many of these wholesalers do not have a normal or routine distribution channel that can absorb the discounted product quickly. The wholesalers are interested, therefore, in turning over products quickly and can do so by passing on a portion of the original discount to other wholesalers or drug purchasers. Thus, the original purchaser makes a large capital investment and attempts to recoup it as quickly as possible by selling portions of the sale product, at a still somewhat discounted price, to other wholesalers.

The second tier of wholesalers are largely in the same position as the original purchaser, although they are handling small volumes of sale products. Nevertheless, they make relatively large capital investments and wish to turn over the discounted product as quickly as possible. In this fashion, the sale product is distributed rapidly and with broad dispersion, throughout the drug distribution industry. This second tier might include any drug wholesale organization, including the Big Five, regional, mail order, or other organizations.
The breadth of dispersion is indicated by the number of transactions that might occur before the sale product reaches the dispenser. According to one secondary wholesaler, it is not uncommon for his company to be among the third tier of distributors to purchase some of the sale product. Further, this executive judged it likely that the product would trade hands two or three more times before reaching the eventual drug dispenser. Thus, from 5 to perhaps 7 transactions involving the sale product are commonplace.

1.6 Topics Related to the Functioning of the Distribution Models

1.6.1 Distribution of Branded vs. Generic Pharmaceuticals and Other Variations

Industry contacts indicated that the distribution patterns for drugs of almost all types are unaffected by the nature of the drug. Thus, the distribution models described are applicable to virtually any form of pharmaceutical. There are two areas, however, where there is some variation away from the distribution patterns described above.

First, generic drugs are less often offered in promotional sales at discounted terms. Generic drugs are substantially less expensive than brand name drugs and, thus, already represent a substantial discount from competing products. In any case, distributors mentioned that generic drugs are handled less frequently through secondary wholesalers. ERG did not identify quantitative data on this point.

Second, some products, such as many parenteral products, must be consumed within a relatively short period after manufacturing. Many parenteral products, due to their water content, are relatively bulky to handle and costly to distribute. As a result, these products are poor candidates for repeated reselling through the wholesaling industry. Most of these products are sold using routine distribution channels and generally would not be handled by secondary wholesalers.
1.6.2 Handling of Recalls

Drug distributors must participate with manufacturers and retailers in efforts to retrieve recalled drugs. ERG contacted several distributors about their approach to accomplishing recalls.

An estimated 10 percent of distributors can track products by lot number (Cast cublo, 2000b). The large majority of distributors must rely on date of shipment information received from the manufacturer to determine when and whether they received the recalled materials. Using this information, wholesalers indicated that they can generally determine whether they still have the material and/or who among their customers might have received the product. Wholesalers store incoming products in their warehouses on shelves but, in most cases, do not track the flow of products through the warehouse on a lot-by-lot basis. Wholesalers also do periodic (e.g., monthly) inventories of the products on their shelves.

Some large wholesalers contacted for this study stated that their firms would use the lot and date information from manufacturer invoices to determine if and when they received the recalled product. One wholesaler also stated that the firms’ employees perform a monthly inventory of the cases on their shelf. Thus, the wholesaler can determine in which month they shipped a recalled product, but cannot determine which of the customers (among those purchasing that product during the month) received the recalled lots.

Wholesalers reported that it was standard operating procedure to notify all customers of all recalls. Customers are then required to make their own checks to determine if they still have the recalled products and to notify their customers, as may be appropriate.

Some secondary wholesalers appear to have greater ability to track information by lot number than other wholesalers. For example, testimony at a recent FDA hearing indicated that secondary wholesalers are able to use lot numbers to identify the exact destination of shipments passing through their warehouses (FDA, 2000).
1.6.3 Combined Efficiency of Distribution Models

The first three models above describe fairly conventional models of distribution while the fourth model, distribution via secondary wholesalers, describes the use of unique sale-by-sale channels for distributing discounted products. This fourth channel provides an outlet for promotional or occasional inventory-reducing sales by drug manufacturers.

Many industries have both routine distribution channels which handle the bulk of product sales and "spot" markets that equilibrate supply and demand of product lots that are not distributed through contractual agreements. The spot market allows manufacturers to sell excess production, thereby avoiding inventory charges, product waste, or other costs. It also allows manufacturers to discriminate between buyers that require a guaranteed, predictable, supply of product for distribution and buyers (e.g., secondary wholesalers) that do not. This spot market, like spot markets in any industry, help equilibrate supply and demand and create a more efficient, smoothly functioning market. The spot market provides additional flexibility, through immediate price fluctuations, to both buyers and sellers of products.
To further characterize drug distribution and drug pricing influences, this section profiles some of the organizations that purchase or are involved indirectly in the purchase of drugs. Separate discussions are provided below on health care institutions and integrated delivery networks (IDNs), pharmacy benefit management companies (PBMs), and retailers. The final section briefly addresses the influence of health maintenance organizations (HMOs) and PBMs on prescription drug prices.

2.1 Health Care Institutions and Integrated Delivery Networks (IDNs)

Health care institutions, including hospitals, clinics, nursing homes, home health care providers, managed care providers (i.e., HMOs), government agencies, and various alternate care providers, collectively purchased around $25.0 billion in prescription drugs in 1998 (NWDA, 1999). Over 75 percent of these purchases were from wholesalers and the remaining volume from drug manufacturers (NWDA, 1999). Health care facilities generally demand a greater quantity of prescription drugs per location and a narrower range of items than retail stores.

Over the years, health care institutions have consolidated to form integrated delivery networks (IDNs), which are organized to provide efficient and cost-effective medical services to a community. According to data compiled by the SMG Marketing Group, Inc., there are a total of 604 IDNs in the United States as of April 1999 (NWDA, 1999). Some health care institutions, including individual hospitals, chains, and IDNs, have combined to form group purchasing organizations (GPOs). While the GPOs do not purchase the drugs themselves or provide drug distribution services, they use the aggregated purchasing power of their members to negotiate favorable contracts with manufacturers and wholesalers on behalf of their members (U.S. District Court for the District of Columbia, 1998).
SMG Marketing Group, Inc., estimates that as of April 2000, there were a total of 701 hospital GPOs in the United States. Further, of these 701 GPOs, 416 are multi-hospital systems that own, manage, or lease two or more hospitals (SMG Marketing Group, Inc., 2000).

2.2 Pharmacy Benefit Management Companies (PBMs)

Pharmacy benefit management companies (PBMs) administer the prescription drug part of health insurance plans on behalf of plan sponsors such as self-insured employers, insurance companies, and health maintenance organizations (HMOs). The objective of these companies is to provide high-quality drug care at the lowest possible cost (GAO, 1995). The development of PBMs in the U.S. coincides with the emergence of prescription drug benefits in health care plans in the 1970s and 1980s. The precursors of PBMs include pharmacy claims processors and mail-order pharmacies. While PBMs continue to provide pharmacy claims processing and mail-order pharmacy services to their customers, many now provide additional services, including

- Rebate negotiations with drug manufacturers,
- Development of pharmacy networks,
- Formulary management,
- Prospective and retrospective drug utilization reviews (DURs),
- Generic drug substitution, and
- Disease management programs (Levy, 1999).

*Rebate Negotiations with Drug Manufacturers.* PBMs represent health plans and their enrollees in dealing with drug manufacturers and pharmacies in the prescription drug market. For example, a PBM negotiates with drug manufacturers to obtain rebates for a plan sponsor in return for inclusion and low-cost designation of the manufacturers' drugs on the plan’s formulary (GAO, 1997). These rebates usually take the form of a direct payment from the manufacturer to the PBM. For example, in a simple rebate arrangement, the PBM may periodically report to the drug manufacturer the number of prescriptions for a given drug filled by the PBM's enrollees; the manufacturer then pays the PBM an agreed-upon amount for each prescription.
Alternatively, the PBM and the drug manufacturer may negotiate an agreement where the PBM is reimbursed for moving market share (i.e., significant increases in the number of prescriptions for the manufacturer's drug) (DHHS, 2000). Although there are no published data available on the magnitude of manufacturers' rebates, they are estimated to range from 2 to 21 percent of acquisition price and can be as high as 35 percent for selected drugs (DHHS, 2000).

PBMs generally pass on the rebates they negotiate with drug manufacturers to their customers. Consequently, the insurer or the self-employed insurer typically receives 70 to 90 percent of the rebates (DHHS, 2000).

Development of Pharmacy Networks. In addition to drug manufacturers, PBMs also negotiate with retail pharmacies to obtain various discounts on prescription drug prices. Additionally, PBMs try to assure adequate sites for patients enrolled in various health plans to obtain their prescription drugs. Thus, PBMs try to optimize their position by obtaining the widest geographic pharmacy coverage while keeping costs at their lowest. Figure 2-1 shows a typical network in which a PBM operates.

As part of their management functions, PBMs provide pharmacists information on a variety of issues before drugs are dispensed to the patients. The type of information provided includes (1) data on applicable co-payments, co-insurance, or deductibles; (2) details relevant to any online claims adjudication; (3) concurrent drug utilization review (DUR) data on basic eligibility requirements, drug interactions, and adverse drug reactions; (4) details about any formulary restrictions; (5) data about any generic substitution requirements; and (6) information on brand-name and generic drug dispensing fees (Levy, 1999).

Formulary Management. Formulary management involves the development of a drug formulary, which is a list of drugs that an insurance plan uses to make reimbursement decisions. Formularies help control drug costs by (1) encouraging the use of formulary drugs through compliance programs that inform physicians and enrollees about which drugs are on the formularies; (2) limiting the number of drugs a plan will cover; or (3) developing financial incentives to encourage the use of formulary products. PBMs rely on pharmacy and therapeutic (P & T) committees, consisting of pharmacists and physicians, to determine the number of drugs to include on the formulary (GAO, 1995).
Figure 2-1
Pharmacy Benefit Management Company (PBM) Network

Source: GAO, 1995
Formularies can be open, incentive-based, or closed. An open formulary usually implies that the plan will cover all drugs except those listed as exclusions to the drug reimbursement policy. An incentive-based formulary provides enrollees with financial benefits if their physicians prescribe formulary drugs. Under the arrangement, the health plan still reimburses enrollees for non-formulary drugs but requires them to make higher co-payments than for formulary drugs. A closed formulary details the specific drugs that meet the plan’s reimbursement policy. Under a closed formulary, enrollees generally pay the full cost of non-formulary drugs prescribed (GAO, 1995 and DHHS, 2000).

Drug Utilization Reviews (DURs). PBMs conduct prospective DURs to control drug use before physicians write prescriptions. Under prospective DUR, PBMs use a computer link with network pharmacists to review each prescription before it is dispensed. Prospective DURs are designed to help PBMs to identify whether there is a generic or formulary alternative to the prescribed drug and whether the drug will duplicate an existing prescription or will adversely interact with other drugs the patient is using. For retrospective DURs, PBMs analyze the drug utilization statistics of a customer’s enrollees to identify any instances in which physicians prescribed potentially inappropriate medications. If PBMs detect inappropriate patterns of prescribing or consumption, they then contact and educate physicians about more appropriate and potentially cost-effective treatments (GAO, 1995).

Generic Drug Substitution. Many PBMs offer incentives to their enrollees to select generic instead of brand-name drugs as these are less costly than their brand-name counterparts. PBMs facilitate these therapeutic substitution programs through the mail-order pharmacies they operate (Levy, 1999).

Disease State Management (DSM) Programs. PBMs also initiate disease state management (DSM) programs to contain spending for chronic conditions such as asthma, cystic fibrosis, hemophilia, and multiple sclerosis. In developing these programs, PBMs evaluate various treatment options, or therapies to identify those that are associated with better therapy management and low overall spending. PBMs then attempt to educate both health plan enrollees and their physicians about these more cost effective treatments and monitor the degree of their compliance with the related protocols over time (GAO, 1995).
There are an estimated 76 PBMs in the United States (SMG Marketing Group, Inc., 1999). The top five PBMs by number of covered lives include PCS Health Systems with 56.0 million, Merck-Medco Managed Care with 51.0 million, Diversified Pharmaceutical Services with 23.9 million, Express Scripts ValueRx with 22.7 million, and Wellpoint Pharmacy Management with 15.5 million (NWDA, 1999). SMG Marketing, Inc., reports that on average, 6.2 prescriptions are written per year for each covered life of which 55.7 percent are branded and 44.3 percent are generic drugs.

Some PBMs are privately owned companies whereas others are either owned by or affiliated with pharmaceutical manufacturers, health maintenance organizations, or pharmacy chains. Table 2-1 presents available data on selected PBMs in the United States as gathered from various sources.

The various purchasing methods (PBMs, IDNs, GPOs) affect the destination of drug products (i.e., they help determine eventual purchasers), but in general they do not affect the physical logistics of drug distribution. ERG did not investigate the extent to which purchasing organizations might indirectly affect the logistics of drug distribution by influencing purchasing patterns.

2.3 Retailers

The retailers, which include independent drug stores, retail chains pharmacies, and mail-order pharmacies, are the major customers of wholesalers with total prescription purchases of $76.4 billion in 1998 (NWDA, 1999).

*Independent drug stores* are defined as companies having three or fewer stores. There are currently an estimated 22,000 independent drug stores in the United States (ERG, 2000). Independent drug stores purchased $19 billion in prescription drug products in 1998, with the majority (96 percent) purchased from wholesalers (NWDA, 1996). Over the years, independent drug stores have joined group purchasing organizations (GPOs) in increasing numbers to gain greater leveraging power with wholesalers and manufacturers.
<table>
<thead>
<tr>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>PCS Health Systems</td>
<td>Rite Aid Corp.</td>
<td>56.0 million</td>
<td>$14,500</td>
<td>77,258</td>
<td>5912</td>
<td>Operates retail drug stores which sell health and beauty aids, proprietary drugs, housewares, tobacco products, sundries, and prescription medicines</td>
</tr>
<tr>
<td>Merck-Medco Managed Care</td>
<td>Merck &amp; Co.</td>
<td>51.0 million</td>
<td>$35,500</td>
<td>62,300</td>
<td>2834, 2833, 2836, 2835</td>
<td>Develops, produces, and markets human health care products, including therapeutic and preventive agents generally sold by prescription; produces animal health products; provides pharmaceutical benefit services</td>
</tr>
<tr>
<td>Diversified Pharmaceutical Services</td>
<td>SmithKline Beecham</td>
<td>23.9 million</td>
<td>$12,300</td>
<td>47,200</td>
<td>2834, 2844, 8071</td>
<td>Researches, develops, manufactures, and markets a wide range of health and personal care products, including pharmaceuticals; provides disease management and pharmaceutical benefit management services; performs clinical laboratory testing services</td>
</tr>
<tr>
<td>Express Scripts Value RX</td>
<td>Express Scripts</td>
<td>22.7 million</td>
<td>$5,520</td>
<td>4,606</td>
<td>5912, 8099, 8093</td>
<td>Provides broad range of pharmacy benefit management services to health benefit plan sponsors including pharmacy network administration, drug utilization review, and mail pharmacy service, and offers infusion therapy services and managed vision care programs</td>
</tr>
<tr>
<td>WellPoint Pharmacy Management</td>
<td>WellPoint Health Networks</td>
<td>15.5 million</td>
<td>$8,290</td>
<td>10,600</td>
<td>6324, 6719</td>
<td>Holding company with subsidiaries that offer managed healthcare plans through health maintenance and preferred provider organizations</td>
</tr>
<tr>
<td>Integrated Pharmaceutical Services</td>
<td>Foundation Health Pharm.</td>
<td>14.0 million</td>
<td>$8,790</td>
<td>12,000</td>
<td>6324, 6719</td>
<td>Holding company with subsidiaries that operate health maintenance organizations and offer managed health care product coordination for multi-regional employers and administrative services for medical groups and self-funded benefits programs</td>
</tr>
<tr>
<td>------------------------</td>
<td>----------------------------</td>
<td>----------------------</td>
<td>--------------------------</td>
<td>-------------------</td>
<td>---------------</td>
<td>----------------------------------------------------------------------------------------</td>
</tr>
<tr>
<td>Advance Paradigm</td>
<td>Advance Paradigm, Inc.</td>
<td>13.0 million</td>
<td>$2.150</td>
<td>1,372</td>
<td>6099</td>
<td>Provides pharmacy benefit management services including clinical and benefit design consultation services to health plan sponsors</td>
</tr>
<tr>
<td>Caremark - Prescription Service Div, Caremark Rx Inc.</td>
<td>10.0 million</td>
<td>$3,890</td>
<td>4,371</td>
<td>6324, 8099</td>
<td>Develops, organizes and manages integrated health care delivery systems that provide primary and specialty health-care services to prepaid managed care enrollees and fee-for-service patients, performs prescription benefit management and therapeutic pharmaceutical services</td>
<td></td>
</tr>
<tr>
<td>First Health Services</td>
<td>First Health</td>
<td>8.0 million</td>
<td>$0.474</td>
<td>3,600</td>
<td>6324, 8742, 8099</td>
<td>Develops and manages payer-based PPO networks that incorporate both group health and workers' compensation medical providers; provides prescription drug benefit plan administration, drug utilization review, and a nationwide network of nearly 50,000 pharmacies; provides centralized clinical management programs and other medical consulting services</td>
</tr>
</tbody>
</table>

Retail chains, defined as having four or more stores, include chain drug stores, mass merchandisers, and food stores. In 1998, retail chains purchased around $16 billion in prescription drugs (NWDA, 1999). While retail chains rely on wholesalers to deliver a certain percentage of their drug needs, the largest retail chains also maintain their own internal distribution system. Like wholesalers, self-warehousing chains receive the drugs from manufacturers in large quantities, store the drugs in their own warehouses, and deliver the drugs to their retail outlets through their own distribution systems. Retail chains are the only dispensers of prescription drugs that self-warehouse to any significant extent. Large chains, such as Rite-Aid and Eckerd, have the capacity to self-warehouse up to 90 percent or so of the prescription drugs that are sold in their stores. Over the years, retail chains have steadily decreased their reliance on wholesalers. At the same time, drug manufacturers, that used to sell exclusively or principally to wholesalers, sell increasing shares of their production directly to the chains. In 1998, over 63.3 percent of purchases by retail chains were for self-warehousing (NWDA, 1999).

Mail-order pharmacies are a hybrid between the distribution and retail ends of the pharmaceutical industry. Mail-order pharmacies receive prescriptions by fax or through the mail and dispense the drugs directly to consumers anywhere in the United States. Mail-order is often used to dispense “maintenance” drugs regularly used by patients over an extended period of time. Mail-order pharmacies often use the services of a wholesaler to buy their prescription drug inventories. They then store their inventories in one or more of their warehouses. There are approximately 63 mail-order pharmacies and 32 retail companies with mail-order pharmacy operations in the U.S. (NWDA, 1999).

2.4 The Influence of Pharmacy Benefit Management Companies (PBMs) and Health Maintenance Organizations (HMOs) on Prescription Drug Prices

Department of Health and Human Services conducted a major study, published in April 2000, assessing prescription drug pricing (DHHS, 2000). This section summarizes one set of findings of the study’s profile of price setting.

Most drug purchasers, almost regardless of their health care coverage or insurance plan, eventually receive their prescription products at a pharmacy. Table 2-2 describes how the
### Table 2-2

An Illustrative Example of Pricing for a Brand Name Prescription Drug

<table>
<thead>
<tr>
<th>Data Element</th>
<th>Cash Customers (No 3rd Party Payment at Point of Sale)</th>
<th>Insurers and PBMs</th>
<th>HMOs [a]</th>
<th>Medicaid</th>
<th>Federal Supply Schedule</th>
</tr>
</thead>
<tbody>
<tr>
<td>List Price (AWP)</td>
<td>$50</td>
<td>$50</td>
<td>$50</td>
<td>$50</td>
<td>$50</td>
</tr>
<tr>
<td>Manufacturer's price (Manufacturer to wholesaler other entity)</td>
<td>$40</td>
<td>$40</td>
<td>$34</td>
<td>$40</td>
<td>$24</td>
</tr>
<tr>
<td>Acquisition price (Wholesaler to pharmacy)</td>
<td>$41</td>
<td>$41</td>
<td>NA</td>
<td>$41</td>
<td>NA</td>
</tr>
<tr>
<td>Retail price at pharmacy (Total of amounts paid by customer and reimbursed by 3rd party payer)</td>
<td>$52</td>
<td>$46</td>
<td>$43.50</td>
<td>$41 + $2.50</td>
<td>NA</td>
</tr>
<tr>
<td>Retail price, less typical manufacturer rebate</td>
<td>NA</td>
<td>$30 to $44</td>
<td>NA</td>
<td>$30 to $37</td>
<td>NA</td>
</tr>
<tr>
<td>Ultimate (net) amount paid by final purchaser and/or consumer</td>
<td>$52</td>
<td>$30 to $44</td>
<td>$30 to $37</td>
<td>$30 to $37</td>
<td>$24</td>
</tr>
</tbody>
</table>

Source: DHHS, 2000

"NA" = Not applicable

[a] The column refers only to those HMOs that buy directly from manufacturers.

[b] Without rebates

Notes:

1. Prices are based on a composite of several commonly prescribed brand-name drugs for a typical quantity of pills. For some cells in the table, the relative relationships have been calculated based on relationships reported in the literature and on other relationships widely reported by industry sources.

2. The prices are used for illustrative purposes only and do not represent an average price.

3. Prices reported in the table include both amounts paid by third-party payers and amounts paid by the consumer as cost sharing.
groups discussed above, including PBMs and HMOs, influence the prices set. The table provides an illustrative hypothetical example of how prices are set under different schemes for a brand name prescription product using a relatively simple set of wholesale transactions.

The table shows that the first transaction, that from manufacturer to wholesaler, occurs at a discount from the average wholesale price (AWP). The AWP serves as a list price for drugs, but most sales occur well below this list price. DHHS reports that average sales occur at a 20 percent discount from AWP as indicated by various industry sources. In the illustration provided in Table 2-2, the HMO has bought the drug directly from the manufacturer and negotiated a steeper discount than that received by insurers or PBMs. This deeper discount would be representative of some of the largest HMOs such as Kaiser Permanente that are running their own pharmacies. Other HMOs use PBMs to manage their clients’ drug purchases.

The wholesaler’s markup to the manufacturer’s price is modest, generally at 2 to 4 percent. In this case, the wholesaler’s markup is shown to increase prices from $40 to $41 dollars, where it is applicable.

Next, the price is marked up by the pharmacy by a percentage amount and, in some cases, by a fixed charge for the dispensing function. The study indicates that the pharmacy will commonly add 20 to 25 percent to the drug cost, or in this case $11 on a $41 drug, for a total $52 purchase for a cash customer. Where insurers or PBMs are involved, they will negotiate discounts from pharmacists (as well as from drug manufacturers), thereby lowering the price paid by consumers and/or insurers. The DHHS authors note that little is known about the average extent of such discounts offered by pharmacies though a $5 markup on the $41 drug is assumed in their example.

Insurers and PBMs generally negotiate manufacturer rebates on their drug purchases. DHHS estimates the possible range of such rebates as 5 to 35 percent, reducing the $46 drug cost to $30 to $44. PBMs that use restricted formularies are best able to negotiate rebates with manufacturers.
Federal programs pay for drugs according to the Federal Supply Schedule. As a very large purchaser of drugs, the Federal government can negotiate steep discounts from retail prices.
GLOSSARY

**Authorized distributor (or authorized distributor of record).** Any distributor of a prescription drug that has a written agreement with the manufacturer of the prescription drug and conducts at least two transactions with the manufacturer of the prescription drug within any 24-month period.

**Average wholesale price (AWP).** The AWP is a published wholesale price or "list price" suggested by the manufacturer of the drug. Although the AWP does not capture the actual transaction prices, it serves as a reference for pricing, negotiations, and reimbursements.

**Brokerage.** The combination of drop-ship and dock-to-dock delivery services provided by wholesalers. In brokerage services, wholesalers do not bring the products into their warehouses.

**Buy-side margin.** The term refers to the early payment discounts and other earned or negotiated rebates and discounts received by wholesalers from drug manufacturers. Further, increases in the value of wholesalers' inventories as manufacturers' prices rise are also considered buy-side margins.

**Chain drug store.** A company that owns and operates four or more pharmacies. Food store and mass merchandiser pharmacies are also considered chain drug stores. Examples include Shaw's, Wal-Mart, Rite-Aid, and CVS.

**Dock-to-dock delivery.** In dock-to-dock delivery, a wholesaler obtains the drugs from the manufacturer and delivers them to a dispenser's own warehouse without taking the drugs into its own inventory. Thus, dock-to-dock sales are also referred to as non-stock sales.

**Drop shipment.** In drop shipments, a drug manufacturer directly delivers the drugs to a dispenser, but the order and payment is made through a wholesaler.

**Drug formulary.** A list of drugs compiled by a government body, third-party insurer or health plan, or another institution that may or may not be dispensed or reimbursed. Some institutions or health plans develop closed (i.e., restricted) formularies where only those drug products listed can be dispensed in that institution or reimbursed by the health plan. Other formularies may have no restrictions (open formularies) or may have limited restrictions such as higher patient co-payments for non-formulary drugs.

**Float.** The time differential between when a wholesaler receives payment from its customer (i.e., retail dispenser, health care organization, etc.) and when the payment is due to its supplier (i.e., pharmaceutical manufacturer or other wholesaler).

**Group purchasing organization (GPO).** An entity consisting of two or more hospitals or other health care entities that is formed to offer its members access to purchasing contracts for health supplies (i.e., pharmaceuticals, biologics, medical/surgical equipment, laboratory supplies, and other capital equipment). GPOs actively negotiate contracts with manufacturers on behalf of their members, provide their members access to the purchasing contracts of other GPOs, and/or have central purchasing supply sites which are utilized by their members.
**In-state wholesaler.** A wholesaler that distributes drug products in a given state and is physically located in that state.

**Independent drug store.** A company that owns and operates three or fewer pharmacies. These are also referred to as community or neighborhood pharmacies.

**Integrated delivery network (IDN).** Also known as integrated healthcare delivery network (IHDN), integrated delivery system (IDS), or integrated health/healthcare system (IHS). A financial and management structure that unites hospitals, physicians, ambulatory care sites, and managed care plans through ownership or exclusive formal agreements to provide a system to deliver a continuum of healthcare services. The IDN appears totally integrated to the patient, provider, and payer throughout the healthcare system. Increasingly, a shared financial information system and optimization of resources connect the structural components of the IDN.

**Mail-order pharmacy.** A pharmacy that dispenses prescriptions to patients who submit their prescriptions by mail or fax. The pharmacy then mails the filled prescription to the patient. Mail-order pharmacies generally serve patients on long-term drug therapies and those without immediate drug needs. The average size of prescriptions (i.e., the number of capsules or tablets) dispensed by mail-order pharmacies is usually 3 times larger than those dispensed by retail pharmacies (NACDS, 2000).

**Manufacturer-direct sale.** The type of sale that bypasses the need for any intermediary distributor. The product is sold and shipped directly by the manufacturer to the dispenser.

**Mass merchandiser.** An establishment, also known as a department store, that is primarily engaged in retailing a wide range of merchandise, including apparel, furniture, appliances, paint, hardware, toiletries, cosmetics, and prescription drugs. Prescription drugs are dispensed through an on-site pharmacy. Examples of mass merchandisers include Wal-Mart, K-Mart, and ShopKo.

**National Wholesale Druggists’ Association (NWDA).** The national trade association that represents pharmaceutical and related healthcare product distributors throughout North America.

**Non-stock sales.** Brokerage sales, dock-to-dock delivery sales, drop shipments, and any other form of sales not placed in inventory. These generally have a significantly lower margin than stock sales.

**Out-of-state wholesaler.** A wholesaler that distributes drug products in a given state but is physically located in another state.

**Pharmaceutical Distributors Association (PDA).** An industry trade association that represents secondary and smaller wholesalers. The association’s membership includes Supreme-Purity Distributors Company, Quality King Distributors, Inc., and Victory Wholesale Grocers Company.

**Pharmacy benefit management company (PBM).** An entity that administers the prescription drug part of health insurance plans on behalf of plan sponsors, such as self-insured employers, insurance companies, and health maintenance organizations (HMOs). PBMs provide pharmacy
claims processing and mail-order pharmacy services in addition to other services, such as rebate negotiations with pharmaceutical manufacturers, development of pharmacy networks, formulary management, drug utilization reviews, generic drug substitution, and disease management programs.

**Rebate.** The amount that the manufacturer of the drug pays to an insurer or health plan for each unit of drug dispensed. Rebate arrangements exist between drug manufacturers and Medicaid agencies, HMOs, and other insurers or drug plans, and generally bypass the pharmacy. Rebates are also referred to as "after market" arrangements because they do not affect the prices paid at the time of service, but are implemented later, ultimately reducing the payer's expenditures or program costs (Kaiser Family Foundation, 1999)

**Self-warehousing.** A type of distribution system where the retail or the institutional dispenser take on the task of distribution itself. Instead of relying on an outside distributor, the retailer or the institutional dispenser buys direct from the manufacturer, stores the drugs in one or more of its own warehouses, and then delivers them to its retail stores or hospitals as needed. Self-warehousing is most prominent among the chain drug stores.

**Sell-side margin.** Wholesaler revenues that are generated from fees and other charges obtained from dispensers. During the 1980 to 1998 period, sell-side margins have declined from 5.5 percent to 0.35 percent (U.S. District Court for the District of Columbia, 1998).

**Upcharge.** The percentage fee that is paid by the dispenser to the wholesaler for the cost of distribution.
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Attachment D
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Appendix A: Table of Anti-Counterfeiting Measures ................................35
EXECUTIVE SUMMARY

FDA Commissioner Mark McClellan established the Counterfeit Drug Task Force in July 2003 as part of FDA's heightened battle against the growing threat of counterfeit drugs. Commissioner McClellan charged the Task Force with developing recommendations for achieving four fundamental goals: (1) preventing the introduction of counterfeit drugs, (2) facilitating the identification of counterfeit drugs, (3) minimizing the risk and exposure of consumers to counterfeit drugs, and (4) avoiding the addition of unnecessary costs on the prescription drug distribution system, or unnecessary restrictions on lower-cost sources of drugs.

The Task Force has reached several interim conclusions. First, there is no single "magic bullet" against the growing number of sophisticated counterfeiters; rather, a multi-pronged strategy to secure the drug supply could be much more difficult for counterfeiters to overcome than any single method. It could also be less costly, because a "one-size-fits-all" approach is unlikely to work for all parts of the complex prescription drug supply system. Second, although drug counterfeiters today are more sophisticated and better organized than ever before, there are many new technologies and approaches that have the potential to prevent and contain counterfeit drug threats. While most of these new approaches have not yet been fully developed, implemented, and tested, they hold the promise of a more secure drug distribution system in the years ahead. Third, because many of these promising ideas have not been fully developed, the Task Force believes that an opportunity for broad public comment is essential to guide its further work.

Consequently, the interim report contains a series of potential options that might be part of a multi-pronged approach to combat counterfeit drugs. The potential options are based on what the Task Force has learned to date from reports, other governmental agencies, and individual stakeholders (e.g., state governments, trade associations, consumer groups, drug manufacturers, wholesale distributors, pharmacies, consumers, academicians, manufacturers of anti-counterfeiting technologies).

The interim report also contains background information compiled by the Task Force on the U.S. drug distribution system and the vulnerabilities that facilitate the introduction of counterfeit drugs into the system.

The background sections also discuss how specific factors, such as emerging anti-counterfeiting technologies, industry business practices, public awareness, and the dissemination of information, affect the ability to deter and detect counterfeit drugs.
The discussion of the U.S. drug distribution system and these specific factors provide the context and basis for the potential options proposed for consideration by the Task Force. These options are in the areas of:

- Technology;
- Regulatory requirements and secure business practices;
- Rapid alert and response systems;
- Education and public awareness; and
- International issues.

Because a principal goal of this report is to stimulate public discussion of the most cost-effective way to keep the drugs used by Americans secure, these options are posed as potential options and are accompanied by a number of questions for the public, highlighting areas where the Task Force wishes to obtain further comment to inform its final report.
I. The Counterfeit Drug Task Force

A. Purpose of the Task Force

On July 16, 2003, Commissioner of Food and Drugs Mark McClellan, M.D., Ph.D., formed an internal FDA Counterfeit Drug Task Force to develop recommendations for steps FDA, other government agencies, and the private sector can take to minimize the risks to the public from counterfeit drugs and biologics (hereinafter, all references to “drugs” refers to both drugs and biologics) getting into the U.S. drug distribution system. This initiative is designed to enhance the existing safeguards that are in place to protect the nation’s drug supply from counterfeit drugs.

Although FDA believes that domestic counterfeiting is not widespread, the agency has recently seen an increase in counterfeiting activities as well as increased sophistication in the methods used to introduce finished dosage form counterfeits into the otherwise legitimate U.S. drug distribution system. FDA counterfeit drug investigations have increased to over 20 per year since 2000, after averaging only 5 per year through the late 1990’s.

Counterfeit drugs pose significant public health and safety concerns. They may contain only inactive ingredients, incorrect ingredients, improper dosages, sub-potent or super-potent ingredients, or be contaminated. As a result, patients may be put at risk for serious adverse health consequences. For example, Procrit, a drug used by cancer and AIDS patients, was recently counterfeited and the drug was replaced with nonsterile tap water, which could have caused a severe infection of the bloodstream. In another recent counterfeiting incident, white tablets with “aspirin” imprinted on them replaced Zyprexa, a drug used for schizophrenia and acute bipolar disorder. This could have been particularly dangerous for patients who are aspirin-sensitive or aspirin-allergic or who have bleeding disorders. In addition, patients no longer received appropriate treatment for their illness. Counterfeiters also have been known to switch lower-strength drug for higher strength drug. As a result, patients receive lower than expected doses of drug, leading to ineffective treatment and therapeutic failure.

Although exact prevalence rates in the U.S. are not known, outside the U.S. drug counterfeiting is known to be widespread and affect both developing and developed countries. For example, in South-East Asian countries approximately 10% of drugs on the market are believed to be counterfeit. In China, authorities believe that for some drugs, counterfeit account for 50% of the product on the market. It is reported that in underdeveloped countries such as Argentina, Colombia, and Mexico, up to 40% of manufactured pharmaceuticals may be counterfeit.
B. Development of the Interim Report

The Task Force consists of senior agency staff from the Office of the Commissioner (Office of Policy and Planning, Office of Regulatory Affairs, Office of External Affairs, and Office of the Chief Counsel) the Center for Drug Evaluation and Research, and the Center for Biologics Evaluation and Research.

As part of this effort, the Task Force has met with several government agencies, such as the Secret Service, U.S. Customs and Border Protection, the Bureau of Engraving and Printing, and the Department of Justice, as well as various individual private sector stakeholders. The Task Force has also reviewed reports prepared by, or on behalf of, federal and state governments, and heard from the public, including such stakeholders as pharmaceutical manufacturers, wholesale distributors, pharmacy associations, consumer groups, academicians, independent consultants, and manufacturers of anti-counterfeiting measures. As described in more detail below, the Task Force intends to continue these interactions before developing its final report.

Based on what it has heard to date, the Task Force believes that the most constructive approach to addressing the problem of counterfeit drugs lies in identifying vulnerabilities in the drug distribution system and addressing those vulnerabilities with a multi-pronged approach. So far, the Task Force has found considerable consensus about these vulnerabilities, as well as new opportunities to address them. The Task Force intends to build on these ideas to identify a set of broadly supported initiatives to improve the security of the U.S. drug supply.

C. What the Interim Report Contains

This interim report contains a series of ideas and potential options developed by the Task Force for consideration in each of the following areas: technology, regulatory requirements and secure business practices, alert systems, education and public awareness, and international issues. The potential options are in the form of potential actions that, if taken, may prevent the introduction of, and help to quickly identify, counterfeit drugs in the U.S. drug distribution system. These options do not represent the recommendations of the Task Force; rather, they are included in this report to stimulate further discussion and critiques, and to support the development of clear proposals that are likely to succeed. Many of the options discussed complement each other and are not mutually exclusive.

In its research and exploration of ways to address counterfeit drugs, the Task Force has been sensitive to the rising cost of drugs and that its efforts should not impose additional costs that could be borne by consumers nor impede access to less expensive, lawfully obtained drugs. In fact, this interim report includes potential options that may bring about cost savings to entities in the U.S. distribution system, which could reduce drug costs while at the same time reducing the likelihood that U.S. consumers would receive a counterfeit product.
Additionally, Section IV of this interim report contains a series of questions highlighting areas where the Task Force wishes to obtain further information to help inform its final report.

D. Development of the Final Report

The Task Force plans to continue gathering information from individual stakeholders and members of the public as it prepares its final report which is scheduled for release in January 2004. As part of this effort, the Task Force will hold a public meeting and technology forum on October 15, 2003, during which the Task Force will hear testimony from the public on the problem of counterfeit drugs and will learn more about specific anti-counterfeiting technologies. See the counterfeit drug initiative web page at www.fda.gov for more information and a copy of the notice announcing the meeting. The questions in this report supplement the questions published in the notice.

The Task Force recognizes that the options presented in this report are based on what it has heard and reviewed to date, and looks forward to receiving comments and information that will provide further basis for the final report and recommendations of the Task Force.

E. Goals of the Initiative

In the final report, the Task Force plans to issue recommendations that will ensure that the U.S. drug distribution system continues to be the safest, most secure system in the world. Features of the system might include:

- the use of cost-effective technologies, including many new and emerging technologies, to authenticate and track drugs from the point of manufacture to the point of dispensing to deter and detect the introduction of counterfeit drugs;

- exercise of a high level of diligence by all purchasers to ensure that drug products are authentic, in accordance with industry standards and secure business practices;

- a regulatory scheme that minimizes the burdens placed on each participant in the system; and

- well-informed stakeholders and consumers.
II. Background: Vulnerabilities in the U.S. Drug Distribution System

In order to better understand how counterfeit drugs are introduced into the U.S. marketplace, the Task Force examined the drug distribution system in the U.S. to better understand existing vulnerabilities.1

A. The Drug Distribution System

Congress created a framework of laws intended to maintain high public confidence in the U.S. drug distribution system and the safety and efficacy of drug products. States also have enacted laws and regulations that are intended to complement Federal oversight to further protect the integrity of the U.S. drug distribution system. Together, State and Federal legislation and regulations work to provide security in the nations drug supply.

The Task Force reviewed and considered information from published reports, criminal investigations, and other sources describing the drug distribution system. What follows is a brief summary of what the Task Force has learned to date.

There are three large wholesalers who account for about 90% of the primary wholesale market. In addition, there are many smaller wholesalers who may have full or partial product lines and who may or may not sell nationally or regionally. Some of these wholesalers concentrate in the “secondary” wholesale market, i.e., they purchase selected drug products from wholesalers and they resell to other wholesalers, including large wholesalers, as well as pharmacies. They generally purchase discounted drug products. There are many reasons why sales from one wholesaler to another may benefit consumers. These may include: 1) taking advantage of price discounts available on certain legitimate drug products, (e.g., when a manufacturer or wholesaler has a temporary overstock or purchases excessive product on speculation that the manufacturer will raise prices), 2) low volume transactions (e.g., involving drugs that are used only occasionally in special populations), 3) quick turnaround (e.g., permitting a wholesaler or pharmacy to meet a temporary and unexpected increase in demand

1 The Food Drug and Cosmetic Act (the Act) defines a counterfeit drug as “a drug which, or the container or labeling of which, without authorization, bears the trademark, trade name, or other identifying mark, imprint, or device, or any likeness thereof, of a drug manufacturer, processor, packer, or distributor other than the person or persons who in fact manufactured, processed, packed, or distributed such drug and which thereby falsely purports or is represented to be the product of, or to have been packed or distributed by, such other drug manufacturer, processor, packer, or distributor.” (21 U.S.C. 201(g)(2))
for a drug), or 4) sale to a remote area (e.g., sales to a small rural community). Figure 1 depicts drug distribution models in the U.S.

**Figure 1**

**Drug Distribution Models**

1. **Manufacturer** → **Retailer**

   ![Diagram](image)

2. **Manufacturer** → **Wholesaler** → **Retailer**

   ![Diagram](image)

3. **Manufacturer** → **Wholesaler** → **Wholesaler** → **Retailer**

   ![Diagram](image)

   **Other Source of Drugs**
   
   (e.g., institutional pharmacies, closed door pharmacies, foreign markets)

[Figure 1 depicts three models showing the movement of drugs through the U.S. drug distribution system. (The dotted lines indicate potential illegal sales.) In the simplest situation, the manufacturer sells directly to a retailer. However, in many instances, there can be one or more wholesalers, or even a repackager, who handles the drug before it reaches the retailer. It is in these intermediate steps, particularly when the wholesaler(s) and/or repackager(s) obtain products from sources other than the original manufacturer, that the greatest opportunities for compromising the security of the U.S. distribution system exist.]

**B. Sources of Counterfeit Drugs**

For a variety of reasons, counterfeit drugs currently are most likely to be introduced as part of a drug distribution process involving multiple wholesalers. However, it is important to recognize that criminal activity to introduce
counterfeit drugs can occur at any stage in the drug distribution system, so that safeguards are needed in all of the transaction processes.

Many drugs in the distribution system are also “repackaged”. In the U.S., wholesale drugs in bulk containers are often repackaged into smaller containers prior to sale to an end user. Repackaging operations are performed by independent entities, wholesale distributors, or by distribution centers owned by large pharmacies. In the current distribution system products are repackaged for several legitimate reasons, such as to improve efficiencies for automated systems. In Europe, products are packaged in quantities that relate to a course of treatment (unit of use,) in general, obviating the need for repackaging.

The Task Force heard from law enforcement personnel that when counterfeit drugs are identified, they are often associated with diversion of the drugs that they purport to be. Diversion is the sale of drugs outside of the distribution channels for which they were originally intended. Diverted drugs can originate domestically, when there is illegal redirection of prescription drugs from other legitimate sources, such as free samples supplied to health care providers or lower-priced drugs intended for nonprofit clinics or Medicaid programs. Additionally, diverted drugs can originate in a foreign market, when donated or lower-priced product intended for use in one country is diverted to another country where the market price is higher. Counterfeit drugs generally are associated with the practice of diversion. Our current regulatory system does not have legitimate, regulated channels for such diverted drugs (even if authentic) to re-enter the drug distribution system. Consequently, there is no reliable mechanism in place to distinguish effective authentic lower-cost drugs from drugs that simply appear to be so, but are not legitimate and may be harmful.

Diversion facilitates the entry of counterfeit drugs into the U.S. distribution system because those individuals or entities that sell or purchase diverted drugs are less able to verify the integrity of these drugs, because they are purchased outside the normal distribution chain and without the usual regulatory safeguards. As a result, counterfeit, substandard, or otherwise adulterated or misbranded products may become commingled with authentic drugs in the U.S. distribution system. Because counterfeiting is often associated with drug diversion, steps to secure the drug supply against counterfeits may also make criminal drug diversion more difficult.

C. Points of Vulnerability in the U.S. Drug Distribution System

As noted above, some business practices that may serve certain desirable purposes, such as discounted pricing, can create opportunities for criminals to introduce counterfeit drugs into the drug distribution system. These practices represent potential vulnerabilities in the drug distribution system and require a high level of diligence by participants in the drug distribution chain in order to deter and detect counterfeit drugs. A more secure distribution system should
include additional features to prevent counterfeit entry beyond the practice of due diligence by all participants.

For reasons that often benefit consumers, a manufacturer may sell a drug product at lower prices to certain end users or wholesalers. When this happens, the cost differential between the discounted price and the market price (which is based on the manufacturer’s usual list price and paid by other end users) can foster multiple profitable transactions before sale to an end user. Both wholesalers and end users who purchase drug products at discounted prices can initiate this chain of transactions. A drug product undergoing multiple transactions between the time it is sold by the manufacturer and the time it is bought by an end user, should be properly authenticated (e.g., via inspection, examination of the product's pedigree, or use of track and trace technology) by each purchaser in order to minimize the possibility that a counterfeit product has been substituted by an unscrupulous entity during one of the transactions.

Therefore, lack of a high level of diligence by members of the U.S. drug distribution chain can facilitate the introduction of counterfeit drugs into the drug U.S. drug supply. Investigations performed by Federal and State authorities have repeatedly shown the existence of illicit nationwide networks designed to capitalize on the inadequate due diligence performed by members of the drug distribution system in order to introduce potentially unsafe diverted and counterfeit drugs into the U.S. drug distribution system.

As drug prices continue to rise, opportunities to obtain lower cost drugs become increasingly important. However, because potential cost savings from discounted pricing provides a target for counterfeiters, the need for due diligence in this circumstance, particularly when multiple transactions occur, also increases.

However, even with a heightened level of vigilance by parties participating in single or multiple transactions or by those seeking lower-cost versions of drugs, there are weaknesses in the drug distribution system that can facilitate the entry of counterfeit drugs. Below, we discuss in more detail, several points of vulnerability in the U.S. distribution system that the Task Force identified.

- **Incomplete Pedigrees**—A pedigree is a statement of origin that traces the drug from the point of manufacture and contains information about all transactions that the product undergoes until it reaches the end user. Products that have incomplete pedigrees, such as pedigrees that do not include all the transactions involving a drug from the time it leaves the manufacturer to the time it is sold to a consumer, make it more difficult to track and trace the authenticity of those drug products than products that have more complete pedigree information.

- **Inadequate or No Authentication**—It is important for purchasers in the U.S. drug distribution chain to ensure that the product they are purchasing is the genuine article (i.e., authenticate the product). Tools and processes are readily available to copy drug products and their
labeling and packaging to such an exact degree that even the manufacturer of the authentic product cannot tell if it is real or fake. On the other hand, technologies are also available (or will be in the near future) to identify whether the product that they are purchasing is authentic or counterfeit. Unfortunately, these authenticating technologies often are not incorporated into the drug product, labeling, or packaging.

- **Importation**—Prior to the passage of the Prescription Drug Marketing Act (PDMA), including section 801(d)(1), drugs manufactured in the U.S. could go to a foreign market and then be reimported into the U.S. This became a common entry point for the introduction of adulterated and counterfeit drugs into the U.S. drug distribution system. Such products posed a public health problem because they were found to be subpotent, lacked active ingredients, contained ingredients that could pose a severe health hazard if taken by a susceptible person (e.g., aspirin), lacked adequate labeling, or were not approved drug products. For example, pre-PDMA, in 1985, over 2 million counterfeit tablets of Ovulen-21 from Panama were widely distributed throughout the U.S. Similarly, in 1985, a counterfeit version of Ceclor, an antibiotic widely used at that time, found its way into the U.S. drug distribution from a foreign source.

In response to this public health problem, Congress passed PDMA, which prohibits reimportation of drugs by any entity other than the manufacturer. Figure 2 depicts the path of a drug in the U.S. distribution system, both before and after passage of the PDMA. The FDA and the States do not have oversight or authority over the foreign marketplace. Under current law, the FDA only has authority over foreign manufacturers when they submit to FDA oversight as part of a new drug application. (See 21 USC 355.) In addition, under current law, FDA has no authority to inspect or assess the practices used in foreign drug distribution systems. Obtaining drugs from a foreign distribution system further exacerbates existing vulnerabilities, similar to, but more severe than, those that facilitate domestic diversion. (See Figure 1, Model 3.) However, unlike entities engaged in domestic diversion, foreign counterfeiters remain outside the reach of U.S. law enforcement. Congress prohibited reimportation to protect American consumers from receiving counterfeit, substandard, or otherwise adulterated drugs.

Furthermore, when consumers order medications from outside the U.S. (e.g., internet purchases, cross-border purchases), whether safe or unsafe, a portal of entry is created for counterfeit drugs into the U.S. distribution system. Counterfeiters can take advantage of this entryway by combining many small purchases from foreign countries into one and selling them to U.S. wholesalers or other unsuspecting entities. Due to the extensive resources involved in preventing small quantities of drugs from entering the U.S., as the volume of unapproved drug
imports increases, it is more difficult for FDA to use its existing resources to identify and stop unsafe importations.
Figure 2

<table>
<thead>
<tr>
<th>Pre- and Post-PDMA</th>
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<tbody>
<tr>
<td><strong>Pre-PDMA</strong></td>
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<tr>
<td>Manufacturer</td>
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<tr>
<td><strong>Post-PDMA</strong></td>
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<td>Manufacturer</td>
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- **Repackaging**—Repackaging may destroy anti-counterfeiting measures used in the original packaging and labeling of the drug. It may also provide a point of entry for expired, adulterated, or counterfeit drugs into the distribution system because they may be repackaged in a way that makes them appear to be legitimate products. Lastly, counterfeit and diverted product may be commingled with authentic product during the repackaging process and find its way to an end user.

- **Tamper-Evident Packaging**—Currently, many prescription drug products do not utilize tamper-evident features. Without tamper-evident features, the original packaging may be reused for counterfeit or diverted product and thereby be more easily passed off as legitimate product. The reuse of old prescription drug containers found in trash facilities or taken from hospitals and clinics is also a significant problem because no tamper-evident feature has to be replicated, thereby enabling easy reuse of the packaging to distribute counterfeit, adulterated, or unapproved drugs. While tamper-evident packaging is important, it is also worth noting that counterfeit drugs can be repackaged into legitimate-appearing packaging (including features intended to mimic legitimate tamper-evident features), so that packaging alone cannot assure that drugs have not been counterfeited.
D. **Background: Regulatory and Legislative History**

1. **Prescription Drug Marketing Act**

As previously alluded to, Congress addressed some of these vulnerabilities by enacting the PDMA in 1988, which was amended in 1992 by the Prescription Drug Amendments. Among other things, the PDMA:

- requires State licensure of wholesale distributors of human prescription drugs;

- requires wholesale distributors of human prescription drugs in interstate commerce to provide a statement of origin, also known as a drug “pedigree”, which traces each prior sale, trade, or purchase of the prescription drug, to and from each wholesale customer prior and subsequent to the sale of the drug to that wholesaler, but exempts manufacturers’ “authorized distributors;”

- with certain exceptions, prohibits the resale of prescription drugs that have been purchased by a hospital or other health care entity or that have been donated or supplied at a reduced price to a charitable organization.

In 1999, FDA published final regulations implementing the provisions of the PDMA. The provisions concerning the pedigree requirements at 21 CFR 203.3(u) and 203.50 were stayed by FDA because of valid concerns expressed by industry, trade associations, and Congress about implementing these provisions. Such concerns included the high cost and logistics of maintaining a pedigree and occasional inability to obtain a transaction history from the prior distributors and the manufacturer, thus calling into question the usefulness of the pedigree. Taking steps to address these requirements using traditional methods could impose substantial costs, at a time when access to affordable drugs is also a major policy concern.

In 2000, FDA held a public hearing to discuss these concerns. In 2001, FDA submitted a Report to Congress outlining the concerns raised by the secondary wholesale industry. The agency noted that in order to enable secondary wholesalers to fully comply with the pedigree requirements, Congress would have to amend section 503(e) of the Act to enable them to get the transaction history from all prior purchasers of the drug (because, currently, wholesalers who are authorized distributors of record are exempt from providing this information.)

In order to give Congress time to consider the information and conclusions contained in the agency’s Report to Congress and to determine if legislative
action was appropriate, FDA subsequently instituted an additional stay of the provisions until April 1, 2004.

In addition to being costly, tracing a drug pedigree on paper, as envisioned in the PDMA, is subject to multiple record keeping failures, and may be subject to fraud. As discussed below, there are many promising developments in anti-counterfeiting technology that will enable the creation of an electronic pedigree for a drug product, thus reducing the need for paper pedigrees. Other steps discussed below can also help address the weaknesses identified in the PDMA. These new approaches are consistent with the desired movement toward electronic health information systems to prevent errors and adverse events, and would also make it easier to maintain the high level of diligence needed throughout the drug distribution system to prevent the introduction of counterfeit drugs.

2. Model Practice Act

As part of the implementation of PDMA, in 1990, FDA published a final rule containing “Guidelines for the State Licensing of Wholesale Prescription Drug Distributors.” The guidelines were codified at 21 CFR Part 205. The guidelines include the minimum standards, terms, and conditions for the storage and handling of prescription drugs and for the establishment and maintenance of records of their distribution. The guidelines followed, among other things, the “Model Regulations for Wholesale Drug Distribution” (Model Rules) issued by the National Association of the Boards of Pharmacy (NABP), which were previously issued as an example for States to adopt in order to comply with the PDMA. Subsequently, all 50 states have enacted some sort of legislation to implement the PDMA.

As the introduction of counterfeit drugs has increased over the past several years, some states, such as Florida and Nevada, have adopted laws and regulations with more stringent requirements intended to minimize the risk of counterfeit drugs appearing in their state. The Task Force believes that such steps could have an impact on the nationwide problem of counterfeit drugs.

To this end, the Task Force is working closely with the NABP to update the Model Rules and is in the process of reviewing the 50 state practice acts that govern wholesale distribution of prescription drugs, identifying strengths and weaknesses of those acts, and suggesting where the Model Rules can be updated. Based on its findings to date, the Task Force views the following as important areas for States to focus on in updating their Model Rules: requirements for licensure, qualifications of employees, handling and storage of drugs, site security, inspection and examination of drugs, record keeping, availability of records to inspectors and law enforcement personnel, due diligence, administrative subpoena power, and criminal penalties.
3. **Penalties and Enforcement**

The Task Force has reviewed the current applicable criminal statutes and sentencing guidelines for various types of counterfeiting and has found that the penalties for counterfeiting drugs are substantially less than for other types of counterfeiting, such as counterfeiting registered trademarks. For example, counterfeiting a prescription drug label (bearing a registered trademark) is punishable by up to ten years in prison, while counterfeiting the drug itself is punishable by a maximum of only three years in prison. Also, the U.S. Sentencing Commission guidelines currently include FD&C Act felonies at the lowest level of all federal crimes. Yet, counterfeiting of drugs may create substantial risks to the health and safety of a large number of consumers.

The Task Force has reviewed the statutes under which drug counterfeiting charges may be brought, as well as provisions that may streamline investigations and facilitate the seizure of counterfeit drugs and the forfeiture of illegal proceeds. The Task Force heard from some organizations that, as implemented to date, these penalties may not be severe enough to deter and punish those responsible for counterfeiting drugs.

The Task Force also reviewed the subpoena authority currently available to certain regulatory agencies, such as the Internal Revenue Service and the Bureau of Customs. The subpoena authority of those agencies is related to their statutory roles and responsibilities, and in conjunction with their other authorities, supports the efficient execution of their mission when other approaches (e.g., surveillance and tracking systems) are unable to provide the information required to address public threats.

**E. Background: Technology Issues**

1. **Types of Anti-Counterfeiting Technologies**

Two types of anti-counterfeiting technologies have existed for many years:

- Authentication technologies, and
- Track and Trace technologies.

Authentication technologies fall into three groups:

- **Overt** technologies are protective measures that are easily visible to the eye, such as holograms, color shifting inks, and some watermarks.

- **Covert** technologies are protective measures that are not visible to the eye and frequently require special equipment for visualization (and
authentication). These include some watermarks, certain inks and dyes that fluoresce or absorb ultraviolet light, and invisible bar codes.

- **Forensic technologies** are protective measures that require sophisticated analytical equipment, usually found in a forensic chemistry lab, in order to be identified. These include chemical markers, taggants, and other unique chemical properties of a substance.

Track and trace technologies include:

- **Radio-frequency identification (RFID)** is a technology that involves the placement of electromagnetic chips/tags that contain product specific information onto cartons, pallets, and individual products. The system includes the tags, antennae affixed to the tags, readers to receive the data in the tags, and an information database that is used to authenticate and track the product as it moves through the distribution system.

- **Barcodes** are symbols (representing an alpha numeric value) printed on labels that are read by a scanner and used to identify drug products. Bar codes can be combined with covert elements (e.g., security ink) that also allow them to function as authentication technologies.

Appendix A to this report contains a list of some basic types of authentication and track/trace technologies along with some of their capabilities and limitations.

2. **Utilization of Anti-Counterfeiting Technologies**

The Task Force recognizes that the functions of authentication and track/trace technologies are complementary. In order to reduce the likelihood of counterfeit drugs being introduced, and to increase the likelihood of identifying counterfeit drugs in the U.S. drug distribution system, both technologies should be utilized. The information reviewed by the FDA to date demonstrates that no single authentication or track/trace technology is a complete solution to facilitating the identification, and preventing the introduction, of counterfeit drugs into the marketplace. Law enforcement officials and other government agencies shared with FDA their experiences with counterfeiting of currency, credit cards, checks, and other documents. Their universal advice is that multiple technologies and measures must be utilized because determined counterfeiters are able to defeat many anti-counterfeiting measures within 18-24 months after the measure is implemented. Therefore, multiple strategies and a continuous evolution of technology are necessary to thwart criminal activity.

The Task Force has heard that track/trace technologies should be incorporated at the point of manufacture, used throughout the distribution system, and inactivated/destroyed at the time of dispensing. When track/trace technologies are used at a pallet and case level, they have the capability of following the
product at each point in the distribution chain. To be maximally effective for authentication purposes, track/trace technologies should be incorporated at the product (individual package) level in addition to the case and pallet level so that individual product, rather than only bulk shipments, can be followed.

The Task Force has learned that the use of radio frequency identification (RFID) chips is undergoing pilot testing in several venues; however, widespread use of RFID may not occur for several years. Aside from the need to work out technical problems, (e.g., attaining 100% read rates,) a significant reason for this delay is that RFID and some other sophisticated technologies will not work without a system-wide infrastructure and an integrated database. An integrated database is one that is accessible to all users in the distribution chain for viewing data and contributing to the tracking of a particular product. Such databases and the associated “reading” technologies could take several years to develop and gain widespread adoption throughout the marketplace. Issues that need to be resolved include: Who will create the database? Who will own the data? And, who has access to the data?

If all entities in the drug distribution chain use RFID chips or other electronic track/trace technology, an “electronic pedigree” will be created de facto for the product. An advantage of an “electronic pedigree” is that it is harder to forge than a paper pedigree. However, for an electronic pedigree to become universally adopted, industry or national standards would have to be developed and implemented.

The Task Force has learned that the use of authentication technologies varies by pharmaceutical company and product. In general, authentication technologies are more widely used than track/trace technologies. However, the way they are used and the number that are used vary. For example, the Task Force has learned that combinations or layers of authentication technologies are more likely to be used in products at high risk for being counterfeited. On the other hand, products considered to be at lower risk may have fewer anti-counterfeiting measures incorporated into their manufacturing, packaging, or labeling.

Moreover, in the event that a suspect counterfeit product is found, there is a need for FDA and stakeholders to rapidly identify whether the labeling, packaging, and product are authentic. Currently, there is no database for FDA, other government regulatory agencies, or stakeholders to use which contains up-to-date information about authentic products, packaging, labeling, and utilization of anti-counterfeiting measures. Such a database could expedite confirmation of a suspect counterfeit drug product’s authenticity.

### 3. Cost/Benefit of Anti-Counterfeiting Technologies

The Task Force has heard a great deal about the costs of adopting anti-counterfeiting technologies. These include costs associated with:

- Purchase of the technology;
• Purchase of associated equipment (e.g., barcode scanners, RFID receivers, access to electronic databases) and services;

• Integrating the technology into the manufacturing process;

• FDA review, if required, for the technology;

• Adopting new anti-counterfeiting measures as old ones are defeated;

• Creation of infrastructure throughout the distribution system.

To date, the Task Force has heard less about the potential benefits of adoption of anti-counterfeiting technologies beyond greater assurance of drug safety. In addition to the public health and economic benefits associated with a reduction in the number of counterfeit drugs, other benefits may include:

• Improved inventory management and control (with resulting reductions in inventory expenses for distributors and pharmacies);

• Reduced labor cost due to automation;

• Reduction in theft and product loss due to other causes;

• Reduction in the amount of diverted product;

• Improved ability to recall product;

• Protection of drugs from intentional tampering;

• Protection of drugs from being used in an act of terrorism.

An area of focus for the Task Force as it gathers more information on anti-counterfeiting technologies will be to find ways to maximize the benefits of new anti-counterfeiting measures while minimizing their costs.


F. **Background: Health Professional and Industry Issues**

1. **Secure Business Practices**

   Given the complicated nature of many features of the drug distribution system, the business practices of the entities involved in those transactions (e.g., wholesalers, repackagers) plays a critical role in determining the ability and likelihood of introducing counterfeit drugs into the supply chain. These business practices may also play a role in the ability of stakeholders to identify counterfeits before they reach a consumer.

   Industry practices in such areas as recordkeeping, inspection and examination of drugs, facility and information security, package disposal, performance of ‘due diligence’ on business partners, and establishing criteria for determining with whom they do business are all crucially important for the integrity of the drug distribution system.

   Based on its research to date, the Task Force is not aware of any pertinent benchmarks or industry standards for business practices among pharmaceutical manufacturers, wholesalers, repackagers, and pharmacies with regard to the sale and purchase of drugs. The lack of adequate benchmarked industry standards is important because legitimate businesses are often involved in the purchase and sale of counterfeit drugs and therefore can be involved, unknowingly, in allowing counterfeit drugs to reach consumers. In addition, the lack of such standards creates opportunities for criminals to introduce unsafe drugs into the U.S. drug distribution system.

   The Healthcare Distribution Management Association (HDMA) has submitted a draft document entitled “Recommended Guidelines for Pharmaceutical Distribution System Integrity,” which was endorsed by the Pharmaceutical Distributors Association (PDA), for the Task Force to consider in its deliberations. The document is a set of draft voluntary guidelines for pharmaceutical wholesalers to use for screening another pharmaceutical wholesaler prior to establishing a business relationship. It emphasizes the need to perform “due diligence” by requesting certain information, performing background checks, and inspecting the facilities of the potential business partner.

   The Task Force will continue to work with HDMA, PDA, and others to gather information about current and best practices in the pharmaceutical industry prior to considering any final recommendations about the nature and extent of any changes to current industry practice that might reduce the risk of counterfeit drugs entering the distribution chain.
2. Rapid Alert and Response Systems

Identifying suspect counterfeit drugs in the distribution system is important to prevent sale of the counterfeit product to the patient. While consumers can help, wholesalers, distributors, repackers, and pharmacists are often best situated to identify and report suspect counterfeit drugs. Recognizing this important role, the Task Force believes that steps should be taken to facilitate reporting of suspect counterfeit drugs and that a central FDA voluntary reporting mechanism be used for reporting by the public.

Recently, a variety of industry groups have begun to take voluntary steps to address this problem. For example, earlier this year, the pharmaceutical industry announced a voluntary program, whereby Pharmaceutical Research and Manufacturers of America (PhRMA) member companies agree to notify FDA’s Office of Criminal Investigations (OCI) within five working days of determining that there is a reasonable basis to believe that a product has been counterfeited. OCI has received several reports since that April 2003. OCI is currently working with industry to standardize reporting requirements and otherwise improve communications. The program also applies to counterfeits discovered in foreign countries if there is clear evidence that the counterfeits are intended for distribution in the United States. HDMA recently announced similar steps that their member companies will take in notifying FDA of suspect counterfeit drugs.

Currently, health care professionals and consumers use FDA’s MedWatch system for reporting adverse events associated with medical products as well as product problems. Policies and procedures are in place to ensure that the information is conveyed to appropriate agency personnel for follow up. For example, if there is a problem with a product (e.g., broken tablets, lack of efficacy) the information is analyzed and/or investigated to determine whether there are steps manufacturers may need to take to correct the problem. Additionally, over 150 health care professional, consumer, and trade organizations have partnered with MedWatch to help disseminate information and alerts generated by MedWatch. The Task Force believes that this system can be adapted to receive reports of suspect counterfeit drugs and communicate important information in the event a counterfeit drug is identified.

As described below, the Task Force is exploring the creation of a counterfeit drug alert network, which would draw on all of these elements and could be utilized to disseminate information when a counterfeit drug is identified. Such a network also could be used as a vehicle for educational messages.
G. **Background: Education and Public Awareness Issues**

The Task Force believes that an educated, vigilant public is an invaluable defense against counterfeit drugs filtering into the U.S. pharmaceutical market. Consumers and health professionals need to know how to proactively avoid these counterfeits. They also need to be familiar with what to look for when faced with a potential counterfeit and the steps that need to be taken if they are suspicious that they have encountered one.

The Task Force explored what appropriate role FDA and its partners could play to educate potentially affected groups. A logical first step to take would be to identify specific stakeholders that would most likely be affected by counterfeit drugs. The next step would be to craft appropriate messages and identify effective communication tools to accurately reach these diverse stakeholders. This step is very important because various communities and professional groups receive health information in different ways.

The Task Force recognizes that once a counterfeit is identified in the stream of commerce, public officials must quickly act to remove the counterfeit drug from the marketplace. However, at the same time, while getting this information out to the public, officials need to take care not to alarm unaffected consumers, thereby causing them to discontinue necessary therapy. The FDA has long held the position that protection of the public health will remain its number one mission, even if public notifications of a counterfeiting scheme might hinder the criminal investigation to determine who is responsible for the counterfeiting.

As part of its assessment of current communication channels, the Task Force consulted with numerous agency components that oversee communication channels potentially pertinent to anti-counterfeit communications. Information from consumer groups, health care provider associations, media representatives, trade organizations, and representatives of state governments/enforcement groups was also reviewed to better understand the current information flow processes between the FDA and outside stakeholders.

Based on this information, the Task Force made the following preliminary assessment:

- There is a need for more comprehensive efforts to educate the public about the threat of counterfeit drugs, how to identify them, and how to minimize the risk of receiving counterfeit drugs. Figure 3 is an example of the type of educational messages that may be used in an educational campaign.

- Efforts to educate pharmacists and other health professionals about current counterfeit events and how to handle these situations exist, but could be improved.
• When a counterfeiting event occurs, there are sometimes delays of varying degrees in alerting and updating the appropriate health professional about the problem. When the messages are delivered, they may not be adequately tailored to the various audiences to be helpful to them. Also, stakeholders complain they have to work too hard to access timely, accurate information - a proactive alarm system was named as a potential solution.

• There may be additional opportunities to work with health care providers and manufacturers to capture data that may help identify counterfeits.

What Can Consumers Do to Protect Themselves from Counterfeit Drugs?

1. To avoid purchasing “buyer beware” drugs, it's safest to purchase ONLY from U.S. state-licensed pharmacies, where the FDA and state governments can assure the safety of drug manufacturing, packaging, distribution, and labeling.

2. If purchasing over the internet, make sure the website has the Verified Internet Pharmacy Practice Sites Seal (VIPPS).

3. Be vigilant about your medicine. Check for changes in packaging, labeling, color, taste, or shape of a pill. Look out for unanticipated side effects.

4. If you suspect you have a counterfeit drug:
   a. Contact the pharmacist that dispensed the drug; OR
   b. Call 1-800-FDA-1088; OR
   c. Contact your doctor.
III. Potential Options for Improving Prescription Drug Security

Based on what it has heard and reviewed to date, the FDA Task Force on Counterfeit Drugs is listing a series of preliminary options with the goals of:

- Preventing the introduction of counterfeit drugs and biologics into the U.S. drug distribution chain;
- Facilitating the identification of counterfeit drugs and biologics;
- Minimizing the risk and exposure of consumers to counterfeit drugs and biologics; and
- Avoiding the addition of unnecessary costs to the prescription drug distribution system, or unnecessary restrictions on lower-cost sources of drugs.

The potential options are premised on several interim conclusions reached by the Task Force. First, there is no single "magic bullet" against the growing number of sophisticated counterfeiters; rather, a multi-pronged strategy to secure the drug supply could be much more difficult for counterfeiters to overcome than any single method. It could also be less costly, because a “one-size-fits-all” approach is unlikely to work for all parts of the complex prescription drug supply system. Second, although drug counterfeiters today are more sophisticated and better organized than ever before, there are many new technologies and approaches that have the potential to prevent and contain counterfeit drug threats. While most of these new approaches have not yet been fully developed, implemented, and tested, they hold the promise of a more secure drug distribution system in the years ahead. Third, because many of these promising ideas have not been fully developed, the Task Force believes that an opportunity for broad public comment is essential to guide its further work.

The Task Force notes that these options are not mutually exclusive. In general, these options could be implemented together or independent of each other.

A. Technology

The Task Force heard from many groups and individuals. According to what we have heard, appropriate long term goals for the use of technology include achieving an electronic pedigree and incorporation of authentication measures for all drug products. However, due to the emerging nature of many of these technologies, a phased in approach for their implementation should be considered. With this in mind, the adoption of one or more of the following options concerning the use of technology to deter and detect counterfeit drugs,
by the Federal government or the private sector, as appropriate, might reduce the likelihood of counterfeit drugs from entering the U.S. drug distribution system and/or reaching a U.S. consumer:

1. Package all finished dosage form drugs in unit of use packaging as appropriate for the particular product (e.g., tablet, multi-dose vial) at the point of manufacture, as is now done in many nations;

2. Use tamper evident packaging from the point of manufacture, with labeling that notes the tamper evident feature, for all dosage forms, active pharmaceutical ingredients (APIs), and bulk chemicals;

3. Incorporate for all drug products at least two types of validated anti-counterfeiting technologies into packaging and labeling at the point of manufacture with at least one of these technologies being covert (i.e., not made public, and requiring special equipment or knowledge for detection) using a phased in approach starting with those products at high risk of being counterfeited and where the introduction of counterfeit product poses a serious health risk;

4. Incorporate for all drug products a taggant, chemical marker, or other unique characteristic(s) into the manufacturing process that is only identifiable with the use of sophisticated analytic technologies using a phased in approach starting with those products at high risk of being counterfeited and where the introduction of counterfeit product poses a serious health risk;

5. Create an electronic database of drugs and biologics for authentication purposes, which consists of photographs of the product, packaging and labeling information, and the anti-counterfeiting measures utilized in the packaging, labeling, and product itself;

6. 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 integrated infrastructure that is able to track and trace products at all points in the distribution chain from manufacturer to end user;

7. 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
introductions), 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;

8. Issuance of an FDA guidance document concerning the appropriate use of anti-counterfeiting technologies as well as the FDA application and review process for incorporating or changing taggants, chemical markers, or other unique characteristic(s) of the product;

9. Issuance of an FDA guidance document concerning physical site security and supply chain integrity.

B. Secure Business Practices and Regulatory Requirements

The Task Force heard that the state requirements for licensure of wholesale distributors need to be updated and that the standards for certain business practices among the entities involved in the U.S. drug distribution system are insufficient. The following options, based on what we have heard, relate to secure business practices that affect the ability to deter and detect counterfeit drugs:

10. 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;

11. 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.;

12. 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;

13. Timely sharing with FDA, by manufacturers, of relevant market tracking and trending data and the analysis of these data for use as a means of identifying counterfeit or diverted product in the marketplace.

C. Rapid Alert and Response Systems

The Task Force heard that there is a need to strengthen the systems used for reporting by, and alerting of, stakeholders and the public as to the existence of counterfeit drugs. The following options, based on what we have heard, relate to alerts systems for counterfeit drugs.

14. Enhance the MedWatch Alert System for use as a tool to receive and disseminate timely information about counterfeit drug products, especially identification of suspect drug product;

15. 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);

16. Further enhance FDA’s internal processes for responding to and investigating reports of suspected counterfeit products.

D. Education and Public Awareness

The Task Force heard from many sources that there is a great need to increase awareness and education of stakeholders and the public concerning counterfeit drugs. The following options, based on what we have heard, address these issues:

17. Increase the efforts of the FDA, other government agencies, and appropriate private sector partners to educate consumers and health care professionals on how to reduce the risk of obtaining counterfeited drugs before an event occurs. Helpful messages could include: (1) what is a counterfeit drug and why U.S. consumers and health care professionals should be vigilant, (2) the dangers of buying drugs over the Internet or from other unknown entities, (3) good purchasing practices that will decrease the chances of encountering counterfeits, and (4) legitimate ways to obtain drugs (e.g. federal or state purchasing programs, private sector purchasing programs for low income consumers);
18. Educate consumers and health care professionals on how to identify counterfeit drugs (including how to recognize anti-counterfeiting technologies on packages, labeling, and drug products themselves) and what to do when they believe they have identified a counterfeit product;

19. Assure flexibility as agency officials determine their outreach approach and create a set of pre-established consumer and professional outreach plans that can be utilized if deemed appropriate (based on risk analysis) after counterfeits are detected in the stream of commerce;

20. Provide outreach efforts appropriate for the diverse elements of the U.S. drug distribution system. We find that individual strategies for educating and increasing awareness should be considered for diverse stakeholders including: consumers, pharmacists, wholesalers, repackers, doctors, nurses, the media, and public health officials. These creative strategies could take the form of public service announcements, educational fliers and communication tools that can be distributed by pharmacists and PBMs, toll-free numbers on labels; permanent messaging on appropriate industry and private group websites to establish a permanent presence, as well as many other potential tools.

21. Explore ways of improving and coordinating agency and industry messages and efforts to address and contain a counterfeit event. Though a drug manufacturer is not responsible for the creation of a counterfeit of its products, ensuring health professionals are well informed about the event and protecting the public from it should be a shared public policy goal.

E. International Issues

The task heard that counterfeiting of drugs is commonplace in many countries. The global nature of counterfeiting suggests that American stakeholders should work with foreign stakeholders to better coordinate their anti-counterfeiting efforts. The following options, based on what we have heard to date, relate to these issues:

22. Strengthen international cooperation in law enforcement efforts, identification of counterfeit products, use of anti-counterfeiting technologies, and education of stakeholders and consumers;

23. Develop global standards for (a) the packaging of final dosage forms and API’s, (b) the use of tamper evident packaging, (c) product pedigrees, (d) the use of anti-counterfeiting measures, and (e) the use of track/trace technologies.
IV. Questions Related to the Potential Options for Improving Prescription Drug Security

A. Questions Concerning Technology (Options 1-9)

1. Discuss the advantages and disadvantages of unit of use packaging. Please provide any information on the economic impact of requiring unit of use packaging.

2. Should the European Union requirements be used as a model for unit of use packaging?

3. Discuss the advantages and disadvantages of using tamper evident packaging on drug products. Please provide any information on the economic impact of requiring tamper evident packaging features on these products.

4. What anti-counterfeiting technologies are currently being used? Are there any data on which technologies are successful?

5. What, if any, minimum number of anti-counterfeiting technologies should be utilized on packaging and labeling? Should technologies be utilized on all dosage forms (e.g., APIs, finished dosage forms) and products or just dosage forms and products at high risk of being counterfeited?

6. Should any specific anti-counterfeiting technologies be utilized? Should covert technologies always be utilized? Should overt technologies always be utilized?

7. Should some anti-counterfeiting technologies only be identifiable by the manufacturer and/or the FDA?

8. 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?

9. What role should the FDA play in reviewing the use of (i) anti-counterfeiting technologies incorporated into the packaging and labeling, (ii) taggants, markers, and other unique characteristics incorporated into the product itself, and (iii) track and trace technologies?
10. How should “validation” of an anti-counterfeiting measure or track and trace technology be determined? Should only “validated” anti-counterfeiting measures be used? Who should do the validation?

11. Should a database, as described in Technology Option 5 be created? If so, who should develop the database? Where should it be housed? Who should have access to the data? Who should be responsible for updating and maintaining it?

12. Discuss the advantages and disadvantages and the role of track and trace technologies, in particular bar codes and RFID.

13. What are the costs and challenges involved with setting up an infrastructure for utilizing various track and trace technologies?

14. 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 entity 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?

15. 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.

16. Discuss the logistic, economic, and public health effects of direct shipment of product to retailers and other end users.

17. For products that are shipped directly from manufacturers to retailers, would the use of track and trace technology on those products provide any additional benefits?

18. Should all products be considered at high risk of being counterfeited? How can products at high risk of being counterfeited be 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?
19. Discuss what could be included in an FDA guidance on the use of anti-counterfeiting technologies.

20. Should FDA conduct research on development or evaluation of anti-counterfeiting technologies? If so what should this research focus on? How should FDA integrate its research efforts with other public and private sector efforts?

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

B. Questions Concerning Regulatory Requirements and Secure Business Practices (Options 10-13)

1. 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.

2. Discuss the advantages and disadvantages of the new Florida and Nevada requirements for wholesale distributors, including the costs involved with compliance.

3. Discuss the advantages and disadvantages of requiring a pedigree if track and trace technology is also being utilized for a given product?

4. Identify areas where the NABP Model Rules for Licensure of Wholesale Distributors could be strengthened. Please give specific language for new provisions.

5. 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?

6. Discuss the advantages and disadvantages of increased penalties for counterfeiting drugs?

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

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

9. Comment on the advantages and disadvantages of manufacturers sharing market data with the FDA for use in identifying counterfeit products.
10. 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.

C. **Questions Concerning Rapid Alert and Response Systems (Options 14-16)**

1. What are the advantages and disadvantages of adapting the MedWatch system for use in disseminating information about counterfeit drugs?

2. What are the current capabilities of private communication systems or networks (e.g., association list-serves, websites) for handling information about counterfeit drugs in a timely manner?

3. What current electronic communication systems or networks are being used by the private sector to share information and can they be linked with MedWatch?

4. 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 less 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?

5. What are the costs associated with developing a new counterfeit alert network? What are the costs associated with adapting current systems or networks to be part of a counterfeit alert network? (In both cases, having the features listed in (d) above)

D. **Questions Concerning Education and Public Awareness (Options 17-21)**

1. How can FDA best assist in making sure the public knows what they need to know to help them avoid counterfeit drugs?

2. What role should the private sector, professional/trade associations and consumer representatives play in educating consumers and health professionals? Are there other groups that FDA should solicit for help?
3. How should FDA interact with various private sector and trade groups to educate consumers about the threats of counterfeits before they enter the stream of commerce?

4. What education and communication tools are available? Which will be the most effective and efficient for this effort?

5. Once a counterfeit drug is identified, what tools are available to the agency to notify potentially affected parties without inappropriately scaring other consumers from taking their medications?

6. How should these efforts be supported or funded? Is partnership with potentially affected parties appropriate?

7. Are there additional long term messages, in addition to those listed above, that the FDA should deliver to its targeted audiences? Similarly, are there additional messages that the FDA should deliver when a report of a counterfeit product is received by the agency?

E. Questions Concerning International Issues (Options 22-23)

1. What measures have foreign governments instituted (or are planning to institute) to address the problem of counterfeit drugs?

2. What global standards are needed to address the problem of counterfeit drugs? Who should develop these standards?

3. What processes will be effective in setting global standards?
V. Request for Comments

FDA seeks comment on issues related to the potential options presented here, as well as the specific questions posed above. Interested persons may submit to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Room 1061, Rockville, Maryland, 20852, written or electric comments by November 3, 2003. Electronic comments can be submitted to http://www.fda.gov/dockets/ecomments. Groups should submit two copies. Individuals may submit one copy. You should annotate and organize your comments to identify the specific options or questions to which they refer. To ensure timely handling, the outer envelope should clearly state the docket number, 2003N-0361.

REFERENCES

1. Profile of the Prescription Drug Wholesaling Industry. ERG. February 12, 2001


4. NABP Model Rules
## Appendix A: Table of Anti-Counterfeiting Measures

### SECURITY TECHNOLOGIES

<table>
<thead>
<tr>
<th>Features</th>
<th>Type</th>
<th>Description</th>
<th>Benefits</th>
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<td>Consumer authenticator</td>
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<td>overt</td>
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<tr>
<td></td>
<td>Fluorescence</td>
<td>covert</td>
<td>Carries fluorescent material</td>
</tr>
<tr>
<td>Optical Pigments &amp; Dyes</td>
<td></td>
<td><strong>Up Converters</strong></td>
<td>Material absorbs long wavelength radiation and re-emits at shorter wavelength, e.g., absorbs infrared radiation and re-emits as visible light or shorter wavelength infrared light</td>
</tr>
<tr>
<td></td>
<td>Down Converters</td>
<td>overt, covert</td>
<td>Material absorbs short wavelength radiation and re-emits at longer wavelength, e.g., absorbs ultraviolet radiation and re-emits as visible or infrared light</td>
</tr>
<tr>
<td>Features</td>
<td>Type</td>
<td>Description</td>
<td>Benefits</td>
</tr>
<tr>
<td>----------</td>
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<td>------------------------------------------------------------------------------</td>
<td>--------------------------------------------------------------------------</td>
</tr>
<tr>
<td><strong>Inks</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td><strong>Offset</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Color Gamut</td>
<td>overt</td>
<td>Printing with colors which cannot be reproduced by the four color process of current copiers and printers</td>
<td>Digital reprographic equipment not able to reproduce certain colors.</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Color Shifting</strong></td>
<td>overt</td>
<td>Color changes with viewing angle</td>
<td>Consumer authenticator, color shift hard to scan or simulate</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Thermochromic</td>
<td>overt</td>
<td>Color change with temperature</td>
<td>Consumer authenticator</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Photochromic</td>
<td>overt</td>
<td>Color shift with light</td>
<td>Consumer authenticator</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>General</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Forensic Tag</td>
<td>covert</td>
<td>Marker for forensic identification that provides a unique product source fingerprint, e.g., unique submicron security features on carrier particles or deuterated tracer materials</td>
<td>Authenticity test and tracking</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Intaglio</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Magnetics</td>
<td>covert, tactile</td>
<td>Magnetic properties</td>
<td>Machine readable</td>
</tr>
<tr>
<td>Infrared</td>
<td>covert, tactile</td>
<td>Infrared active</td>
<td>Machine readable</td>
</tr>
<tr>
<td>Features</td>
<td>Type</td>
<td>Description</td>
<td>Benefits</td>
</tr>
<tr>
<td>-----------------------</td>
<td>--------</td>
<td>-----------------------------------------------------------------------------</td>
<td>-----------------------------------------------</td>
</tr>
<tr>
<td>Other, Printed</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Digital Watermark</strong></td>
<td>overt, covert</td>
<td>A printed feature with embedded encrypted digital information that can only be read by software having the correct decryption key</td>
<td>Authenticator, machine readable</td>
</tr>
<tr>
<td><strong>Latent image</strong></td>
<td>overt</td>
<td>Variation in surface relief of an intaglio print resulting in an observable image at very low angles</td>
<td>Consumer verification; will not reproduce on copiers</td>
</tr>
<tr>
<td><strong>Moire Inducing Patterns</strong></td>
<td>overt</td>
<td>Printed patterns which cause frequency interference in low to medium resolution digital scans</td>
<td>Consumer authenticator, degrades imaging on copiers and low to medium resolution scanners/printers</td>
</tr>
<tr>
<td><strong>Lenticular/Scrambled Indicia</strong></td>
<td>overt</td>
<td>Printed, embedded image viewable with a special lens</td>
<td>Consumer authenticator, machine readable</td>
</tr>
</tbody>
</table>
SECURITY TECHNOLOGIES (cont.)

<table>
<thead>
<tr>
<th>Features</th>
<th>Type</th>
<th>Description</th>
<th>Benefits</th>
</tr>
</thead>
<tbody>
<tr>
<td>Other, Non-printed</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><em>Microperf</em></td>
<td>overt</td>
<td>Laser perforations in a grid pattern, acts as an optically variable device,</td>
<td>Consumer authenticator, cannot be scanned, difficult to reproduce</td>
</tr>
<tr>
<td></td>
<td></td>
<td>visible when viewed in transmitted light at 90° angle</td>
<td></td>
</tr>
<tr>
<td><em>Holograms</em></td>
<td>overt</td>
<td>3D-like images</td>
<td>Consumer authenticator, machine readable</td>
</tr>
<tr>
<td><em>Optically Variable Devices</em></td>
<td>overt</td>
<td>Devices that change optical character via viewing angle or stimulation</td>
<td>Consumer authenticator, machine readable</td>
</tr>
<tr>
<td><em>Radio Frequency Identification Devices</em></td>
<td>covert</td>
<td>Electronic device that transmits, via radio frequency over a limited distance, encrypted info when interrogated, info resides in the computer chip of the RFID tag</td>
<td>Machine readable, tracking</td>
</tr>
<tr>
<td>Passive</td>
<td>covert</td>
<td>No battery, power drawn from reader</td>
<td>Machine readable, short distance tracking</td>
</tr>
<tr>
<td>Semi-passive</td>
<td>covert</td>
<td>Battery powers chip, transmitting power drawn from reader</td>
<td>Machine readable</td>
</tr>
<tr>
<td>Active</td>
<td>covert</td>
<td>Self-contained battery for chip and RF transmissions</td>
<td>Machine readable</td>
</tr>
</tbody>
</table>
### SECURITY TECHNOLOGIES (cont.)

<table>
<thead>
<tr>
<th>Features</th>
<th>Type</th>
<th>Description</th>
<th>Benefits</th>
</tr>
</thead>
<tbody>
<tr>
<td>Other, Taggants</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Marker tags</td>
<td>overt, covert</td>
<td>Components which can be added to fibers, planchettes, inks, thread; and provide specific properties such as fluorescence</td>
<td>Authenticator possible, machine readable</td>
</tr>
<tr>
<td>Organic vapor</td>
<td>overt</td>
<td>Unique odor signature, e.g., perfume</td>
<td>Consumer authenticator, machine readable</td>
</tr>
<tr>
<td>Micro-barcode tag</td>
<td>covert, overt</td>
<td>Color layered barcode patterns on 20 - 600 micron size particles, which can hold information</td>
<td>Authenticator, tracking, machine readable</td>
</tr>
<tr>
<td>Organic tag</td>
<td>covert</td>
<td>Organic chemical markers, such as DNA, that can be detected by instrument or animals, e.g., quadrupole, ion mass spectrometry</td>
<td>Machine readable, tracking</td>
</tr>
<tr>
<td>Inorganic tag</td>
<td>covert</td>
<td>Inorganic chemical markers that can be detected by instruments, e.g., magnetometers, x-ray units, IR/UV/visible spectrophotometers</td>
<td>Machine readable</td>
</tr>
</tbody>
</table>
Attachment E
EPC Fact Sheet

What is the Electronic Product Code (EPC)?

The Auto-ID Center at MIT developed a technology called Electronic Product Code (EPC). The Electronic Product Code (EPC) is a unique number that identifies a specific item in the supply chain. The EPC is stored on a radio frequency identification (RFID) tag, (which combines a silicon chip and an antenna) and is applied to individual items. This allows for each individual item to be uniquely identified. Limiting the information on the tag helps keep the cost of the tag down. Additionally, the lower cost tag will be a passive tag. A passive RFID tag is a tag that has no power of it's own. It is activated and powered by passing in the proximity of a reader. The reader sends out electromagnetic waves for a limited distance to activate the tags. Once the EPC is retrieved from the tag, it can be associated with dynamic data such as from where an item originated or the date of its production. Much like a Global Trade Item Number (GTIN) or Vehicle Identification Number (VIN), the EPC is the key that unlocks the power of the information systems that are part of the EPC Network.

What is RFID?

RFID stands for radio frequency identification. It is a technology that has existed for decades. At a simple level, it is a technology that involves tags that emit radio signals and devices called readers that pick up the signal. RFID technology is a fundamental element of the EPC Network.

Why RFID?

RFID is a technology that uses radio waves to automatically identify items. RFID tags have been used for over 30 years in industry, but, traditionally, have been too expensive to use widely throughout the supply chain. The Auto-ID Center has worked with technology companies to create “cheap chip” RFID tags. The target price of the tags is $.05. The tags carry an electronic product code (EPC) that uniquely identifies a particular item. The EPC includes identification of the manufacturer, the product, and a unique serial number. For example, if EPC tags were placed on individual cans of soda in a case of 24 cans, each of the cans of soda would be uniquely identified. The system could tell one can from another by reading the EPC tag on the individual can.

What is the EPC Network?

The EPC Network is a set of technologies that enable immediate, automatic identification and sharing of information on items in the supply chain. In that way, the EPC Network will make organizations more effective by enabling true visibility of information about items in the supply chain.

How does the EPC Network function?

The EPC Network uses radio frequency identification (RFID) technology to enable true visibility of information about items in the supply chain. The network is comprised of five fundamental elements: the Electronic Product Code (EPC), the ID System (EPC Tags
and Readers), Object Name Service (ONS), Physical Markup Language (PML), and Savant.

Essentially, the EPC is a number designed to uniquely identify a specific item in the supply chain. The EPC number sits on a tag comprised of a silicon chip and an antenna, which is attached to an item. Using radio identification technology (RFID), a tag “communicates” its number to a reader.

The reader then passes the number to a computer or local application system, known as the Object Name Service (ONS). ONS tells the computer systems where to locate information on the network about the object carrying an EPC, such as when the item was produced.

Physical Markup Language (PML) is used as a common language in the EPC Network to define data on physical objects.

Savant is a software technology that acts as the central nervous system of the EPC Network. Savant manages and moves information in a way that does not overload existing corporate and public networks.

**How Does a Company Get Started in Implementing the EPC Network?**

Now is the time to begin preparing for this technology. Fundamentally, there are three steps to take:

1. Form an EPC team at a senior level.
2. Subscribe to EPCglobal and take advantage of the many valuable opportunities the EPC Network provides for trading partners to collaborate in new ways.
3. Begin sharing your implementation plans with trading partners so they can plan and adapt accordingly.

Companies that are interested in a subscription to EPCglobal should contact their national EAN Member Organization (see EAN International website for details: [www.ean-int.org](http://www.ean-int.org)). Prospective subscribers based in the U.S. should contact Brooke Peterson, director of business development, EPCglobal US, at: bpetersen@uc-council.org or visit the EPCglobal US website ([www.epcglobalus.org](http://www.epcglobalus.org)) where subscription applications are available.

**How is an EPC Manager Number Different From an EAN.UCC Company Prefix?**

The Electronic Product Code (EPC) is the next generation of product identification. Like the EAN.UCC GTIN, the EPC is divided into numbers that identify the manufacturer, product, version, and serial number. But, the EPC uses an extra set of digits, a serial number, to identify unique items. The EPC is the only information stored on the EPC tag. This keeps the cost of the tag down and provides flexibility, since an infinite amount of dynamic data can be associated with the serial number in the database.
**What is the Current Status of EPC?**

Although RFID has been around for decades, the electronic product code is a technology still in its infancy stage. The EPC revolution has been led by the consumer product goods (CPG) industry with the pharmaceutical industry becoming increasingly more involved. Several pharmaceutical manufacturers, distributors and chain pharmacies are currently involved in an industry-group to pilot the usage of EPC tags in the healthcare supply chain. (AccenturePharma Jumpstart Pilot). In addition, several pharmaceutical manufacturers are running pilots within their own distribution centers.

HDMA is actively working with all stakeholders to further the education and awareness of EPC in healthcare. We have hired AT Kearney to conduct a feasibility study on the cost/benefit of using EPC in healthcare and will be examining several products for identification. The products have been highly susceptible to counterfeiters and are either in a tablet or injectable formulation.

**What are the Expected Implementation Timeframes?**

Timeframes for implementation will depend on many factors such as executive level commitment, cost/benefit analyses, company and product attributes, etc. However, there have been several organizations and Associations who have set the bar high for a percentage of adoption by the industry.

- WalMart has mandated that EPC tags be used all C2 products (at the unit level) by March, 2004 and on the case level by 2005.
- DOD has mandated the use of EPC tags at the case/pallet level by 2005.
- HDMA has requested the use of EPC tags at the case/pallet level by 2005 and each level by 2007.

**What is EPCglobal?**

EPCglobal is a joint venture between EAN International and the Uniform Code Council (UCC). EPCglobal is a not-for-profit organization entrusted by industry to establish and support the EPC Network as the global standard for immediate, automatic, and accurate identification of any item in the supply chain of any company, in any industry, anywhere in the world. The objective is to drive global adoption of the EPC Network. The EPC Network was developed by the Auto-ID Center, an academic research project headquartered at the Massachusetts Institute of Technology (M.I.T.) with labs at five leading research universities around the globe.

**What are Some of the Benefits of the Technology**

The EPC Network will make organizations more effective by enabling true visibility of information about items in the supply chain. Having more accurate, immediate information about the location of items, the history of items, and the number of items in the supply chain will enable organizations to be more responsive to customers and consumer needs through more efficient, customer-driven operations.

In the pharmaceutical industry, benefits include:

- Inventory management (recalls/withdrawals, stock rotation, reduce shrinkage)
- Anti-counterfeiting strategies (track and trace capabilities)

**Will EPC Tags Replace Bar Codes?**

Bar coding is a line-of-sight technology, meaning that each individual item would have to be handled to scan serial numbers with a bar code reader. For example, in a shipment of 6 cases with 12 vials in each box, each vial would need to be read individually for the bar code scan before the shipment could be sent. This method is labor intensive and time consuming; in addition, there is potential for error in reading the same vial twice or missing a vial. EPC tags enable automatic, non-line-of-sight identification. With RFID, this process would occur as the cases, not the individual items, are moved passed the reader. This reduces the possibility of errors and the labor necessary to achieve the same results.

EPC is an exciting technology that represents a potential new standard to uniquely identify products. But, its implementation will evolve over time with applications driven by market and consumer demand. We will be living in a world where bar codes and EPC tags co-exist for quite some time to come.

**Is the EPC Network An Industry Standard, and When and How Will It Become an Industry Standard?**

It is the goal and mission of EPCglobal to establish and support the EPC Network as a new global standard for immediate, automatic identification of any item in the supply chain of any company, in any industry, anywhere in the world. EPCglobal will lead a neutral, user-driven, consensus-based process where every organization has the opportunity to contribute.

**Is the EPC Network Very Susceptible to Hacking and Other Security Breaches? What are you Doing to Ensure the Integrity of the Network?**

Security is an important part of the EPC Network. The EPC Network uses industry recognized best practices to protect its data. In addition, the EPC Network functions like a virtual private network or VPN. Data lives both behind a subscriber company's firewall and inside the data registry system at EPCglobal.

**What about Privacy Concerns?**

EPCglobal is strongly committed to protecting personal privacy. This is an issue the organization takes very seriously and, under the Auto-ID Center's leadership, have been proactively addressing since the earliest stages of the research effort to develop the EPC Network. This proactive effort has generated technical and policy solutions, including a set of guiding principles.
HDMA EPC

PROTECTING SAFETY AND IMPROVING EFFICIENCIES IN THE HEALTH CARE SUPPLY CHAIN -

USING ELECTRONIC PRODUCT CODES

A WHITE PAPER SUBMITTED BY

THE HEALTHCARE DISTRIBUTION MANAGEMENT ASSOCIATION'S (HDMA) COLLABORATIVE COMMERCE COMMITTEE

NOVEMBER 1, 2003

WRITTEN BY

HAMACHER RESOURCE GROUP
INTRODUCTION

The pace of commerce is not only accelerating, our world is becoming a smaller and more volatile place. Both factors exert pressure on the pharmaceutical supply chain to improve its security and its efficiency. Clearly, the business practices of the past few decades cannot cope with today's emerging concerns. Supply chain constituents are keenly aware of these changes, as are federal and state governments. While no one doubts the need to improve supply chain safety and efficiency, what is needed is a consensus on a single solution.

A true solution will improve safety and efficiency without overburdening any of our constituents. Although change usually expends both time and money, in this case, finding the right solution will streamline and improve practices and procedures, eliminating costs that have traditionally wasted human resources and time. In the end, those who bear the expense of investing in the solution should reap cost-saving benefits brought about by it.

We, the HDMA's Collaborative Commerce Committee, have been generally charged with exploring ideas that will streamline and improve collaborative commerce's best practices, processes, and technologies. More specifically, the committee is now focusing on ways to increase safety and efficiency at all levels within the supply chain and the arenas it serves. This white paper grows out of that charge. In the process of investigating solutions, we, the committee, considered these issues:

- Medication dispensing and administration errors
- Counterfeiting and product adulteration
- Legislative initiatives, such as the Georgia Returned Goods Act, importation/re-importation, and Florida pedigree
- The growing number of products with special handling or storage needs
- Product recalls
- Cost concerns
- Increasing the efficiencies within the supply chain
- A true solution must embrace an open-systems concept, giving members options that meet their needs while still fitting in an overall industry framework

Keeping in mind these criteria, the committee has worked in partnership with the Massachusetts Institute of Technology's Auto-ID Center. Founded in 1999, the Auto-ID Center is a unique partnership of almost 100 global companies and five of the world's leading research universities: the Massachusetts Institute of Technology in the US; the University of Cambridge in the UK; the University of Adelaide in Australia; Keio University in Japan; and the University of St. Gallen in Switzerland. This consortium is in charge of designing and researching a global infrastructure - a layer on top of the Internet, allowing products to be identified and tracked at any point along the supply chain.
RECOMMENDATION

Based on the committee's work with the Auto-ID Center since October 2002, we, the committee, have concluded that the combination of a Radio Frequency Identification (RFID) system and a unique numbering system that delivers mass serialization offers the power and practicality to meet the needs of the healthcare supply chain. This white paper explains the factors that led us to this conclusion.

The committee realizes that implementing a new technology within the supply chain will take time, and most likely, the technology will be introduced in phases. This paper addresses the advantages of a fully implemented Electronic Product Code (EPC) Network, with all parties in the chain reading and recording the information that the system delivers. While the committee understands that all of these benefits will not be attained immediately, the paper presents the capabilities of the mature technology - as it will ultimately operate. That time is not too distant. A case in point: it is being reported that Wal-Mart is already asking its top 100 suppliers for pallet and case identification by early 2005. Wal-Mart's mandate will hasten standards development, which may mean that unit identification may be only another year or two further away.

BACKGROUND

THE BAR CODE
Paving the way for more advanced technology

Twenty-five years ago, the creators of bar code technology envisioned that the bar code would evolve and eventually give way to a new standard. Two-and-a-half decades later, the needs of the supply chain have grown more complex, and the need for a new standard is very near on the horizon.

In this Information Age, the need for greater product detail, faster, easier "reads," and fewer errors are rendering bar code technology in all its forms inadequate in meeting the increasing demands of the 21st century. The symbologies that began as National Drug Code (NDC) numbers and evolved into Universal Product Codes (UPC) simply cannot store the amount of detail needed.

The supply chain needs a system that can identify individual product units. This is a critical need, the lynchpin solution that solves myriad safety and material management problems. For example -

- To be able to track and trace individual units enables the supply chain to react quickly and surely to avert threats to the nation’s drug supply.
- Identifying single units protects patient safety when routinely dispensing medications in pharmacies and hospitals.
- Item-level identification simplifies inventory management at all levels within the supply chain: from moving product through the chain, to more widespread efficiencies, such as expediting recalls, improving forecasting, reducing shrinkage, and simplifying contract administration to name a few.

Using traditional bar codes is not an efficient way to meet the need of single-unit identification. Traditional bar code technology is time-consuming and labor-intensive. In a shipment of 6 cases of 12 vials each, every vial must be scanned. Moreover, scanning item-by-item invites errors - vials can be missed or scanned twice. Lastly, the bar code is a line-of-sight technology, which means that the codes can be read only when the item is positioned toward the scanner and nothing hinders the scanner's view. Many of us have witnessed this drawback as a grocery checker repeatedly scans a bag of frozen food in which the wrinkled UPC code is further obliterated by a layer of frost. Repeated scannings often come to no avail, and the checker keys in the item. While Reduced Space Symbology (RSS) bar codes address the issue of holding more information in a smaller space, they still require line-of-sight and item-by-item scanning. Note: the UCC and EAN recommend that
companies currently considering Reduced Space Symbology should implement it now to gain the benefit for unit-dose packaging. As EPC is introduced, it will complement the symbologies currently in use, including UPC, RSS, and UCC/EAN-128.

Today's marketplace needs more. More information. Greater efficiency. More flexibility. Easier use. The modern pharmaceutical arena is looking for ways to develop "smart products" that will talk to us, giving us detailed product information. With such information, we can connect the entire supply chain - from manufacturer to consumer, and all of the links in between.

Massachusetts Institute of Technology's (MIT) Auto-ID Center has lead the effort to design a standardized system to identify products using RFID tags. The tags will be embedded into products so that the product can "talk" to tag readers that items encounter all along the supply route. Tags can be attached to pallets, cases, and individual units, enabling readers to "see" the contents of entire cases and pallets at a glance. Readers at all stages of the supply chain can obtain the information needed to check-in and ship products as they work their way toward the consumer.

AUTO-ID TECHNOLOGY DEFINED

Auto-ID technology (Automated Identification) is a general term that refers to any technology that helps tag readers identify objects. Often used in a process that automatically captures product data, Auto-ID technology identifies items, captures details about them, and transfers the data into a computer system. All is done automatically, without employees keying in the information. The goal of Auto-ID technology is to improve efficiency, reduce data entry errors, and relieve employees of tedious work, freeing them to work at higher levels to further the company's goals.

Some examples of Auto-ID technologies are bar codes, smart cards, voice recognition, optical character recognition, electromagnetic identification (EMID), and radio frequency identification (RFID).

ABOUT RFID TECHNOLOGY

RFID technology, a form of Auto-ID, identifies objects using radio waves. The RFID application best suited to the supply chain works by storing a serial number on a microchip smaller than a grain of sand. Embedded on this tiny chip is an Electronic Product Code, an EPC™. The code on the chip identifies the product in varying degrees of detail. An antenna is attached to the chip, and together, the chip and its antenna are called a transponder - in everyday lexicon, they're known as the tag.

The tag's antenna transmits the product identification information. The information is detected by a reader, which is also equipped with an antenna. Readers can be hand-held or installed in the environment, positioned on shelves, floors, or doors. The tag and the reader exchange radio waves, and the reader then transfers the item information to computers, using a language that computers "understand."

An item's EPC is different from all other identical stock-keeping units. The EPC is similar to an item's Social Security number. In a case of 24 bottles of PseudoRx, each has a different EPC, even though they may all be Pseudo-Rx, low-dose, 81 mg, 50-count.

An EPC tag contains four pieces of information:

1. Header: the EPC version number
2. EPC Manager: the manufacturer
3. Object Class: the type of product
4. Serial Number: a number unlike any other item number
Tags can be active or passive. Lower in cost, passive tags have no power - they are simply read, answering the call of the reader. Active tags are internally powered, they have memory, and their data can be modified. Tags enable an item to be identified, counted, and tracked by readers throughout the supply chain. Tags can be added to items, cases, and pallets, and each tag carries information that relates to its identity. Pallets carry larger tags that can be read from farther away and supply more information than case- and unit-level tags. Tags define product pedigree, relating items to cases and lot numbers, cases to pallets, and pallets to warehouses.

A word about performance: In a recent demonstration, a flatbed reader "read" EPC tags on rolls of film hanging from a rack. The reader "read" 200 tags per second with 100% accuracy. Hollister Inc. reports that using an RFID system has lowered distribution costs 6% and labor costs 9% at its Tennessee plant. Says Craig Hourigan, Manager of Supply-Chain Logistics for Hollister, "The system has increased the efficiency of every aspect of the material handling process by virtually eliminating manual data entry, [and] time spent looking for product .... Improvements in receiving, putaway, and replenishment have reduced shippable backlog by 40%".1

AN EPC APPLICATION

THE SYSTEM
Step-by-step: Let's follow a case of Acme's PseudoRx through the supply chain. (See Diagram #1). Keep in mind that this is an oversimplified explanation of the process used to illustrate a broad view of the system. In reality, the system will handle much more complex supply paths. Moreover, the illustration assumes that supply chain members have agreed to a level of visibility of the data.

A. The chemical plant places raw materials in drums, each uniquely numbered and tagged. B. The drums are shipped to Acme, the manufacturer, who then combines the raw materials to make PseudoRx. As the manufacturer fills bottles with PseudoRx, tags containing the manufacturer's pedigree are affixed to the bottles. C. The bottles are then staged to ship to the wholesaler.

The wholesaler receives the order, breaks up the quantities of PseudoRx to fill retail orders, and begins to distribute PseudoRx to various retailers. D. These retailers can track the movement of the product from its inception to the moment it arrives in the store. When PseudoRx is purchased and leaves the shelf, the technology will tell the retailer this, too.

Now let's examine how the technology works.

The case of PseudoRx gets loaded onto a pallet in the manufacturing plant. As the pallet moves out of the loading dock, a reader positioned atop the loading dock door activates the smart tags on the bottles, one at a time, by bouncing radio waves on the EPC tags.

The reader sends the information to a computer system that runs a software program, called Savant. The Savant system counts and identifies the bottles of PseudoRx that are going out the door in this shipment, acting as a clearinghouse that translates data and hands it over to the Object Naming Service (ONS).

The ONS server matches the EPC number on the tag to an "address" on the Internet where information about a product is stored. The address maintains extensive information about the item. While the EPC tag itself acts only as a "license plate," the serial number on the tag unlocks an infinite amount of data stored at the item's Internet address. This data can be read by Savant systems with appropriate access around the world.

1 Global Logistics & Supply Chain Strategies, November 2002.
Because the ONS system can identify the reader that introduced the item into the system, the ONS knows which plant manufactured the PseudoRx. In the event of defect or tampering, this information could track and trace the item and easily recall specific bottles.

The ONS system then uses a language based on XML, (eXtensible Markup Language), called PML (Physical Markup Language). PML stores comprehensive data about the item - and does even more. PML enables computers to gather information and act on it. To clarify the point: a PML file will include the basics - product's name and its broad product category, when and where the product was made, its expiration date, its current location, and its temperature (if relevant). The PML file could also contain instructions for shipping the pallet to its destination, or instructions for a point-of-sale display to lower the price of an item as it nears its expiration date, or instruction for use. See diagram, Appendix A, for more about how the system works.

Industry has used RFID systems since World War II. Today, RFID systems authenticate a variety of products: bank cards, consumer goods, biometric devices, hospital patients, medical devices, and anti-theft devices. However, until now, the technology's expense has made it impractical for many commercial uses. What was needed was a "cheap chip." Such a chip has been developed: it is economical enough to be widely accepted. The prediction is that chips will cost less than 5¢, and readers will cost under $200. Procter & Gamble's CIO, Stephen David, made the point at InformationWeek's 2003 spring conference: it's a small price for a manufacturer to pay to protect a $10,000 bottle of 1,000 pills.

INVESTMENT EFFICIENCY

As with any business investment, the amount of money saved or earned must at least equal that of the amount spent. A November 2002 AMR Research study found that increased inventory visibility reduced supply costs 3-5% and improved revenues 2-7%. The savings grew out of improving the accuracy of shipments, lowering inventory carrying costs, and reducing shrinkage.

In early February of 2003, the Auto-ID Center released five new studies detailing business cases for implementing Electronic Product Code technology. One of the reports suggests that a company could save 35% in labor costs alone - RFID's ability to prevent theft and administrative error should add even more. Details on the reports can be found at www.epcglobalinc.org.

BENEFITS

The benefits of an RFID/EPC system are numerous, and they reward government, manufacturers, wholesalers, and pharmacies alike. In many instances, a single benefit applies to more than one constituent. This list of benefits is organized by the audiences.

BENEFITS TO ALL PARTICIPANTS IN THE SUPPLY CHAIN

Protecting Patient Safety: counterfeit and adulterated drugs

A fake meningitis vaccine is thought to have caused an estimated 3,000 deaths in Niger in 1996. In Florida, pharmacists found white pills thought to be aspirin in bottles labeled Zyprexa®, a schizophrenia medication. The case is not an isolated
At first glance, preventing fraudulent or adulterated drugs seems to fall more squarely within the category of government benefits. However, manufacturers are intimately associated with their brand. Even when brands are counterfeited, adulterated, or tampered with, the pharmacy, wholesaler, and manufacturer suffer the ill effects - enduring the press coverage and seeing their name repeatedly associated with the criminal action. Such press coverage erodes consumer confidence in the brand. It is a public relations debacle that is best avoided at all levels.

Incident. Ten types of counterfeit drugs have appeared in that state in the past two years. In addition to counterfeit drugs, diluted drugs are making their way into the marketplace. Florida investigators seized vials of Procrit® and Epogen® that contained only one-twentieth of the active ingredient on the label. In South Florida alone, $20 million in adulterated pharmaceuticals were seized last year.

According to the WHO (World Health Organization), counterfeit drugs account for more than 7% of global pharmaceuticals, a percentage that translates into an estimated $2 billion in lost sales for pharmaceutical companies. This number is lower than might be expected, considering that many developing countries have counterfeit rates as high as 40%. The global number is low because the dominant volume of drugs is consumed in the U.S., currently the safest market in the world. The safety of the U.S. offsets the high counterfeit rates elsewhere in the world.

However, as drugs grow more expensive, the allure of counterfeiting will grow stronger, threatening the nation's low numbers. As noted elsewhere in this paper, the number of counterfeit drugs in the U.S. has already increased in 2003. Some analysts speculate that organized crime and illicit drug dealers are entering the counterfeit prescription business in this country, and it stands to reason that they will focus their efforts on the home front, the world's most profitable pharmaceutical market. More organized counterfeiters in the U.S. will only enlarge the scale and increase the capabilities of the counterfeit prescription enterprise. We must take steps to strengthen our security to keep our numbers low.

Another danger that looms on the horizon is the threat of terrorist tampering. Whether this threat is real or imagined, there are consumers who worry about malice spurring counterfeiting/tampering activities. The national news recently reported that terrorist organizations have cited corrupting the nation's prescription drug supply as part of their overall plan of attack.

Many of the current drug imitations already appear so authentic that pharmacists find it difficult to distinguish the fakes from the genuine medications. As the price of new drugs escalates, producing cheap imitations promises lucrative rewards. The perpetrators of these crimes are producing sophisticated labels that credibly mask fraudulent pharmaceuticals. Adding to the problem is the circuitous, often byzantine, paths that drugs legitimately take in moving from one wholesaler to another, creating a secondary market. Further, drugs sold to physicians, alternate care facilities, and hospitals are sometimes illegally bought back - sold to unethical distributors at a discount - creating a black market. Such activity provides a perfect cover for imposters to enter and circulate in the marketplace.

The situation is alarming, and any breach of security within the drug system in America calls urgently for resolution. Indeed, the presence of counterfeit drugs within a fully implemented RFID network would virtually set off an alarm because of the way the system works. Two features discourage intruders. First, an EPC tag gives an authentic drug a singular identity within an RFID network. To create a counterfeit drug, perpetrators would have to create an identical EPC tag. A duplicate tag would immediately call attention to itself within the system. A second feature, tracing, follows a drug's movement from manufacturer to distributor to retailer/hospital, establishing a pedigree. Once again, the impostor drug would be instantly recognized as counterfeit because the duplicate drug would appear in an incorrect location within the system. An RFID/EPC system could have avoided the problems Florida experienced by keeping the pedigree of prescriptions clear.

* Julie Appleby, USA Today, May 15, 2003, p. 1A.
The Importance of Public Perception

Americans are skittish in this post-9/11 era. They are more fearful of villai ny that can occur from both inside and outside the nation. They want assurances that they are being protected. If the health care/pharmaceutical supply chain network fails to provide that protection, such inaction will garner ill will, damaging reputations of individual entities within the industry and the industry as a whole. This year, the public has witnessed a recall of more than 100,000 counterfeit bottles of Lipitor® as well as an attempt to sell batches of bacteria-tainted water masquerading as Procrit®.

USA Today reports a four-fold increase in counterfeit-drug cases in 2003. As the counterfeit drug industry becomes ever more lucrative - and it will, with genome-based pharmaceuticals entering the market - bogus and adulterated drugs will become a greater threat. To stymie these fraudulent activities and prevent medical tragedies attributed to human error, the supply chain constituents must stay alert to emerging technologies. When viable solutions present themselves, the healthcare supply chain is obliged to act in an ethical, responsible, effective, and responsive manner. The RFID/EPC system's ability to track and trace will go far toward providing the desired security.

Simplifying Product Recalls

Product recalls are particularly labor intensive and expensive. To retrieve a small percentage of tainted or defective products, all units must be recalled, a process that affects many parties within the supply chain. Staff must spend time searching for lot numbers that often were never received or have been long since gone. As a result, the entire supply chain faces increased pressure to wring out yet additional cost savings to compensate for the cost of the recall.

Because an RFID/EPC system can identify specific units and their whereabouts, the system can distinguish safe from unsafe units during a recall, retrieving only the affected units - thereby saving the supply chain time, effort, and enormous amounts of money. Currently, the practice is to return more items than actually necessary to eliminate any possibility of error.

Tracking Inventories

Accurate and constant monitoring at item level reduces errors - malicious and non-malicious - throughout the inventory supply chain process. To be able to immediately "read" a pallet's contents without opening cases is a major advance in inventory efficiency. So is being able to turn on shelf readers and instantly know how much product is on-hand. Such practices reduce cost and labor for all constituents in the supply chain.

BENEFITS TO GOVERNMENT

Reducing Recycling Costs

The biggest cost of recycling is dealing with identifying and sorting plastic containers according to materials and color. RFID/EPC systems can read loads at a glance.

Tracking Imported and Re-imported Drugs

Counterfeit or adulterated product can enter the system through foreign channels, increasing the demands on the US Customs Service, the DEA, and the FDA at a time when these agencies are also focusing their efforts on matters of homeland security. An RFID/EPC system provides a way to authenticate questionable drugs and free agencies to tend to other matters.

BENEFITS TO MANUFACTURERS, WHOLESALERS, AND PROVIDERS

Effective Inventory Management

Knowledge is power. When participants within the supply chain can see that goods
are available and know where they are within the supply chain, parties all along the supply chain can reduce their inventories, without risking sales.

Smart shelves with RFID/EPC readers will "know" how many units are on the shelves. When the number drops to a trigger point, the system alerts staff to replenish the shelf. At the retail level, replenishment can mean either retrieving additional stock from the storeroom or ordering more product. When the stockroom's stock levels fall below a certain point, the system can signal that it's time to contact the distributor or manufacturer.

**Keeping Stock Visible - Even When it's in the Wrong Place**
As frustrating as out of stocks are, it is even more frustrating to have the goods on-hand, but miss a sale because goods were misplaced and no one knew more stock was available. An RFID/EPC system always knows where goods are, even when they are stored in unconventional places or stored in error.

**Improving Flexibility in Storage**
Because an RFID/EPC system can always "find" the location of a product, goods can be stored anywhere on the premises. Overflow stock can be located in several places without getting lost or overlooked. Orders can be fragmented - shelved most efficiently without regard to losing track of the goods.

**Reducing Shrinkage**
Each year, the University of Florida conducts a National Retail Security Survey. The survey reveals that nearly 2% of the nation's sales are lost to shrinkage. RFID/EPC can reduce the incidence of shrinkage on all levels by providing real-time inventory visibility.

Manufacturers and Wholesalers. Processing and administrative errors account for approximately 78% of manufacturer shrink losses. An RFID/EPC system can monitor shrinkage accurately and instantly, correcting process errors at the point of occurrence. By matching EPCs arriving or leaving with the scheduled deliveries or shipments, real-time tracking recognizes inaccurate inventory audits and on-hand adjustments. It verifies internal and external department transfers, and it identifies delivery errors. All are ways to substantially reduce cost.

Pharmacies. By individually tagging all products, RFID readers can identify items as "purchased" or "not purchased," thereby reducing internal and vendor theft. Since product delivery quantities can be instantly read and verified, RFID/EPC systems also reduce supplier fraud, such as phantom deliveries, invoice errors, and over/under delivery. Lastly, non-malicious "paper shrink" such as pricing errors, scanning errors, and incorrect physical inventory can be automatically detected and corrected.

Moreover, if we broaden the scope of RFID/EPC systems, as seems natural, to include merchandise in the front-end of pharmacies, the technology would be particularly valuable in quashing shoplifting. Shelf readers can call attention to suspicious shopping behavior that takes place on department shelves. By alerting staff to the removal of multiple units of product, the system can avert the theft.

**Managing Stock About to Expire**
Many providers, wary of dispensing medications that are approaching their expiration date, "hold" these items rather than release them to retail outlets or patients. Storing these medications ties up millions of dollars in unproductive inventory. The items cannot be returned until they expire, and huge numbers of medications sit in warehouses, sometimes for as long as a year, depending on the policy of the organization.

To carry out these safety policies, today's providers check expiration dates manually, bottle-by-bottle, rather than risk releasing expired or nearly expired medication to a
patient. RFID systems, with their track-and-trace capabilities can automate this process, keeping medications "active" longer. Distributors who feel more confident about reducing the possibility of human error may be inclined to loosen their "holding" policies, shortening the time these medications are stored.

Managing Returns
Like shrinkage, accepting returns is another example of the costly price of doing business. RFID technology eliminates the expense of fraudulent returns because the returned item's EPC tag will confirm or deny its pedigree with unerring accuracy. In addition, RFID/EPC systems can track legitimate returns, thereby reducing unrecorded returns or preventing inaccurate calculations. The returns will automatically be entered into the system as debits and credits.

ADDITIONAL BENEFITS TO MANUFACTURERS
Supporting Valid Results in Drug Research
The potential uses of RFID/EPC to ensure patient safety extend far beyond false pedigrees. For example, a similar system in packaging can be used to track compliance in clinical drug trials. A Swedish company has developed blister packaging that uses conductive inks to print circuits on the plastic bubbles that hold pills. As a patient breaks open each bubble within the blister pack, the package records the date and time, creating a record of drug usage. Additionally, a keypad could be used to record how patients feel after they take the pills. Electronic patient diaries could become key components in the clinical trial process. "Smart" packages hold all of this information until they are returned to a doctor's office where the data is downloaded to a PC using a tag reader.

Reducing the Cost of Anti-theft Packaging
The theft-prevention features of an RFID/EPC system would remove the need for manufacturers to protect small, high-ticket items by packaging them in expensive bubble clamshells.

Other Uses
- Prescription vials that report non-compliance when patients forget or refuse to take their medication.
- Prescription vials that remind patients to refill a prescription when the contents get low.
- Smart packages can "sense" the degradation of a medication. The potential for this technology is far-reaching.

ADDITIONAL BENEFITS TO THE PROVIDERS
Intelligence About Merchandising
Behind the pharmacy counter, an RFID/EPC system could track the whereabouts of medications that are stocked or restocked in an incorrect location. The technology will prevent a common problem in pharmacies: false out of stocks. Pharmacies often needlessly reorder product when a bottle is on hand but has been misplaced.

If the technology extends itself to the front-end of the pharmacy, shelf readers will record not only when products are removed from shelves, but also when they are picked up and put back, providing a record of customer behavior on a shelf-by-shelf basis. Smart Shelves can help retailers identify peak purchasing hours and patterns. Shelf readers can track shopper response to promotions, recording unit movement that can be variously organized by product, store, region, or chain. Such intelligence helps match forecasts to demand and helps tailor future promotions to specific market segments.

More Efficient Use of Pharmacists' Time
The theft-prevention features of an RFID/EPC system enable retailers to move small high-ticket OTC items from behind pharmacy counters so that consumers can serve
themselves. Many pharmacists currently secure these items behind the counter to thwart theft. However, when customers want to look at these products, the pharmacy staff must bring the products out, not a productive use of their time.

More Accurate Dispensing
RFID has the potential to eliminate prescription errors and their attendant costs. Automatically reading the EPC on the medication bottle assures that the correct product is being dispensed.

RISKS OF NON-ADOPTION

Given the recent Lipitor and Procrit recalls, virtually everyone connected with the healthcare industry understands that the supply chain needs a system that is as secure, intelligent, efficient, and responsive as possible.

Furthermore, if we as an industry do not recommend a practical efficient system, others who know less about our industry may impose a more cumbersome, less workable system on us. Although Florida's recently amended wholesaler licensure law contains a "pedigree paper" definition and a provision that appears to require a paper pedigree in 2006, the legislature and Department of Health are open to a technological solution. Numerous discussions took place with the department and legislators by HDMA and its Florida distributor members in crafting the law that was enacted. Because the department advocated for full pedigree on all products, a separate section of the bill was drafted broadly with the intention to allow for a technological solution and to meet the department's position on the issue. This section does not specifically recommend what the technological solution should be, but instead was left open and limited to say that effective July 1, 2006, distributors would be required to pass pedigree, tracing back to the manufacturer, on all prescription drug products they sell to other distributors and retail pharmacies. Though the department wanted this requirement to become effective a year earlier, it acquiesced to the distribution industry to allow time to develop and implement a technological solution.

VIABILITY QUESTIONS

IS THIS TECHNOLOGY REAL AND ATTAINABLE?

Wal-Mart is mandating RFID/EPC capability from its suppliers by 2005. A conservative company, cautious about its technology investments, Wal-Mart has always focused on cutting costs as a way to lower prices, thereby increasing sales.

Several companies have already piloted RFID/EPC systems: Coca-Cola, Gillette, Johnson & Johnson, Kraft, Procter & Gamble, Sun Microsystems, Unilever, and Wal-Mart. Tagged cases were shipped to and from selected distribution centers and retail stores in more than eight states. In one test, Procter & Gamble saw RFID-enabled product inventories automatically replenish the supply when inventory was running low.

Hollister Inc. in Tennessee has used an RFID network with quantifiable success. (See page 3.) Proctor & Gamble's CIO, Stephen David is quoted as saying that RFID is a matter of economics and competitive advantage. Mr. David feels that a great benefit of RFID lies not just in the selling of retailers products, but providing them with the intelligence that the product will make possible.

Several companies have created radio frequency ID patient wristbands with an ultra-thin RFID tag embedded in them. Some companies are in the process of
developing low-cost RFID tags that track medical and surgical instruments such as scalpels, forceps, and so forth. Scanners in surgical suites will monitor patients before surgeries are completed to detect tags on any misplaced instruments that may still reside in patients. From hearing aids to medical records to glucose readers, RFID is already providing efficiencies and safety within the healthcare arena.

**BARRIERS TO ENTRY - Why hasn’t the technology been implemented yet?**

1. Standards creation. The move by UCC and EAN to take over EPC Network is a giant step forward. UCC and EAN are well known, accepted standard-setting organizations whose association with the technology will validate it. In addition, at the EPC Symposium held in Chicago, September 15-17, 2003, EPCglobal announced the release of Version 1.0 of the EPC Network.

2. Data ownership and sharing issues. EPC will succeed only if issues surrounding the data are resolved. Without visible data, the true value of EPC’s benefits described in this paper will never be realized. The Collaborative Commerce Committee will deal with this issue aggressively and propose recommendations. Rules for data sharing will need to be developed among industry and across the supply chain to ensure access to the data.

3. Lack of detailed cost analysis. Companies are having difficulty evaluating the cost/benefit analysis for EPC adoption. To help companies estimate expenses and evaluate benefits, EPCglobal at www.epcglobalinc.org has added a calculator to its web site. In addition, HDMA’s Healthcare Foundation will be conducting a study in the pharmaceutical industry to truly evaluate this area.

4. Technology considerations. These issues are considered temporary obstacles that can be rectified.

   - Because RFID/EPC technology will track individual SKUs, some analysts speculate that the amount of data to be managed could increase significantly. A case in point: instead of scanning and tracking a single case of product made up of 24 units, the new technology would allow for tracking all 24 items when necessary. The question has arisen, *Do we have systems large enough to handle all the data?* Technologists and vendors are rapidly addressing these issues as of the writing of this paper.

   - There are issues in achieving a 100% read rate. Companies will need to determine the electromagnetic properties of products, packaging, and pallet configurations. Properties of certain packaging (e.g., fluids in vials) as well as properties of the product itself may hinder reading.

5. Role of bar code technologies in an EPC environment. Currently available bar code formats, such as RSS, will continue to have applicability in an EPC environment. RSS and other similar formats have an advantage: they can be applied to smaller package labels, such as unit dose tablets and capsules. For the near future, RFID/EPC tags may be too large to attach to individual unit doses within a box of 100 tablets. In addition, the technology to read the RFID tag on individual packages may not be readily available in a hospital of 500 beds, for example, which would likely require a minimum of several hundred readers to provide bedside medication identification. In addition, some details require further exploration: such as the potential incompatibility with existing RF and other such networks used in clinical monitoring and IS systems.
THE NEXT STEP
The clock is ticking - not only to comply with the FDA mandate but also to expedite a much-needed solution to safety and efficiency. RFID provides a viable solution. The Collaborative Commerce Committee invites interested volunteers, primarily manufacturers and wholesalers, to step forward to help refine and develop the new supply chain protocols. Collaboration is needed from all sectors of the supply chain to succeed and to move the process along.

Taking action. The effort will also need preparation within the supply chain constituencies. We hope that senior executives will encourage staff at all levels to begin to educate themselves about RFID/EPC technology and its implications for their organizations. Transitions never happen overnight. The process begins with preparation at all levels: committees of managers, IT technicians researching the topic, warehouse and loading dock supervisors thinking about how new systems may affect their current procedures and processes.

Further study. The committee needs volunteers who would form a commission to study pilots in more detail. In addition, we would like to engage a pharmacy school to collect pilot data and validate the results. On another front, further government regulations, both state and federal, need to be monitored. As the need arises, RFID/EPC proponents will be needed to speak to government representatives, presenting the case for this technology in a considered and cautious manner.

To pro-actively pursue ways to protect the nation's drug supply - and in so doing, ultimately protect the nation's patients - is the message that Americans want to hear. It is a message that must be supported by action that is genuine and practical. Improving the control of items in the health care supply chain is more than a response to a government mandate. It is an opportunity to make a statement about our industry, its vigilance, its responsiveness to the need for change, and its determination to accept only the "right" solution.

HDMA is working collaboratively with EPCglobal and Auto-ID Labs to further the education, adoption, and implementation of electronic product codes in healthcare distribution.
ACKNOWLEDGEMENTS

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AN ACCOUNTABLE SUPPLY CHAIN: PHARMACEUTICAL PEDIGREE

The pharmaceutical supply chain is now a complex one. Not knowing the process by which pharmaceuticals make their way into pharmacies should not be an acceptable risk for patients. Auto-ID technology helps manage this risk and maintain product traceability by tagging pharmaceuticals and product packaging with radio frequency identification (RFID) tags or other unique identifiers. This allows pharmaceutical companies to track and trace their products, ensuring that each step in the supply chain is accounted for. Here's how it works:

1. FROM THE CHEMICAL PLANTS

Chemical plants create raw materials and place them into drums. Each drum is uniquely identified and tagged with RFID tags so the EPC™ Network can track them to the manufacturer. From this point on, the history of all raw materials is recorded in the EPC™ Network.

2. TO THE MANUFACTURERS

Raw materials are tracked and shipped from the chemical plant to the manufacturer. The manufacturer takes the tagged drums and combines raw materials to make pharmaceuticals, e.g., pills and liquids. Next, the pills or liquids are placed into tamper proof bottles and tagged with RFID tags. The EPC™ Network can easily account for the raw materials that go into each bottle. The tagged bottles are then shipped to wholesalers.

3. TO THE WHOLESALERS

Each bottle is tracked to the wholesaler, Product safety requires detailed records and an audit trail. The EPC™ Network provides information about each container at every stage. In case of product recalls, the information can be used to quickly and accurately identify affected bottles.

4. TO THE RETAIL PHARMACY

Pharmaceuticals are tracked into and out of the pharmacy. Auto-ID technology tells the pharmacist which pharmaceuticals have been sold and when. Bottles tagged with RFID tags hold each party in the pharmaceutical supply chain accountable for their actions, ensuring the safety of each product.

THE EPC™ NETWORK: HOW DOES IT WORK?

With the new EPC™ network, manufacturers, distributors, and retailers will be able to track and trace items automatically throughout the supply chain. Here's how it works:

- **THE RFID TAG**: An electronic product code (EPC) is embedded into the product container. The manufacturer tags the container and places it in the supply chain. Bar code scanners and RFID readers can read the product as it moves through the supply chain.
- **THE READERS**: RFID readers and scanners are used to read and identify EPCs in a supply chain environment. These devices can read and record data from EPCs.
- **THE RFID SYSTEM**: The RFID system consists of readers, scanners, and databases that can capture and store data.
- **THE PHARMACY**: The pharmacy is the final link in the supply chain. The pharmacist can use the EPC™ Network to track and trace pharmaceuticals, ensuring the safety and quality of the medication.
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APPENDIX C:
Glossary

CIO: Chief Information Officer
DEA: Drug Enforcement Agency
EAN: European Article Numbering
EDI: Electronic Data Interchange
EMID: Electromagnetic Identification
EPC: Electronic Product Code
FDA: (U.S.) Food and Drug Administration
HDMA: Healthcare Distribution Management Association
MIT: Massachusetts Institute of Technology
NDC: National Drug Code
ONS: Object Naming Service
PML: Physical Markup Language
RFID: Radio Frequency IDentification
RSS: Reduced Space Symbology
UPC: Universal Product Code
WHO: World Health Organization
XML: eXtensible Markup Language
January 12, 2004

Patricia F. Harris
Executive Officer
California Board of Pharmacy
400 R Street, Suite 4070.
Sacramento, CA 95814

Re: Enforcement Committee Draft Revisions to Wholesaler Statutes

Dear Ms. Harris:

On behalf of the Healthcare Distribution Management Association (HDMA) and its California pharmaceutical wholesaler members, we are writing to express our concern with the Enforcement Committee's Draft Revisions to the California Wholesaler Statutes. We appreciate the opportunity to comment on these proposed revisions.

HDMA's membership is comprised of full-service wholesalers and specialty distributors that deliver healthcare products and services nationwide. Fifteen (15) member companies are located in the State of California, employing approximately 3,000 California residents.

Our membership is most concerned with the significant changes the Enforcement Committee is recommending regarding paper pedigree, closed door pharmacy ownership, and the bond requirement. We have addressed these concerns, as well as those pertaining to the other sections affecting HDMA members, and offer our suggestions below. Where HDMA proposes alternative or additional revisions to the Committee's proposal, we have included our suggested changes in bold, underlined text. Specifically, our comments support the following:

- Electronic pedigree and track and trace technology over paper pedigree;
- A requirement for only one "non-resident exemptee-in-charge" per company;
- Allowing exceptions or substitutes to the $100,000 bond requirement;
- Further discussion with the Board regarding the closed door pharmacy issue; and
- Implementing stronger penalties for those who are "knowingly and willfully" involved in counterfeiting or trafficking counterfeit drugs or related fraudulent acts.
Pedigree (§ 4034)

The Enforcement Committee’s proposal includes a new definition of pedigree requirement for “dangerous drugs” and “dangerous devices” in California, effective January 2006, for all prescription drug wholesalers. As currently proposed, section 4034 defines pedigree as a document that records each distribution of a drug back to its manufacturer and includes specific identifying information about the drug it represents.

First, HDMA suggests that the proposed section be amended by deleting any reference to “devices.” The expansion of pedigree requirements to include devices far exceeds HDMA’s understanding of the Prescription Drug Marketing Act (PDMA). More importantly, we believe that before such a requirement is imposed on the medical device industry, the Board should, at a minimum, consult with that industry’s representative bodies such as the Health Industry Distributors Association (HIDA) or the Advanced Medical Technology Association (AdvaMed) to ensure that pedigree requirements would not make the availability of such products cost prohibitive.

While HDMA supports the concept of tracing a drug’s migration path from manufacturer to end-user/retailer in order to help combat counterfeiting and diversion, HDMA does not believe that paper pedigree is the answer. Paper pedigrees have proven not to be a very effective deterrent against counterfeiting. In fact, many counterfeit drugs have been discovered to have had a fraudulent pedigree associated with them. Paper pedigree is a dated, inefficient, and ineffective way to stem counterfeiting. Therefore, HDMA strongly recommends that efforts be focused on modernizing the pedigree system to build on the rapidly developing capabilities of track and trace technology rather than increasing reliance on paper.

To that end, we suggest that section 4034 be broadened to accommodate the future use of track and trace technology when it becomes available to the pharmaceutical industry. We propose that the pedigree definition be amended as follows:

4034. “Pedigree” means a document containing information that records each distribution of any given dangerous drug or dangerous device, from sale by a manufacturer, through acquisition and sale by any wholesaler, until final sale to a pharmacy or other person administering or dispensing the drug. In lieu of a paper document, pedigree may include electronic transmission technologies.

Furthermore, should the Board move forward with the Enforcement Committee’s proposal, HDMA urges the Board to amend section 4163, which sets the pedigree effective date as January 1, 2006. Through HDMA’s efforts, it is hoped that in the near future the same information previously transmitted on paper will be available electronically with a unique identification number that will immediately reveal if the product or the number has been tampered with. While we cannot predict a date certain
for the availability of such technology, HDMA proposes that the proposed effective date for a new pedigree requirement be extended. It is HDMA’s position that pharmaceutical manufacturers and wholesalers should target utilization of electronic product code (EPC) technology at the caseload level by the end of 2005 and work towards a goal for deployment at the selling unit level by 2007. It is recommended that wholesale distributors concurrently develop the appropriate infrastructure for tracking and tracing products using EPC technology. However, please note that these are target dates; it is the pharmaceutical companies (not distributors) that must actually apply the technology to the drugs at the manufacturing site to ensure compliance with FDA’s stringent packaging and labeling regulations.

**Non-resident wholesalers (§ 4161)**

The current proposal includes new licensure requirements for non-resident (out-of-state) wholesalers. Specifically, the Enforcement Committee is recommending the addition of an “exemptee-in-charge” designation for each non-resident company. HDMA and its members support the concept of each wholesaler having one individual, or “exemptee”, under the definition of section 4053, who is responsible for compliance with all federal and state laws. However, we do not believe that it is necessary for each non-resident facility to have a designated “exemptee-in charge.” Rather, it is HDMA’s position that this function could be carried out by one corporate-level employee, officer, outside counsel, or consulting specialist with responsibility for multiple locations.

In the alternative, HDMA suggests that the Board delete its proposed subsections (j) and (k) regarding the exemptee-in-charge requirement for non-resident licensees and create a new subsection (j) defining a “non-resident exemptee-in-charge” as follows:

(j) “Non-resident exemptee-in-charge” is an individual who meets the requirements of section 4053 with the exception of the requirement that each licensee designate one individual per facility. Non-resident wholesalers may designate one individual as a non-resident exemptee-in-charge who is responsible for the company’s compliance with applicable California and federal laws. The non-resident exemptee-in-charge shall be employed at a location that is up to the discretion of the wholesaler. The individual may have responsibility for multiple locations and may be a corporate employee or officer, outside counsel, or consulting specialist with the authority to help ensure compliance.

**Bond requirement (§ 4160)**

The Enforcement Committee is proposing to require a $100,000 bond for each wholesaler applicant. Each location would be required to have a separate bond (e.g., coverage
required is not $100,000 per company but rather $100,000 in coverage per location). HDMA recommends that the requirement be changed to require only one “surety bond” per company, regardless of the number of locations owned by the licensee. Also, a clarification by the Board needs to be made as to whether it intends this to be a “bond” or a “surety bond.” We recommend that the Board change this requirement to mean “surety bond.” A “surety bond” would be secured by the licensee through a third party but would not require the full $100,000 to be paid up front.

In addition, HDMA suggests that the Board consider alternatives to the bond requirement. For example, if a wholesaler has adequate coverage such as liability insurance, an irrevocable letter of credit, or funds deposited in a trust account or financial institution, it should not be required to obtain a surety bond. Further, if a wholesaler has already obtained a surety bond of an adequate amount for the purpose of meeting another state or federal requirement for pharmaceutical wholesalers, it should not be required to obtain a separate surety bond for its California license. HDMA believes that if every state required a $100,000 bond like California, its members would not be able to afford the millions of dollars that would be required to be paid to obtain wholesale distributor licenses in multiple states.

Therefore, HDMA suggests (with underlined changes) the following language for § 4160 (g):

An applicant for a wholesaler license or an applicant for the renewal of a wholesaler license must submit a surety bond of $100,000 payable to the Pharmacy Board Contingent Fund, or other equivalent means of security acceptable to the Board, such as adequate liability insurance, an irrevocable letter of credit, or a deposit in a trust account or financial institution. A separate surety bond is not required for each location. The purpose of this surety bond is to secure payment of any administrative fine imposed by the board and any cost recovery ordered pursuant to Section 125.3. The board may make a claim against the surety bond if the licensee fails to pay a fine within 30 days of the issuance of the fine or costs become final.

Closed Door Pharmacy (§ 4160)

The draft revisions include section 4160 (f) which would not allow wholesalers to obtain or renew their licenses if they are “beneficially interested” in a closed door pharmacy. HDMA understands this to mean that a person (and presumably a company) with an ownership/partnership interest in a closed door pharmacy (as defined under proposed section 4021.5), or a person who is a major stockholder/officer/director of a closed door pharmacy, may not be licensed as a wholesaler. In other words, a wholesaler cannot own any interest in a closed door pharmacy.
This section is of particular concern for HDMA, and we would like to engage the Board in further discussion regarding this issue. While we are not clear about the Board’s objective or what may have precipitated drafting of this section, HDMA has serious concerns about the restrictions it may place on ownership of closed door pharmacies by wholesalers. HDMA believes that this section has the potential to restrain wholesalers’ future business activities unnecessarily, and perhaps there are other less drastic measures that can be taken to reach a workable solution to the Board’s concerns. We would like to discuss this issue in greater depth with the Board and explore alternative solutions to alleviate any concerns the Board may have about wholesalers’ involvement in this segment of the pharmaceutical industry.

**Business License (§ 4168)**

In section 4168, the revised language states that “a county or municipality shall not issue a business license for any establishment that requires a wholesaler license unless the establishment possesses a current wholesaler license issued by the board.” HDMA seeks clarification as to whether “establishment” means a single facility or an entire corporation. For example, in the proposed language, HDMA suggests the following as clarification:

> A county or municipality shall not issue a business license for any establishment that requires a wholesaler license unless the establishment possesses a current wholesaler license issued by the board. **For the purposes of this Title, an “establishment” is defined as a licensee’s physical location in the state of California.**

**Penalties (§ 4169)**

Although HDMA agrees that penalties should be strengthened, we believe that penalties should be strengthened more for those who actually do the adulteration, misbranding or counterfeiting. However, the Enforcement Committee’s proposal does not specifically address the act of counterfeiting. HDMA recommends that if the Board’s main objective is to address counterfeiting and protection of the public’s health and safety, then the penalty provisions should reflect this objective. We believe there should be stronger penalties for those who intentionally counterfeit the drug. (Currently, a violation of section 111295 or 111300 of the Health and Safety Code is classified as a misdemeanor and carries with it a penalty of a maximum of $1,000 or six months in the county jail, or both.)

We also recommend inserting “knowingly and willfully” language in part (a) (3) regarding the purchase, trade, sale or transfer of adulterated drugs and part (a) (4) regarding the purchase, trade or sale of expired drugs. The laws and penalties for
knowingly counterfeiting or trafficking in counterfeit drugs or knowingly committing related fraudulent acts should be commensurate with the nature of the serious patient harm that may come about as a result of their actions. HDMA suggests the following amended language in section 4169, part (a) (3) and (4):

(3) Knowingly and willfully purchase, trade, sell or transfer drugs or devices that are adulterated as defined in Health and Safety Code Division 104, Part 5, Chapter 6, Article 2.5

(4) Knowingly and willfully purchase, trade, sell or transfer dangerous drugs or dangerous devices after the beyond use date on the label.

Conclusion

HDMA appreciates the effort that is being made by the Board in addressing the problem of counterfeit drugs. We look forward to working with you in developing a solution on how to solve this critical issue. We respectfully submit the above comments and hope that that increased emphasis will be placed on technology-based solutions, strengthening and making uniform licensing procedures and enforcement, and stiffer penalties for knowingly trafficking in counterfeit drugs and committing related fraudulent acts.

In addition, as you may know, HDMA’s Board of Directors has recently approved Recommended Guidelines for Pharmaceutical Distribution System Integrity. We have attached a copy of these HDMA-developed, voluntary “Best Practices,” which are designed to help ensure the integrity of the distribution system through due diligence measures adopted by individual companies.

If you have any questions or would like more information on any of HDMA’s comments, please contact me at 703-787-0000, ext. 240, or Liz Gallenagh, at ext. 234.

Sincerely,

Anita T. Duca
Director, Regulatory Affairs
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.

Approved 11/5/03
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:
Administrative/Management
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.
Definitions for the Recommended Guidelines for Pharmaceutical Distribution System Integrity

1. **ADR** means Authorized Distributor of Record as defined in

   A. 21 CFR 203.3 or as defined under appropriate FDA guidances (e.g., FDA Letter to Industry and Other Interested Persons, Aug. 1, 1988) in the absence of final regulatory specification;

   OR

   B. state laws;

   OR

   C. The HDMA recommended guideline for the definition of the Authorized Distributor of Record which is as follows

      • must be on the manufacturer’s list
         o list to be updated monthly
         OR
      • have a written agreement currently in effect with the manufacturer
         OR
      • have a verifiable account with the manufacturer and minimal transactional or volume requirement thresholds as follows:
         o 5000 sales units per company within 12 months
         OR
         o 12 purchases (invoices) from manufacturer within 12 months

      whichever is more stringent.

   (Note: It is recommended that your legal counsel be consulted to ensure that the most stringent definition is being applied)

2. **Identifying Statement** is defined as specified in 21 CFR 203.50 or as defined under appropriate FDA guidances (e.g., FDA Letter to Industry and Other Interested Persons, Aug. 1, 1988) in the absence of final regulatory specification. In addition, any state laws that may include additional qualifications are included in this definition of Identifying Statement when doing business in or with entities located in those states.

3. **Prescription Drug Wholesaler** means state licensed Non-Manufacturer Vendors including both ADRs and non-ADRs.

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1 There is a consensus that the definition of Authorized Distributor of Record should be enhanced from the 1988 Food and Drug Administration PDMA Guidance to incorporate elements of the Food and Drug Administration’s 1999 regulation and objective criteria that can be met based on transactions with the pharmaceutical manufacturer. Usage of the HDMA definition is optional.

2 "Verifiable account" means 1) an account which the manufacturer confirms (in written or oral form) is assigned to the customer in question or 2) copies of manufacturers' invoices containing a printed account number and the name and address of the customer are obtained.

3 A sales unit is the unit of measure the manufacturer uses to invoice its customer for the particular product.
December 22, 2003

Mr. Kurt R. DeWeese  
Health & Human Services Analyst  
Speaker's Staff, IL House of Representatives  
Room 516 State House  
Springfield, IL 62706

Dear Mr. DeWeese:

As a follow up to our phone conversation on November 25, I am providing to you our comments regarding HB 3898. Supreme Distributors (and the Pharmaceutical Distributors Association, or "PDA"), is intimately familiar with the Florida law upon which your proposed legislation has been crafted. Sal Ricciardi, President of Supreme Distributors and the PDA, was a member of the Ad Hoc Committee on drug pedigrees, who had responsibility for developing the new Florida law.

The Florida Bureau of Pharmacy Services is to be commended for the intent of the new Florida Prescription Drug Safety Act, but it is clear to all (including the Bureau), that it created several issues that will severely hamper the industry, and ultimately the consumer. Following are our comments regarding HB 3898:

Section 2.43
Currently, in the absence of technological solution, there are many significant issues concerning the requirement that all pedigree papers “contain information that records each distribution of any given legend drug, from sale by a pharmaceutical manufacturer, through acquisition and sale by any wholesaler, until final sale…”

First and foremost, current industry practice is not consistent with this requirement, and has not been since the passage of the Prescription Drug Marketing Act (“PDMA”) of 1998. The “status quo” practice is that drug pedigrees trace a products origination back to the manufacturer or the last Authorized Distributor of Record (“ADR”). Many of this country’s largest drug wholesaling firms have presented testimony to the FDA stating that they are unable to trace each product origin back to the manufacturer because of the high volume of transactions they process, and because of cost and logistical constraints. A visit to a wholesalers warehouse (which I understand may be arranged through HDMA) to observe their daily operation will make this point more clearly to you and/or other staff who are able to attend. Since 90% or more of the drugs that enter into commerce move through a “large wholesaler”, it is clear that enactment of such a requirement would bring the current drug distribution system to its knees.
Secondly, one of the concerns in this requirement is that it is inconsistent with the current status quo standard in the vast majority of the 50 United States. It becomes extremely difficult for a company who operates in multiple states to create systems to comply with different requirements from one state to the next. Below is an example of a scenario that would no longer be able to lawfully occur (but which currently occurs on a regular basis) because of the inconsistent requirements:

\[ \text{Wholesaler} \]
Located in Ohio and sells to customer in 48 States.

\[ \text{↓} \]

\[ \text{Wholesaler} \]
Located in Illinois

\[ \text{↓} \]

\[ \text{Retailer} \]
Located in Illinois

In today’s scenario (pre HB 3898), a wholesaler located outside of Illinois gets product from multiple sources. These sources do not provide pedigrees tracing the drug back to the manufacturer because there is no requirement on the books in the state where this transaction occurred that necessitates them to do so.

This Ohio wholesaler now sells the drug to the Illinois wholesaler, and does not pass a pedigree that goes back to the manufacturer because he was required to obtain such a pedigree when he first purchased the product from his source. If the proposed pedigree requirement in HB 3898 goes into effect, this transaction to the Illinois wholesaler cannot lawfully occur because the Ohio wholesaler will not be able to pass the requisite pedigree paper. Thus, fewer drugs will get into Illinois for consumption by its citizens.

**Section 3.21(d):**
Section 3.21(d) states that the pedigree paper for drugs received in a wholesale distribution must be attested to as “accurate and complete” by the wholesale distributor. In today’s practice, the accuracy of certain portions of a pedigree paper is determinable by physical observation of the product being distributed, specifically the item name, strength, size and lot number. The transaction information on the pedigree (i.e. prior sources and transaction dates) which cannot be physically observed, is deemed accurate through assertions made by the seller to the purchaser on a “seller guarantee and indemnification” agreement that is widely used in the industry.

While there are procedures used by companies to determine the accuracy of drug pedigree information, they are typically used on a “random sampling” basis. Conceptually, this is referred to as pedigree authentication. Therefore, this discussion of 3.21(d) rolls into Section 3.23(d) regarding the criminal penalties involved for failure to authenticate a drug pedigree paper prior to further distributing the products. The issues with authentication are numerous, and we have learned of them first hand or by discussion with wholesalers in Florida who are attempting to operate under the same requirement.
First, there must be guidance on what is meant by “authenticate”, and how it (authentication) is to be performed. The State of Florida held several rule-making workshops on this subject, and it is still an issue surrounded by a certain degree of confusion.

Secondly, authentication of every item received has proven to be a logistical nightmare for wholesalers. I am personally aware of a smaller wholesaler and a regional wholesaler that have closed their distribution centers in Florida because of the issues they were facing. For your convenience, I am attaching a copy of testimony that Sal and I presented to the National Association of Boards of Pharmacy in Chicago this past October. This testimony summarized our platform for solving the counterfeit drug issue and outlined numerous issues with the Florida law, including those dealing directly with authentication.

Kurt, while you are reading this letter it may generate more questions than answers. Sal and I appreciate this opportunity to provide our remarks and I truly believe that a face-to-face meeting, in which we could discuss the industry and the issues in detail, will be most beneficial to you and Representative Franks in developing HB 3898.

Please call either of us if you need more information or if we can arrange a time to meet in Illinois.

Sincerely,

Sal Ricciardi
President & CEO

Bruce Krichmar
VP of Accounting & Pharmaceutical Guidance

cc: Representative Jack D. Franks
My name is Sal Ricciardi, and I am the president of the Pharmaceutical Distributors Association, also known as the PDA, an association representing the interests of the 6,000 small licensed prescription drug wholesalers operating throughout the United States. I am also the President and Co-Owner of Purity Wholesale Grocers. Our Pharmaceutical Division, Supreme Distributors, has been wholesaling prescription drugs for more than 20 years.

As an industry, PDA members service other wholesalers, hospitals, retail pharmacies, doctors' offices, clinics, emergency response units, military and private dispensaries and others who are not adequately serviced by the large national and or regional distributors. All member wholesalers operate under the same state and federal laws as the large national and regional wholesalers. Our presence in the marketplace helps to stabilize prices by creating competition.

We understand that NABP is looking at Florida and Nevada as potential models for its own development of model wholesaling regulations, in an effort to reduce the occurrence of counterfeit drugs entering the marketplace. PDA applauds this effort, and wants to share our comments about items we endorse, that will help achieve this objective and also some practical problems that need to be considered in following the Florida and Nevada models.

First, increasing the standards for licensing is critical, and we totally endorse any efforts to do so. In looking at the series or articles in the Washington Post two (2) weeks ago, it is clear that issuing licenses to numerous "bad players" (ex convicts, etc.) has caused the counterfeit problem to grow. Also, the ease with which licenses can be obtained, and the lack of consistent follow up by the various licensing authorities on licensees, allows potentially problematic activities to go unnoticed (see various article highlights).
Secondly, PDA also supports the concept of increased criminal penalties for dealing in counterfeit drugs. We support Florida's efforts in doing this, and as all legitimate companies will attest to, the only people who ultimately profit from counterfeits are the counterfeitors themselves, PDA's members, and all small wholesalers nationwide. We are left with a tarnished image and much potential liability if we have knowingly or unknowingly been involved in distributing these bad drugs. To this point in time, however, the penalties for dealing in counterfeits have not been viewed as a strong enough deterrent from the risk/reward viewpoint of the counterfeitors.

PDA feels that there must be uniformity among the 50 states, because developing different standards in each state makes it impossible to develop systems to deal with differing requirements. Differing definitions of authorized distributor, differing pedigree requirements etc, creates a logistical situation that is virtually unmanageable. That is one of the reasons we are in support of some type of federal guidelines on these issues.

PDA endorses raising the bar on the requirements to become an Authorized Distributor, as follows:

1. Appear on the Manufacturer's list of ADR's.

2. Have a written agreement currently in effect with the manufacturer.

3. Have a verifiable account number with the manufacturer, and a minimal transactional or volume requirement as follows:

   - 5000 sales units within 12 months OR
   - 12 purchases (invoices) from the manufacturer within 12 months

While there are several things PDA endorses about the Florida model, it is important to note
that the new law is not without it's problems.

1. The proposed pedigree authentication requirements slow down the speed by which
   drugs can be distributed
   - Product is backing up on the docks of companies who must authenticate all items
     received. The response time of vendors in terms of answering phone calls, emails,
     etc. has a direct impact on this.
   - The AD list being maintained by the state is very incomplete, and contains many
     inaccuracies (bankrupt companies, acquired companies), and also is far from
     comprehensive because of extremely poor responses from manufacturers. As a
     result, companies have to go thru the more time consuming processes of
     authenticating one's ADR status.

2. The proposed pedigree requirement slows down and/or restricts commerce.
   - The requirement that the invoice number of the source selling the drug be included
     on a pedigree paper causes wholesalers to "hold" inventory for days, pending
     receipt of an invoice number from their source. It is not unusual for product to
     arrive several days in advance of the vendors invoice, and this product cannot be
     legally resold because the seller will not be able to include the required invoice
     number on the pedigree paper.
   - Because of differing requirements from state to state on pedigrees (and the ADR
     definition) there are many transactions that can no longer take place in Florida
     because the sources involved in the distribution chain had no knowledge of the
     Florida law or more importantly, no legal requirement to comply with the law (give
     example). Limiting the amount of good product from getting into the state is not a
good result.

3. The bond requirement, while a good concept, could become extremely cost prohibitive if every state decides to implement a similar requirement. There should be consideration given to a bond being posted in the wholesaler’s home state, and somehow allowing other states to draw on the bond if violations occur in their states.

4. The proposed Authorized Distributor requirement will reduce the number of ADR’s dramatically, and potentially eliminate the ADR status of some smaller companies who buy almost exclusively from the manufacturer. This should not be the intent of the law. If the manufacturers don’t include these companies on their lists, the companies risk losing their ADR status. In addition, if the other objective requirements set in the Florida law, all of which are based upon $100 Million in sales, can’t be met, these companies could again lose their ADR status. PDA does not believe that this is the intent of the drug manufacturer.

Ultimately, as recent history has shown us, licensed companies have introduced counterfeits into the marketplace that probably didn’t deserve to be licensed. It is our belief that raising the licensing standards and raising the criminal penalties will be a significant deterrent to counterfeiters. Also, the introduction of "best practice" guidelines being introduced by HDMA will also increase the level of self-policing performed by industry, and will help to uncover and remove bad players from the marketplace.

In the long run, we believe that a technological solution is what will ultimately provide assurances that drug products are genuine.
Thank you for the opportunity to present the views of the PDA.
November 3, 2003

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

RE: Anti-Counterfeit Drug Initiative (68FR51270)
[Docket No. 2003N-0361]

Dear Sir or Madam:

On behalf of McKesson Corporation (hereafter McKesson), I am pleased to submit comments to the Food and Drug Administration (FDA) concerning the anti-counterfeit drug initiative and the agency’s Counterfeit Drug Task Force Interim Report, issued October 2003. McKesson commends the agency for its important work to enhance pharmaceutical product safety throughout the pharmaceutical supply channel and its ongoing support of public and private sector collaboration to address this significant issue.

McKesson is the world’s largest pharmaceutical supply management and health information technology company. As the nation’s largest healthcare services corporation, we do business with over 5,000 hospitals, 35,000 physician practices, 10,000 extended care facilities, 700 home care agencies, 25,000 retail pharmacies, 600 payors, 450 pharmaceutical manufacturers and 2,000 medical-surgical manufacturers. We are the largest pharmaceutical distributor in North America, through our ownership of McKesson Canada and an equity holding in Nadro, a leading distributor in Mexico.

For the past 170 years, McKesson has led the industry in the delivery of medicines and health care products to drug stores. Today, a Fortune 20 corporation, McKesson delivers vital medicines, medical supplies, and health information technology solutions that touch the lives of more than 100 million patients each day in every health care setting. We understand the critical importance of medication safety and the need to protect the integrity of the pharmaceutical supply chain.
McKesson Corporation
Comments on FDA Counterfeit Drug Interim Report, Docket No. 2003N-0361
November 3, 2003

McKesson was the first drug distributor to fully automate our distribution process by implementing radio frequency and scanning technology throughout our entire warehouse and distribution network. Today, we are engaged in a joint innovative effort with Wal-Mart to beta-test RFID (radio frequency identification) technology for use in tracking inventory and assuring product safety.

We are the industry leader and only single-source provider of drug distribution, automation, scanning and information technologies to help healthcare organizations reduce medication errors throughout the continuum of care. Over 10,000 hospitals, outpatient, and retail pharmacies utilize our bar code-based automation for pharmaceutical products. With the recent purchase of Sky Pharmaceuticals Packaging, Inc., a leading supplier of unit dose bar coded packaging solutions, McKesson now operates two GMP compliant packaging facilities for pharmaceutical products. Through these operations, we purchase pharmaceutical products in bulk quantities directly from the original manufacturer and repackage the tablets or capsules into smaller units, in FDA approved packaging, with a machine-readable bar code for our customers.

McKesson pioneered retail pharmacy automation with the Baker Cell pill counting technology with products in over 10,000 retail and outpatient pharmacies world-wide. We invented the first robotic dispensing system, which automates the dispensing of unit dose bar coded medications, and introduced the product to the hospital market in 1992. We also manufacture medication dispensing cabinets for nursing units that support bar code scanning for accurate drug restocking, and we have incorporated bar code scanning which utilizes a hand-held wireless scanner at the point of medication administration at the patient’s bedside.

McKesson is working with our trading partners to develop and implement technology designed to improve electronic tracking for healthcare product distribution.

**POTENTIAL OPTIONS FOR IMPROVING PRESCRIPTION DRUG SECURITY**

Based on our long history and expertise in the distribution business and our commitment to a safe and secure drug supply, we welcome the opportunity to share our unique insights on issues surrounding the safe distribution of pharmaceutical products. To that end, we have focused our comments on questions concerning Technology and Packaging, Secure Business Practices and a Rapid Response and Alert System.
McKesson Corporation
Comments on FDA Counterfeit Drug Interim Report, Docket No. 2003N-0361
November 3, 2003

A) Technology and Packaging

Unit of use and unit dose packaging

Unit of use and unit dose packaging are important delivery solutions for certain health care settings, and both can provide increased security and protection for the product and the patient. To ensure integrity of the product, we offer the following recommendations:

1) all repackagers must source product directly from manufacturers or wholesalers;
2) wholesalers should purchase all pharmaceuticals intended for repackaging directly from the manufacturer;
3) a bar code should be applied to all unit dose packaged products.

Barcoding of unit dose medications further complements safety measures under implementation by the drug manufacturing and distribution industries to assure accurate drug delivery to patients in hospitals and other institutional settings. Our experience in providing unit dose services for hospitals, nursing homes and other institutional health care settings has shown that combining barcoding requirements with packaging technologies will also facilitate the adoption of pharmacy robotic fill and dispensing systems and enable point-of-care bar code scanning. Expanding the use of these automated, electronic solutions will improve the effectiveness of tracking solutions and help prevent counterfeiting.

McKesson supports packaging technologies that will improve the safety, security, and authenticity of manufacturers' products. However, as a repackager and a distributor, we believe that any requirement for the manufacturer to package pharmaceuticals for unit of use or unit dose dispensing should be balanced against the increased economic costs to the distribution and supply chain and, ultimately, to the consumer.

We encourage the FDA to continue to work with manufacturers and wholesalers to strengthen and enforce existing standards and good manufacturing practices (GMPs) to protect against counterfeiting of repackaged product.
McKesson Corporation
Comments on FDA Counterfeit Drug Interim Report, Docket No. 2003N-0361
November 3, 2003

Tracking technologies

We believe electronic tracking capabilities will significantly enhance counterfeit prevention efforts and will negate the need for an ineffective and potentially fraudulent pedigree paper trail. While paper pedigrees may provide some level of additional deterrence from counterfeiting, they themselves are subject to counterfeiting. Electronic tracking technology, such as RFID, would make it much more difficult for illegitimate and rogue operators to develop entry points within the distribution supply system. RFID has also demonstrated cost effectiveness by improving inventory control, expediting delivery shipments and reducing product waste and diversion. In order for this technology to be implemented, manufacturers must embrace RFID and assume the responsibility for placing electronic tags on their pharmaceutical products.

We support the use of RFID for all drugs and biologics to authenticate products, starting at the case level for products at “high risk of being counterfeited” and progressively moving to tracing capabilities for all products at the unit of sale level. Based on beta testing efforts with our trading partners, McKesson urges the FDA to endorse RFID tracking technology as the industry standard for pharmaceutical distribution.

As the agency addresses methods to prevent counterfeiting, we also encourage the FDA to promote the use of health information technology solutions to track pharmaceuticals through the healthcare system. We support the use of bar code “tracking” technology within the hospital setting to assure product distribution safety and efficiency. Proposed requirements should take into consideration the significant investments that many hospitals have made to date in barcoding technology and give them the flexibility to support and build upon these investments.

Product Shipments

Prescription drug distributors are a vital component in a dynamic health care delivery system. Leading pharmaceutical distributors save the health care system billions of dollars each year by maximizing economies of scale, creating efficiencies, reducing the number of transactions and simplifying product distribution. McKesson purchases products from more than 450 pharmaceutical manufacturers and supplies more than
75,000 customer sites. We offer our customers maximum access to thousands of products, delivery times and other value added services. At the same time, we comply with stringent storage, handling, safety and recordkeeping requirements from multiple federal and state regulatory bodies. Electronic track and trace technology will continue to enhance these efficiencies.

In contrast, direct manufacturer shipments to retail dispensers and other end users would increase transaction costs and complexities. Furthermore, expanding the number of shipments could increase the potential opportunities for diversion, thereby potentially compromising product and consumer safety. According to industry estimates, direct shipments from manufacturers to end-customers would add $50 billion in costs to the U.S. health care delivery system and redundancies to the current pharmaceutical distribution system (*Healthcare Distribution Management Association industry study, 2000*). A significant portion of these added costs would ultimately be borne by consumers and payers.

**High risk drugs**

Electronic tracking technologies will mitigate the need to develop “high risk” prescription drug lists for pharmaceutical products and will allow verification of a product’s chain of custody. McKesson currently has a policy of purchasing 99.5% of all of its pharmaceuticals directly from the pharmaceutical manufacturer. This includes high-priced or break-through drugs, which we consider to be “high risk” for counterfeiting. To assure product safety prior to widespread adoption of electronic tracking technology, FDA could require all distributors to purchase “high risk” prescription drugs directly from the pharmaceutical manufacturer.

**B) Regulatory Requirements and Secure Business Practices**

McKesson strongly believes good business practices are the most effective deterrent to counterfeiting and enhance the security of the supply chain. Good business practices should include greater scrutiny in the purchasing process, background checks, and on-site inspections. Lack of due diligence and other screening procedures greatly exacerbates problems with rogue distributors. **We oppose the use of paper pedigrees, which can be easily forged and which cannot be effectively transmitted through the channel to ensure the integrity of the process. Electronic tracking technology offers the most secure way to police the drug distribution channel.**
Product safety

Based on our experience with the Florida Department of Health, we believe that better screening procedures prior to the issuance of a wholesale drug distributor license would greatly enhance product safety. We support the Healthcare Distribution Management Association’s (HDMA) guidelines to assure the integrity of the pharmaceutical distribution system and enhance efforts to prevent counterfeiting of pharmaceutical products. The HDMA guidelines address the purchase of product by prescription drug distributors, and draw on best practices followed by its leading members. The new guidelines uniformly raise the standard of practice throughout the entire distribution system by recommending that distributors conduct rigorous due diligence, background checks, on-site inspections and ongoing reviews of suppliers and purchasers to ensure compliance with federal and state laws pertaining to prescription drugs.

The guidelines also recommend establishing systems and processes for reporting suspicious product and/or entities suspected of unlawful activity. Such practices adopted by industry and state regulators will go a long way toward identifying and excluding businesses that may engage in criminal activity.

McKesson’s stringent business procedures

McKesson’s unwavering commitment to product safety is reflected in the stringent processes and procedures we have instituted with our suppliers and throughout our pharmaceutical distribution network.

McKesson buys 99.5% of its pharmaceutical products, including specialty, biotech, HIV and oncology drugs, directly from the pharmaceutical manufacturer. Such injectables as Serostim®, Epogen® and Procrit® and more than 200 additional products, including those considered to be at “high risk” for adulteration or counterfeiting, are sourced exclusively from the pharmaceutical manufacturers. This buying practice has been in place since 2000 and has enabled McKesson to enhance the safety of the product it delivers.

Our primary goal is to distribute product of the highest quality. While not required, McKesson has taken the initiative to establish a comprehensive review process for the limited number of alternate source vendors (ASVs) that supply less than 0.5% of our
product. Before entering into a supplier arrangement with an ASV, McKesson completes a rigorous due diligence process for potential suppliers. The McKesson review includes a Dun & Bradstreet Report on the company and its owners, background and security checks, and assurance of appropriate licensing and insurance. Additionally, we conduct yearly site inspections, which include a review of the company’s purchasing practices and a detailed check of the product.

Upon receipt at McKesson, the product is subjected to an extensive check-in and quality control process to verify packaging, dating and barcodes. Any product that does not pass these tests does not enter the McKesson distribution network. Once in the network, the products are carefully stored, controlled and tracked in accordance with the PDMA, FDA regulations, and individual state laws and regulations.

We recommend that FDA consider these procedures as examples of secure business practices which should be promoted on a widespread basis.

**PDMA reforms**

The minimum PDMA guidelines contained in 21USC353(e) et seq., and 21 CFR Part 205 should be strengthened to establish uniform national licensing standards and electronic tracking guidelines for qualified pharmaceutical distributors. The FDA should work closely with the state regulatory bodies to ensure implementation and enforcement of these licensing requirements, which will limit opportunities for rogue distributors to operate within the distribution system. McKesson also recommends that PDMA revisions include stronger criminal and administrative penalties and enforcement actions against product counterfeiting. Severe penalties and tougher sentences are needed to deter and punish those responsible for counterfeiting/adulterating drugs as well as those who knowingly distribute such products. To that end, we recommend the following:

1) Establish fines that match the potential illicit financial gain;
2) Heighten and enforce criminal penalties for those who knowingly distribute adulterated or counterfeit product;
3) Establish lesser penalties for those who unknowingly distribute adulterated or counterfeit product due to negligence or poor business practices;
4) Support state action to quickly suspend/revoke licenses of those in violation of laws or regulations;
5) Work with states to inhibit rogue operators from receiving licenses in other states;
6) Establish fines for individuals who purchase prescription pharmaceuticals from “non-certified” internet pharmacies for their own personal use.

**Pharmaceutical returns**

As the FDA considers comprehensive solutions to prevent the proliferation of counterfeit drugs, McKesson believes that prescription drug returns must be addressed. Our company policy is to use the expertise of third party processors to handle unsaleable returned products safely and expeditiously. For drugs that are likely candidates for counterfeiting or adulteration, we will accept saleable returns of these products from our customers only within 48 hours if the chain of custody can be verified.

We encourage the agency to continue to work with the industry to develop a solution that is economically viable and will ensure that prescription returns are handled with appropriate security, safety and efficiency.

**Internet pharmacy sales**

Prescription drug sales via the Internet are increasing rapidly. Unfortunately, the lack of international, federal and state regulations governing these internet sales has left consumers vulnerable to counterfeit drugs. McKesson believes that the FDA should ban domestic and international prescription drug sales via the Internet unless those transactions and businesses are held to the same regulatory standards established by the PDMA, state Boards of Pharmacy, and Departments of Health and currently applied to distributors and pharmacies, and that a monitoring effort is initiated. We encourage the FDA to work with the National Association of Boards of Pharmacy (NABP) and state attorneys general to ensure that internet pharmacy sites are certified and can provide chain of custody and electronic verification to validate the authenticity of their products.
C) Rapid Alert and Response Systems

McKesson supports FDA’s efforts to improve rapid response systems to curtail and prevent counterfeit products from entering the domestic pharmaceutical product supply channels, and we advocate greater collaboration between the FDA and the DEA to protect the controlled substances market. Participation in a first response system by suppliers, distributors, providers, and dispensers is essential to protecting the public against counterfeit or adulterated product. Additionally, an electronic “alert” system could be helpful to other healthcare system improvements, such as HHS’ efforts to develop a bioterrorism and emergency infrastructure response system.

Conclusion

It is unlikely that any single solution will be able to halt all counterfeit practices. However, the combination of electronic tracking technologies, secure repackaging procedures, direct manufacturer purchasing, and enhanced business practices by all members of the supply chain will greatly reduce potential entry points for counterfeiting.

McKesson appreciates the opportunity to provide its comments and recommendations based on our experience and current business practices. We welcome the FDA’s commitment to enhancing public health and safety, and look forward to ongoing collaboration and cooperation to improve the safety, efficiency and effectiveness of the pharmaceutical distribution system through improved technology and regulatory reforms.

Sincerely,

Ann Richardson Berkey
Vice President, Public Affairs
Attachment F
(a) No prescriber shall dispense drugs or dangerous devices to patients in his or her office or place of practice unless all of the following conditions are met:

1. The dangerous drugs or dangerous devices are dispensed by the prescriber, to the prescriber's own patient. A registered nurse may hand to the patient the dangerous drugs or dangerous devices dispensed by the prescriber, and the drugs or dangerous devices are not furnished by a nurse or physician attendant.
2. The dangerous drugs or dangerous devices are necessary in the treatment of the condition for which the prescriber is attending the patient.
3. The prescriber does not keep a pharmacy, open shop, or drugstore, advertised or otherwise, for the retailing of dangerous drugs, dangerous devices, or poisons.
4. The prescriber fulfills all of the labeling requirements imposed upon pharmacists by Section 4076, all of the recordkeeping requirements of this chapter, and all of the packaging requirements of good pharmaceutical practice, including the use of childproof containers.
5. The prescriber does not use a dispensing device unless he or she personally owns the device and the contents of the device, and personally dispenses the dangerous drugs or dangerous devices to the patient packaged, labeled, and recorded in accordance with paragraph (4).
6. The prescriber, prior to dispensing, offers to give a written prescription to the patient that the patient may elect to have filled by the prescriber or by any pharmacy.
7. The prescriber provides the patient with written disclosure that the patient has a choice between obtaining the prescription from the dispensing prescriber or obtaining the prescription at a pharmacy of the patient's choice. This disclosure shall include information relating to the availability of generic drug alternatives and a statement that the drugs dispensed may be available at lower cost through purchase at a pharmacy.
8. A certified nurse-midwife who functions pursuant to a standardized procedure or protocol described in Section 2746.51, a nurse practitioner who functions pursuant to a standardized procedure described in Section 2836.1, or protocol, or a physician assistant who functions pursuant to Section 3502.1, may hand furnish dangerous drugs or dangerous devices to a patient of the supervising physician and surgeon a properly labeled prescription drug or dangerous device prepackaged by a physician and surgeon, a manufacturer as defined in this chapter, or a pharmacist.

(b) The Medical Board of California, the State Board of Optometry, the Dental Board of California, the Osteopathic Medical Board of California, the Board of Registered Nursing, and the Physician Assistant Committee shall have authority with the California State Board of Pharmacy to ensure compliance with this section, and those boards are specifically charged with the enforcement of this chapter with respect to their respective licensees.

(c) "Prescriber," as used in this section, means a person, who holds a physician's and surgeon's certificate, a license to practice optometry, a license to practice dentistry, or a certificate to practice podiatry, and who is duly registered as such by the Medical Board of California, the State Board of Optometry, the Dental Board of California, or the Board of Osteopathic Examiners of this state.
Article 13 – Non-Profit or Free Clinics

4180. (a) (1) Notwithstanding any provision of this chapter, any of the following clinics may purchase drugs at wholesale for administration or dispensing, under the direction of a prescriber physician, to patients registered for care at the clinic:

(A) A licensed nonprofit community clinic or free clinic as defined in paragraphs (1) and (2) of subdivision (a) of Section 1204 of the Health and Safety Code.
(B) A primary care clinic owned or operated by a county as referred to in subdivision (b) of Section 1206 of the Health and Safety Code.
(C) A clinic operated by a federally recognized Indian tribe or tribal organization as referred to in subdivision (c) of Section 1206 of the Health and Safety Code.
(D) A clinic operated by a primary care community or free clinic, operated on separate premises from a licensed clinic, and that is open no more than 20 hours per week as referred to in subdivision (h) of Section 1206 of the Health and Safety Code.
(E) A student health center clinic operated by a public institution of higher education as referred to in subdivision (j) of Section 1206 of the Health and Safety Code.
(F) A nonprofit multispecialty clinic as referred to in subdivision (l) of Section 1206 of the Health and Safety Code.
(G) A group practice.

(2) The clinic shall keep records of the kind and amounts of drugs purchased, administered, and dispensed, and the records shall be available and maintained for a minimum of seven years for inspection by all properly authorized personnel.

(b) No clinic shall be entitled to the benefits of this section until it has obtained a license from the board. Each license shall be issued to a specific clinic and for a specific location.

(c) For the purposes of this article, “group practice” means more than one prescriber operating a practice providing health care services at a specific location.

(e) Prescribers in a group practice shall maintain the following information for each prescription on file and this information shall be readily retrievable:

(1) The date dispensed, and the name or initials of the dispensing prescriber.
(2) The brand name of the drug or device; or if a generic drug or device is dispensed, the distributor's name which appears on the commercial package label.
(3) If a prescription for a drug or device is refilled, a record of each refill, quantity dispensed, if different, and the initials or name of the dispensing prescriber.
(4) A new prescription must be created if there is a change in the drug, strength, prescriber or directions for use, unless a complete record of all such changes is otherwise maintained.

(f) This section shall not apply to an individual prescriber practicing at a licensed location who dispenses drugs from the prescriber’s personal stock of dangerous drugs and dangerous devices only to the prescriber’s patients pursuant to Section 4170.

4181. (a) (1) Prior to the issuance of a clinic license authorized under Section 4180 (a)(1)(A) – (F), the clinic shall comply with all applicable laws and regulations of the State Department of Health Services relating to the drug distribution service to insure that inventories, security procedures, training, protocol development, recordkeeping, packaging, labeling, dispensing, and patient consultation occur in a manner that is consistent with the promotion and protection of the health and safety of the public. The policies and procedures to implement the laws and regulations shall be developed and approved by the consulting pharmacist, the professional director, and the clinic administrator.

(2) Prior to the issuance of a clinic license authorized by 4180(a)(1)(G), the group practice shall
comply with all applicable laws and regulations relating to drug distribution to insure that inventories, security procedures, training, protocol development, recordkeeping, packaging, labeling, dispensing, and patient consultation occur in a manner that is consistent with the promotion and protection of the health and safety of the public. The policies and procedures to implement the laws and regulations shall be developed and approved by the consulting pharmacist and the professional director of the group practice.

(b) These policies and procedures required by this section shall include a written description of the method used in developing and approving them and any revision thereof.
(c) The dispensing of drugs in a clinic shall be performed only by a physician, a pharmacist, or other person lawfully authorized to dispense drugs, and only in compliance with all applicable laws and regulations.

4182. (a) Each clinic that makes an application for a license under Section 4180 shall show evidence that the professional director is responsible for the safe, orderly, and lawful provision of pharmacy services. In carrying out the professional director's responsibilities, a consulting pharmacist shall be retained to approve the policies and procedures in conjunction with the professional director and the administrator. In addition, the consulting pharmacist shall be required to visit the clinic regularly and at least quarterly. However, nothing in this section shall prohibit the consulting pharmacist from visiting more than quarterly to review the application of policies and procedures based on the agreement of all the parties approving the policies and procedures.
(b) The consulting pharmacist shall certify in writing at least twice a year that the clinic is, or is not, operating in compliance with the requirements of this article. The clinic shall maintain these written certifications in the clinic for at least three years, and the most recent of those written certifications shall be submitted with the annual application for the renewal of a clinic license.
(c) For the purposes of this article, "professional director" means a physician prescriber acting in his or her capacity as medical professional director.

4183. No clinic dispensing drugs pursuant to this article shall be eligible for any professional dispensing fee that may be authorized under the Medi-Cal program (Chapter 7 (commencing with Section 14000) of Part 3 of Division 9 of the Welfare and Institutions Code).

4184. No Schedule II controlled substance shall be dispensed by the clinic. This limitation shall not be construed to prohibit a physician dispensing a Schedule II drug to the extent permitted by law. Clinics that dispense Schedule II and Schedule III controlled substances shall report those prescriptions to the CURES program pursuant to Section 11165 of the Health and Safety Code.

4185. The board, and any other authorized officer of the law, shall have the authority to inspect a clinic at any time in order to determine whether a clinic is, or is not, operating in compliance with this article.

4186. (a) Automated drug delivery systems, as defined in subdivision (h), may be located in any clinic licensed by the board pursuant to Section 4180. If an automated drug delivery system is located in a clinic, the clinic shall develop and implement written policies and procedures to ensure safety, accuracy, accountability, security, patient confidentiality, and maintenance of the quality, potency, and purity of drugs. All policies and procedures shall be maintained at the location where the automated drug delivery system is being used.
(b) Drugs shall be removed from the automated drug delivery system only upon authorization by a pharmacist after the pharmacist has reviewed the prescription and the patient's profile for
potential contraindications and adverse drug reactions. Drugs removed from the automated drug delivery system shall be provided to the patient by a health professional licensed pursuant to this division.

(c) The stocking of an automated drug delivery system shall be performed by a pharmacist.

(d) Review of the drugs contained within, and the operation and maintenance of, the automated drug delivery system shall be the responsibility of the clinic. The review shall be conducted on a monthly basis by a pharmacist and shall include a physical inspection of the drugs in the automated drug delivery system, an inspection of the automated drug delivery system machine for cleanliness, and a review of all transaction records in order to verify the security and accountability of the system.

(e) The automated drug delivery system used at the clinic shall provide for patient consultation pursuant to Section 1707.2 of Title 16 of the California Code of Regulations with a pharmacist via a telecommunications link that has two-way audio and video.

(f) The pharmacist operating the automated drug delivery system shall be located in California.

(g) Drugs dispensed from the automated drug delivery system shall comply with the labeling requirements in Section 4076.

(h) For purposes of this section, an "automated drug delivery system" means a mechanical system controlled remotely by a pharmacist that performs operations or activities, other than compounding or administration, relative to the storage, dispensing, or distribution of prepackaged dangerous drugs or dangerous devices. An automated drug delivery system shall collect, control, and maintain all transaction information to accurately track the movement of drugs into and out of the system for security, accuracy, and accountability.

4187. (a) Notwithstanding any other provision of law, an automated drug delivery system located in a clinic licensed pursuant to Section 4180(a)(1)(G) shall be owned and operated by a licensed pharmacy.

(b) Notwithstanding any other provision of law, a pharmacist may supervise a single pharmacy technician at a remote location where an automated drug delivery system is operated in a clinic licensed pursuant to Section 4180(a)(1)(G), and this pharmacy technician shall not be subject to the ratio established in Section 4115.
Attachment G
STATEMENT ON U.S. COURT OF APPEALS DECISION
DENYING A STAY ON RxDEPOT DECISION

On Friday, November 21, 2003, the 10th Circuit Court of Appeals decision, which denied a motion from RxDepot to stay the District Courts ruling, pending appeal, sent yet another clear signal that those persons, whether public or private, who would put profit before safety will not be allowed to threaten the public health.

Importation of illegal medicines is risky business. Americans should not have to choose between safe products and products that are affordable.

Congress is poised to provide access to safe and affordable drugs for all Americans through actions like a Medicare prescription drug benefit and new laws to improve access to inexpensive generic drugs. Such legislation would help millions of Americans obtain medicines that are both safe and affordable.

FDA is continuing to uphold its longstanding obligation under the law that Congress has given us to protect Americans from illegal drugs that may be unsafe, ineffective, poorly made, substandard or counterfeit.

###
UNITED STATES District Court, 
N.D. Oklahoma.

UNITED STATES of America, Plaintiff, 
v. 
RX DEPOT, INC. and Rx of Canada, LLC, 
corporations, and Carl Moore and David 
Peoples, individuals, Defendants. 

No. 03-CV-0616-EA. 

Nov. 6, 2003.

Cathryn Dawn McClanahan, United States Attorney, 
Tulsa, Alan Phelps, U S Dept of Justice, 
Washington, DC, for United States of America, plaintiff.

Gary L Richardson, Fred Everett Stoops, Sr, Keith 
Allen Ward, Nancy C Curtis, Richardson Stoops 
Richardson & Ward, Tulsa, for Rx Depot, Inc., 
corporation, Rx of Canada, LLC, corporation, Carl 
Moore, individual, David Peoples, individual, defendants.

FINDINGS OF FACT AND CONCLUSIONS OF 
LAW 
EAGAN, District J.

*1 This matter came on for hearing on October 8-9, 
2003, on motion of plaintiff, United States of 
America, for preliminary injunction against 
defendants, Rx Depot, Inc., Rx of Canada, LLC, Carl 
Moore and David Peoples (Dkt.# 2); and motion by 
defendants for preliminary injunction (Dkt.# 10). 
Upon consideration of the pleadings and the 
evidence, the Court finds and concludes as follows:

I. FINDINGS OF FACT 
A. Procedural History

1. The plaintiff instituted this suit on September 11, 
2003, by filing a complaint for injunction (Dkt.# 1) 
and a motion for a preliminary injunction (Dkt.# 2). 
Plaintiff's complaint alleged violations by defendants 
of the Federal Food, Drug, and Cosmetic Act 
("FDCA"), 21 U.S.C. §§ 331(d) and (t).

2. Defendants filed a response on October 6, 2003 
(Dkt.# 10), wherein they moved for their own 
preliminary injunction against the plaintiff's attempt 
to enforce the FDCA. Defendants filed an answer and 
counterclaim on October 8, 2003 (Dkt.# 14).

3. On October 8-9, 2003, the Court heard and 
received evidence relating to both preliminary 
injunction motions. Plaintiff and the defendants 
presented witnesses and exhibits, and thereafter filed 
proposed findings of fact and conclusions of law.

B. The Plaintiff

4. Plaintiff brings this action in its own name 
pursuant to 21 U.S.C. § 337(a) to preliminarily and 
permanently enjoin alleged violations of the FDCA 
by defendants.

C. The Defendants

5. Defendant Rx Depot, Inc. ("Rx Depot"), was 
incorporated under the laws of the State of Nevada on 
December 2, 2002, and does business at 4908 South 
Memorial Drive, Tulsa, Oklahoma, within the 
jurisdiction of this Court. Appendix to Pl. 
Memorandum in Support of Plaintiff's Motion for 
Preliminary Injunction ("App." ) Ex. A, Tab 1. Rx 
Depot does business throughout the United States.

6. Defendant Rx of Canada, LLC ("Rx Canada"), is a 
Nevada limited liability company. Rx Canada is 
owned by defendant Carl Moore's son, Joe-Max 

7. Rx Canada's website, www.rxofcanada.net, is 
substantially similar to Rx Depot's website, 
to many purported Rx Canada store locations are 
actually links to Rx Depot stores, including some 
stores located in the Northern District of Oklahoma. 
Similarly, links to some purported Rx Depot 
locations on the Rx Depot website actually lead to 
contact information for Rx Canada stores. Transcript 
of Proceedings, October 8-9, 2003 ("Trans." ) at 66-
69; Plaintiff's Preliminary Injunction Hearing Ex. 
("Pl.Ex." ) 11-12.

8. Defendant Carl Moore, an individual, is the 
President of Rx Depot and a member of its Board of 
Directors. He has overall responsibility for, and 
authority over, all operations of the corporation, 
including the sales arrangements involving ordering, 
purchasing, and shipment of prescription drugs from 
Canada. He performs these activities at 4908 South 
Memorial Drive, Tulsa, Oklahoma, within the
jurisdiction of this Court. App. Ex. A, Tab 1; Pl.Ex. 6; Trans. at 50, 178.

*2 9. Defendant David Peoples, an individual, is the Secretary of Rx Depot. He is responsible for receiving and processing orders for Rx Depot. He performs these activities at 4908 South Memorial Drive, Tulsa, Oklahoma, within the jurisdiction of this Court. App. Ex. A Tab 1; Pl.Ex. 6.

10. Defendants Carl Moore, David Peoples, Rx Depot, and Rx Canada (collectively, "defendants" or "Rx Depot") operate approximately 85 Rx Depot/Rx Canada stores located throughout the United States, which serve about 800 customers each day. Trans. at 188-89.

D. Operation of Rx Depot/Rx Canada

11. Rx Depot assists individuals in procuring prescription medications from pharmacies in Canada. Trans. at 178-79. Each Rx Depot/Rx Canada location has one or two employees who accept prescriptions from U.S. customers. Customers also are asked to fill out a medical history form and other forms provided by Rx Depot. Customers can deliver these documents to defendants' stores in person, or can mail or fax to the nearest Rx Depot/Rx Canada store. Trans. at 20-24, 44-46, 48, 51-52; Pl.Ex. 2, 6, 11-12.

12. Once an Rx Depot/Rx Canada customer has submitted the required forms and prescription to defendants, the papers and the customer's credit card information or a certified check are transmitted to a cooperating pharmacy in Canada. Trans. at 46, 184, 195. A Canadian doctor rewrites the prescription, [FN1] and the Canadian pharmacy fills the prescription, ships the prescription drugs directly to the U.S. customer, and bills the U.S. customer's credit card. Trans. at 22, 45-46, 48, 51-52; Pl.Ex. 6.

*3 18. Although defendants presented evidence that the amount of prescription drugs shipped from Canadian pharmacies never exceeds a ninety-day supply, Trans. at 184; Pl.Ex. 24, that defendants do not allow Canadian pharmacies to ship temperature-sensitive drugs, Trans. at 193, and that defendants do not deal with any third parties, Trans. at 194, unapproved prescription drugs and drugs imported from foreign countries by someone other than the U.S. manufacturer do not have the same assurance of safety and efficacy as drugs regulated by the Food and Drug Administration ("FDA."). Because the drugs are not subject to FDA oversight and are not continuously under the custody of a U.S. manufacturer or authorized distributor, their quality is less predictable than drugs obtained in the United States. For instance, the drugs may be contaminated, counterfeit, or contain erratic amounts of the active ingredient or different excipients. Also, the drugs

Canadian pharmacies. Trans. at 189-90; Pl.Ex. 6.

14. Defendants are essentially commissioned sales agents for Canadian pharmacies. Trans. at 191.

15. An Oklahoma state court recently ordered the defendants' stores in Oklahoma to close after finding that the defendants acted as storefronts for Canadian pharmacies and, as such, were operating as unlicensed pharmacies. Trans. at 190-91; Pl.Ex. 25.

16. Defendants admit in their answer to the plaintiff's complaint that they are engaged in the business of causing the shipment of U.S. manufactured and unapproved, foreign-manufactured prescription drugs from Canadian pharmacies to U.S. citizens. See Defendants' Answer and Counterclaims, Dkt. # 14, ¶ 6.

17. The defendants actively solicit other individuals to open "affiliate" Rx Depot/Rx Canada stores by distributing promotional materials that describe their business practices and the potential profits to be made from opening a franchise. Defendants estimate that an affiliate would receive an average 9% commission on each sale of Canadian prescription drugs, about $24.75. The net commissions for an affiliate in the first year would be an estimated $141,570, according to the defendants. Pl.Ex. 1. The defendants' affiliate "Agreement" also states, however, that the service "may at some date be determined to be unlawful or otherwise prohibited." Id. at 29.

E. Prescription Drugs from Foreign Countries

13. Defendants receive a 10 to 12 percent commission for each sale they facilitate for the Canadian pharmacies. The defendants also receive commissions for refill orders, which generally are arranged directly between customers and the
may have been held under uncertain storage conditions, and therefore be outdated or subpotent. Trans. at 127-28, 141-42, 144; App. Ex. B (McGinnis Decl.) at ¶¶ 11, 14.

19. Prescription drugs obtained through Rx Depot frequently are dispensed in greater quantities than are requested by the prescribing physician. Although defendants presented evidence that the amount of prescription drugs shipped from Canadian pharmacies never exceeds a ninety-day supply, Trans. at 184; Gov't Ex. 24, Rx Depot advertises the availability of, and causes the importation of, preset quantities of drugs and dispenses these preset quantities regardless of the quantity of the drug the patient's U.S. physician prescribed and without directions to take the drug for only the number of days prescribed by the U.S. physician. Trans. at 46-47, 62-63, 97-98; P1.Ex. 10, 11-12. American patients could, therefore, take a drug for many days more than their physicians intend without supervision. This practice can be dangerous in instances where drugs have potentially life-threatening side effects with continued use. Trans. at 98; App. Ex. C (Katz Decl.) at ¶ 14.

20. Prescription drugs obtained through Rx Depot also do not contain the FDA-approved patient package inserts included with certain prescription drugs in the United States. Nor are prescription drugs obtained through Rx Depot shipped in FDA-approved unit-of-use packaging. This type of packaging is used in the United States to help ensure that certain drugs received by customers arrive in designated dosages with the approved patient package insert. Trans. at 98-104; P1.Ex. 10, p. 16-17, Ex. 18.

21. The fact that there are currently no known cases of someone being harmed by a drug received as a result of using Rx Depot, Trans. at 137-38, or that plaintiff is currently unaware of anyone being harmed by prescription medications ordered through Rx Depot and imported from Canada, Trans. at 85, does not diminish the legitimate safety concerns of the FDA with unregulated commercial reimportation of U.S.-manufactured drugs by someone other than the manufacturer and importation of foreign-manufactured drugs not approved by the FDA.

F. Undercover Purchases by FDA

*4 22. In May 2003, FDA made an undercover purchase through Rx Depot. An FDA investigator in Maryland downloaded the necessary Rx Depot order forms and related paperwork from the Rx Depot website and filled them out as though he were a patient. The investigator also prepared a prescription for 60 pills, to be taken twice a day for 30 days, of the FDA-approved prescription drug Serzone, which is used to treat depression. The prescription allowed one refill. On the Rx Depot form, the investigator ordered a 100-pill package offered on the Rx Depot website rather than the 60 pills indicated on the prescription. Trans. at 46-47, 62-63; P1.Ex. 9.

23. On May 10, 2003, a second FDA investigator in Oklahoma took the order forms and prescription to an Rx Depot store located at 5801 N. May, Suite 101, Oklahoma City, Oklahoma. The investigator provided the order forms and prescription to the store manager. The Rx Depot manager accepted the paperwork and faxed or mailed the information to a Canadian pharmacy. The manager did not indicate that ordering a greater number of pills than what the prescription called for would be a problem. In fact, the manager stated that drugs obtained through Rx Depot usually came in packages of 100 pills. Trans. at 43-48; P1.Ex. 8-9.

24. In late May 2003, FDA received a package from Pharmacy North, Inc., in Winnipeg, Manitoba, Canada. The package contained 99 pills (and was labeled as containing 100) of a foreign-manufactured version of Serzone, known as APO-Nefazodone. The labeling provided with the APO-Nefazodone did not direct the patient to take the drug for 30 days or for any other specified period of time. Trans. at 64-65; P1.Ex. 10.

25. APO-Nefazodone is not generally recognized among qualified experts as safe and effective for use under the conditions prescribed, recommended, or suggested in its labeling. Trans. at 93; App. Ex. C (Katz Decl.) at ¶ 11.

26. APO-Nefazodone does not have in effect FDA approval of any new drug or abbreviated new drug applications filed pursuant to 21 U.S.C. § 355(b) or (j). It does not have in effect a valid exemption from such approval requirements under 21 U.S.C. § 355(d). Trans. at 94; App. Ex. D (Richman Decl.) at ¶ 4.

27. In the United States, Serzone is sold in "unit-of-use packaging" designed to ensure, as much as possible, that the patient receives a designated dose with an FDA-approved patient package insert. The insert includes important information regarding the drug, such as warnings related to potentially serious
side effects. One potential side effect of Serzone, and
generic versions of Serzone such as APO-
Nefazodone, involves increased risk of serious liver
damage. Trans. at 95, 99, 103; Pl.Ex. 17-18.

28. The labeling provided by the Canadian pharmacy
with the APO-Nefazodone included fewer and far
less descriptive warnings regarding potential side
effects than the FDA-approved patient package
insert for Serzone. For example, the Canadian instructions
do not specify some of the liver failure symptoms
listed on the Serzone insert, do not mention drugs
that should be avoided when taking APO-
Nefazodone, and do not convey the sense of urgency
reflected in the Serzone insert. These substandard
instructions could increase the risk of adverse events,
including life-threatening liver failure. Trans. at 95,
101-02, 120-21; Pl.Ex. 10, 18.

5 29. Patient safety also can be compromised when
a pharmacy provides more pills than the number
prescribed by the doctor. In the case of
antidepressants such as Serzone and APO-
Nefazodone, potential problems associated with
taking a longer-than-prescribed course of medication
include increased risk for serious liver problems.
Pharmacies in the United States typically do not
supply patients with refills until their previous
prescriptions are nearly completed. Trans. at 97-98,
106.

30. In late July 2003, an FDA investigator made a
second undercover purchase by faxing an order for
Sporanox to Rx Depot's Tulsa, Oklahoma, location.
Trans. at 20-21; Pl.Ex. 2-3.

31. Sporanox is an FDA-approved prescription drug
manufactured in Puerto Rico by Janssen
Pharmaceutica, Inc., that is used to treat nail fungal
infections. Trans. at 20, 24, 38; Pl.Ex. 5.

32. In early August 2003, FDA received the
Sporanox order from Pharmacy North, Inc., in
Winnipeg, Manitoba, Canada. The Sporanox was
shipped into the United States by a party other than
the manufacturer. Trans. at 22-23; Pl.Ex. 4.

33. The drug products purchased by FDA through
undercover buys represent just two of the hundreds of
prescription drugs advertised on the defendants'
websites. Pl.Ex. 11-12.

34. The fact that the FDA did not test for
adulteration the individual tablets of APO-
Nefazodone or Sporanox received in the undercover
purchases, Trans. at 27-29, 40, 76, or that an
American pharmacy would have filled the Sporanox
prescription, Trans. at 31, is irrelevant to the safety
concerns of the FDA at issue in this case. The safety
concerns of the FDA relate to reimportation of U.S.-
manufactured drugs by someone other than the
manufacturer and importation of foreign-
manufactured drugs not approved by the FDA.
Complaint, Dkt. # 1, at ¶¶ 12, 13. Defendant Moore
admitted at the hearing that prescription drugs from
Canadian pharmacies are not approved by FDA and
that some of them are manufactured in the United
States. Trans. at 190. Defendants' websites also state
that the advertised drugs are not FDA-approved.
Pl.Ex. 11-12.

G. FDA Warnings to the Defendants

35. On March 21, 2003, FDA issued a Warning
Letter to the Rx Depot store located at 200 S.
Bloomington, Ste. El, Lowell, Arkansas; copies of
the letter were sent to defendants Moore and Peoples.
The letter informed the defendants that FDA believed
them to be violating 21 U.S.C. § 381d(d)(1), because
they caused prescription drugs manufactured in the
United States to be reimported by persons other than
the manufacturer of the drug. Further, the letter stated
that the defendants violated 21 U.S.C. § 355 by
causing unapproved new drugs to be imported into
the United States. Trans. at 69-70, 187-88; Pl.Ex. 13.

36. On May 6, 2003, the defendants responded to
FDA's Warning Letter. Defendants stated that all
drugs they cause to be obtained from Canadian
pharmacies are "manufactured in the United States,"/Defendants also stated that the drugs advertised on
Rx Depot's website and obtained by their customers
from Canadian pharmacies "are not" FDA
approved." Trans. at 70-71; Pl.Ex. 14.

*6 37. In their response to FDA's warnings,
defendants did not indicate any intention to halt their
illegal practices. By letter dated June 10, 2003, FDA
informed the defendants that their response was
inadequate. Trans. at 71; Pl.Ex. 14-15.

38. Since receiving the FDA Warning Letter, the
defendants have opened approximately 50 additional
Rx Depot and Rx Canada stores. Trans. at 190.

39. Defendant Moore testified at the hearing that the
defendants would continue their activities unless this
Court enjoins them. Trans. at 192.

40. FDA has sent numerous other Warning Letters
and informational letters to operations similar to Rx Depot and individuals considering engaging in such activities. Pl.Ex. 20. In these letters, some of which pre-date the start of the defendants' business, FDA has consistently stated to interested parties that "a U.S. pharmacy or other business virtually always violates U.S. law by importing or causing the importation of [drugs from Canadian pharmacies]." Id. at 8.

H. Cost of Prescription Drugs


42. The United States ranks significantly higher than other countries, including Canada, in terms of prescription drug costs. Trans. at 8, 132-36, 171, 176, and 213.

43. Because of the high cost of prescription drugs in the United States, some citizens cannot afford their medications at U.S. prices. Defendants presented three highly credible witnesses to testify to this effect at the preliminary injunction hearing. These witnesses use or used Rx Depot to purchase their medications at a significantly lower price. Trans. at 38, 162-66, 171-72, and 199-214. The high cost of prescription drugs in the United States especially impacts those on fixed incomes, such as senior citizens and the disabled. See id.

44. American cities and states are either looking at ways to import drugs from Canada, or are already doing so, to alleviate the high cost of prescription drugs on their citizens. Trans. at 130, 161-70, and 173.

45. Congress has found that "efforts to enable such purchases [of prescription drugs at prices comparable to the prices for such medicines in other countries] should not endanger the gold standard for safety and effectiveness that has been established and maintained in the United States." MEDS Act, 21 U.S.C.A. § 348, Historical and Statutory Notes, Congressional Finding 5.

46. Not only is Congress the best forum to address the high cost of prescription drugs for U.S. citizens, but also Congress is currently considering legislation which could allow prescription drug importation from Canada.

I. FDA Personal Use and Enforcement Discretion Policies

*7 47. The FDA has a personal importation policy which allows entry of foreign drugs by U.S. citizens who bring prescription drugs from foreign countries for personal use. Trans. at 128-29; Pl.Ex. 21; Def. Ex. 1p.

48. The FDA also has an "enforcement discretion policy" whereby the FDA allows small quantities of prescription drugs to be brought into the U.S. by individuals for personal use without recourse. Trans. at 130-31. In this regard, the FDA does not enforce the FDCA against individuals who travel to Canada or use the Internet to purchase prescription drugs from Canada for personal use. Trans. at 35-36, 131, 151, 163, 171, and 175.

49. Any conclusion of law which is more appropriately characterized as a finding of fact is incorporated herein.

II. CONCLUSIONS OF LAW

1. This Court has jurisdiction over the subject matter and over all parties to this action under 28 U.S.C. § § 1331, 1337, and 1345, and 21 U.S.C. § 332 (a).

2. Venue in this district is proper under 28 U.S.C. § § 1391(b) and (c).

3. The defendants violate 21 U.S.C. § 331 by causing the importation of prescription drugs from Canadian pharmacies.

4. APO-Nefazodone is one of the prescription drugs that the defendants cause to be imported. It is a drug within the meaning of the FDCA, 21 U.S.C. § 321(g)(1), and a new drug under 21 U.S.C. § 321(p).

5. Defendants violate 21 U.S.C. § 331(d) each time they cause to be introduced or delivered for introduction into interstate commerce unapproved new drugs in violation of 21 U.S.C. § 355. Specifically, the defendants cause the importation of the unapproved new drugs, such as APO-Nefazodone, listed on their website.

6. Sporanox, another one of the prescription drugs the defendants cause to be imported, is manufactured in Puerto Rico. Pursuant to 21 U.S.C. § 321(a)(1),
Puerto Rico is a "state" for purposes of 21 U.S.C. § 381(d)(1). Thus, Sporanox is a U.S.-manufactured drug and cannot be imported into the United States by anyone other than the drug's manufacturer.

7. Defendants violate 21 U.S.C. § 331(i) each time they cause the importation of prescription drugs in violation of 21 U.S.C. § 381(d)(1). Specifically, the defendants cause the reimportation of U.S.-manufactured drugs, even those approved for use in the United States, violates the FDCA, because only the manufacturer of a drug can reimport that drug into the United States. 21 U.S.C. § 381(d)(1).

A. Preliminary Injunction Standard

8. Plaintiff seeks a preliminary injunction to stop defendants from further FDCA violations. Generally, an injunction may issue where the movant shows: (1) a substantial likelihood of success on the merits; (2) irreparable injury if the injunction is not granted; (3) that injury outweighs any harm the injunction will cause the opposing party; and (4) the injunction is not adverse to the public interest. O Centro Espirita Beneficente Uniao Do Vegetal v. Ashcroft, 342 F.3d 1170, 1177 (10th Cir.2003); SCFC ILC, Inc. v. Visa USA, Inc., 936 F.2d 1096, 1098 (10th Cir.1991). Where an injunction would alter the status quo, a heightened standard of scrutiny normally applies. O Centro Espirita, 342 F.3d at 1177-78, n.3.

B. Status Quo

10. In O Centro Espirita, the Court of Appeals rejected an "absolute" approach to defining the status quo, instead holding that "the definition of 'status quo' for injunction purposes depends very much on the facts of a particular case." O Centro Espirita, 342 F.3d at 1178. The status quo need not be the state of affairs immediately preceding litigation. Id.

11. Plaintiff contends that, in this case, Congress established the status quo by outlawing the activities in which the defendants now engage. Unlike the facts of O Centro Espirita itself, which implicated two seemingly conflicting federal statutes, Rx Depot's importation of prescription drugs clearly violates the law. The decision in SCFC ILC, Inc. v. Visa USA, Inc., 936 F.2d 1096 (10th Cir.1991), cited by defendants, is also distinguishable in that it involved a dispute between two private litigants. Id. at 1097-98. As set out above, the normal requirements applicable to private litigants do not necessarily apply where, as here, plaintiff seeks to enforce a duly enacted statute designed to protect the public. By definition, such an action can be brought only after the law is broken; where the violation is obvious, preserving the "status quo" as defendants define it would mean protecting illegal activity.

*9 12. Plaintiff has conclusively shown that the relevant statutory provisions explicitly prohibit exactly what the defendants' continue to do. Weighing the particular facts of this case, as required by O Centro Espirita, the Court finds that the defendants altered the status quo when they began to build a nationwide business based on violating the...
FDCA. Thus, their actions constitute the requisite furtherance of these transactions prohibited by the established more than a substantial likelihood that it liable under FDCA those who have a "responsible injunction by this Court. Defendant Moore admitted v. Dotterweich.

that his storefronts would remain open absent a court order. Even aside from this admission, the probability of future violations may be inferred from past unlawful conduct. Commodity Futures Trading Commission v. British American Commodity Options Corp., 560 F.2d 135, 142 (2d Cir.1977); see Odessa Union, 833 F.2d at 176.

16. As discussed above, weighing the respective harms to the parties is not required here; even were such a test necessary, the defendants would suffer only the "harm" of being ordered to refrain from illegal activity. Despite the defendants' assertions to the contrary, the FDCA is a constitutional exercise of the commerce power. United States v. Walsh, 331 U.S. 432, 434 (1947). The defendants have no vested interest in an illegal business activity. Diapulse, 457 F.2d at 29 (citations omitted); see also U.S. v. Articles of Drug, 825 F.2d 1238, 1248 (8th Cir.1987) (a defendant may not successfully defend against the issuance of an injunction by assertions that the injunction would drive it out of business.).

17. As stated above, plaintiff need only show the defendants' violations of the FDCA in order to prove public harm. "The passage of the statute is, in a sense, an implied finding that violations will harm the public and ought, if necessary, be restrained." Diapulse, 457 F.2d at 28 (citing United States v. City and County of San Francisco, 310 U.S. 16 (1940)); see Biogonic Safety Brands, Inc. v. Ament, 310 U.S. 277, 284 (1943) (holding that the defendants' actions constitute the requisite "causing" under 21 U.S.C. § 331. See United States v. Dotterweich, 320 U.S. 277, 284 (1943) (holding liable under FDCA those who have a "responsible share in the furtherance of the transaction which the act unlawful"); United States v. Brittain, 931 F.2d 1413, 1419 (10th Cir.1991) (applying the same rationale to the Clean Water Act). Plaintiff has established more than a substantial likelihood that it will succeed on the merits.

18. The Court recognizes that individual customers of the defendants believe that they benefit from the low prescription drug prices offered by Rx Depot/Rx Canada. This Court is not unsympathetic to
the predicament faced by individuals who cannot afford their prescription drugs at U.S. prices. However, the defendants are able to offer lower prices only because they facilitate illegal activity determined by Congress to harm the public interest. Congress, not this Court, is the best forum for weighing all of the costs and benefits of the national statutory scheme regulating prescription drug importation. Cf. United States v. 91 Kg. Containers, More or Less, of an Article of Drug for Veterinary Use, 854 F.2d 173, 179 (7th Cir.1988) ("Subjects such as these [FDA approval and certification process] are for Congress and the FDA to consider. Judges' role is to decipher and enforce the existing scheme, whatever they think of its wisdom.").

D. Selective Enforcement Claim

19. Defendants' claim of unconstitutionally selective enforcement by FDA is unavailing. FDA's personal importation policy outlines specific circumstances in which the agency generally will decline to prosecute the illegal importation of small quantities of prescription drugs by individuals. By its express terms, this policy of enforcement discretion does not apply to commercial operations such as Rx Depot/Rx Canada. See Pl.Ex. 21.

20. Moreover, the Supreme Court has held that "an agency's decision not to proseute or enforce, whether through civil or criminal process, is a decision generally committed to an agency's absolute discretion." Heckler v. Cheney, 470 U.S. 821, 831 (1985). To prevail on a claim of selective prosecution, therefore, the defendants must show that others similarly situated have not been subject to enforcement proceedings by the government, and that there was a constitutionally impermissible basis for the decision to institute enforcement action against the defendants such as race, religion, or other arbitrary classification. United States v. Armstrong, 517 U.S. 456, 464-65 (1996) (citing Oyler v. Boles, 368 U.S. 448, 456 (1962)); Wayne v. United States, 470 U.S. 598, 608 (1985). Defendants have made no such showing here. Instead, the defendants point to FDA's failure to prosecute all individuals who cross the Canadian border on their own or use the Internet to buy their prescription drugs. Defendants claim that this fact evidences some vague policy of "geographical" discrimination. It is reasonable, however, for FDA to marshal its limited resources against large-scale, commercial operations such as Rx Depot/Rx Canada rather than small-scale, individual violators.
articulated in a statute, as to what behavior should be prohibited. 'Once Congress, exercising its delegated powers, has decided the order of priorities in a given area, it is ... for the courts to enforce them when enforcement is sought."


III. CONCLUSION

27. FDA warned the defendants that their violations would subject them to enforcement action. Notwithstanding this warning, the defendants failed to comply with the FDCA; in fact, they expanded their operations. Unless restrained by order of this Court, the defendants will continue to violate 21 U.S.C. § 331(d) and (i).

28. Plaintiff's motion for a preliminary injunction (Dkt.# 2) is granted.

29. For the same reasons described herein, defendants' motion for a preliminary injunction (Dkt.# 10) is denied.

30. Plaintiff's motion in limine (Dkt.# 11) is granted as to lay testimony regarding safety and effectiveness of particular drugs, and denied as moot as to all other evidence sought to be excluded.

*12 31. Any finding of fact which is more appropriately characterized as a conclusion of law is incorporated herein.

ORDER OF PRELIMINARY INJUNCTION

Plaintiff, United States of America, having filed a complaint for injunction and a motion for preliminary injunction against defendants Rx Depot, Inc. and Rx of Canada, LLC, corporations, and Carl Moore and David Peoples, individuals (collectively "defendants"); and defendants having filed their own motion for preliminary injunction; and the Court having heard the evidence at a hearing on October 8-9, 2003; and the Court having considered the pleadings, the evidence, and arguments of counsel; and having entered its findings of fact and conclusions of law simultaneously herewith; and it appearing that the defendants are violating and, unless restrained by order of this Court, will continue to violate the Federal Food, Drug, and Cosmetic Act (the "Act"), 21 U.S.C. § 331(d), by importing, or causing importation of, drugs in violation of 21 U.S.C. § 381(d)(1), and by introducing or delivering for introduction, or causing to be introduced or delivered, into interstate commerce unapproved new drugs; and it appearing that, despite repeated warnings that their actions violate the law, the defendants will not stop these illegal practices unless enjoined by the Court; and it appearing that the defendants' practices expose the public health to risk.

IT IS HEREBY ORDERED, ADJUDGED, AND DECREED that:

1. This Court has jurisdiction over the subject matter herein and has personal jurisdiction over all parties to this action.

2. The complaint for injunction states a cause of action against the defendants under the Act, 21 U.S.C. § 332 et seq.

3. There is a substantial likelihood that plaintiff will succeed on the merits of its claim that the defendants violate 21 U.S.C. § 331(d), by importing, or causing to be imported, into the United States drugs that were manufactured in the United States by persons other than the defendants, in violation of 21 U.S.C. § 381(d)(1).

4. There is a substantial likelihood that plaintiff will succeed on the merits of its claim that the defendants violate 21 U.S.C. § 331(d), by doing or causing the introduction or delivery for introduction into interstate commerce of drugs that are new drugs within the meaning of 21 U.S.C. § 321(p), that have not been approved by the Food and Drug Administration ("FDA"), in violation of 21 U.S.C. § 355(a).

5. The defendants and each and all of their officers, agents, representatives, employees, successors, assigns, attorneys, and any and all persons in active concert or participation with any of them (including franchisees, affiliates, and "doing business as" entities) who have received actual notice of this Order by personal service or otherwise, are hereby preliminarily restrained and enjoined under 21 U.S.C. § 332(a), from directly or indirectly doing or causing, during the pendency of this action, the introduction, or delivery for introduction into interstate commerce, including, but not limited to, the importation of, any article of drug, and from directly or indirectly receiving any commission associated with the refill of any prescription.

*13 6. Upon the entry of this Order, the persons and entities identified in the preceding paragraph shall cease offering, advertising, or promoting, through
any media, including, but not limited to, the websites www.rxdepot.com and www.rxofcanada.net, any service that causes or facilitates the importation or assistance in importing articles of drug from any place outside the United States.

7. Within 10 calendar days of entry of this Order, the defendants shall send a letter, which must be approved in advance in writing by FDA, to all of their customers notifying them that the defendants' business violates the law and that the safety, purity, and efficacy of drug products obtained through the defendants cannot be assured.

8. Representatives of FDA shall be permitted, without prior notice and as and when FDA deems necessary, to make inspections of the defendants' facilities and, without prior notice, take any other measures necessary to monitor and ensure continuing compliance with the terms of this Order. During such inspections, FDA investigators shall be permitted access to all equipment, finished and unfinished drugs, and all labeling, including promotional materials and website information; to take photographs and make video recordings; to take samples of the defendants' finished and unfinished materials and products, containers, and labeling; and to examine and copy all records relating to product formulation, adverse reactions, complaints, the relationship between defendants and their franchisees, affiliates, and "doing business as" entities, the ordering of prescription drugs from Canada and any other countries, and the receipt, processing, labeling, packing, manufacture, and distribution of any product. Such inspections shall be permitted upon presentation of a copy of this Order and appropriate credentials. The inspection authority granted by this Order is apart from, and in addition to, the authority to conduct inspections under 21 U.S.C. § 374.

9. The defendants shall provide a copy of this Order, by personal service or registered mail, within 10 calendar days of its entry, to each of their officers, agents, representatives, employees, successors, assigns, attorneys, and any and all persons in active concert or participation with any of them (including all franchisees, affiliates, and "doing business as" entities). The defendants shall provide an affidavit of compliance, signed by a person with personal knowledge of the facts, stating the fact and manner of compliance with the first sentence of this paragraph, and identifying the names and positions of all persons so notified, to FDA within 30 calendar days after the date of entry of this Order. All physical locations and websites shall be identified as such in this written affidavit to FDA.

10. If the defendants or any of their officers, agents, representatives, employees, successors, assigns, attorneys, and any and all persons in active concert or participation with any of them (including, but not limited to, franchisees, affiliates, and "doing business as" entities) violate this Order and are found in civil or criminal contempt thereof, the defendants shall, in addition to other remedies, pay attorney fees, travel expenses incurred by attorneys and witnesses, court costs, expert witness fees, and investigational and analytical expenses incurred by plaintiff in bringing such action.

2003 WL 22519473, 2003 WL 22519473 (N.D.Oka.)
Attachment H
Memorandum

To: Enforcement Committee  

From: Patty Harris  
Executive Officer  
Board of Pharmacy  

Subject: Implementation of Compliance Provisions from SB 361

SB 361 (Figueroa) was the legislative vehicle for the Board of Pharmacy sunset extension and contained statutory recommendations approved by the Joint Legislative Sunset Review Committee. The following compliance provisions will be added to California Pharmacy Law effective January 1, 2004.

- **Add Section 4083 – Order of Correction**
  Will allow an inspector to issue an order of correction to a licensee directing the licensee to comply with pharmacy law within 30 days by submitting a corrective action plan to the inspector, or the licensee can contest the order of correction to the executive officer for an office conference. If an office conference is not requested, compliance with the order does not constitute an admission of the violation noted in the order of correction and the order of correction is not considered a public record for purposes of disclosure. A copy of the order of correction and corrective action plan must be maintained on the license premise for at least three years from the date the order was issued.

- **Add Section 4315 – Letter of Admonishment**
  Will authorize the executive officer to issue a letter of admonishment to a licensee for failure to comply with pharmacy law and directs the licensee to come into compliance within 30 days by submitting a corrective action plan to the executive officer documenting compliance, or the licensee can contest the letter of admonishment to the executive officer for an office conference. If an office conference is not requested, compliance with the letter of admonishment does not constitute an admission of the violation noted in the letter of admonishment. The licensee must maintain on the licensed premises a copy of the letter of admonishment and corrective action plan for at least three years from the date the letter was issued. The letter of admonishment will be considered a public record for purposes of disclosure.

- **Add Section 4314 – Issuance of Citations**
  Will allow the board to issue an order of abatement that will require a person or entity to whom a citation has been issued to demonstrate how future compliance with the pharmacy law will be accomplished and provides that such demonstration may include, but not be limited to,
submission of a corrective action plan, as well as requiring the completion of up to six hours of continuing education courses in subject matter specified in the order of abatement.

These new changes will be incorporated into the board’s investigation process as follows:

During a routine inspection or investigation, if it is believed that a violation of pharmacy law took place, the licensee may be advised of the alleged violation by an “Order of Correction,” directing the licensee to comply with pharmacy law within 30 days by submitting a corrective action plan to the inspector. This process will simply notify the licensee of the violations of law that the inspector believes occurred. This notification may not be the board’s final or formal determination regarding the matter depending on the seriousness of the alleged violation. It is also neither a citation nor is it a disciplinary action.

At this time, the licensee will be provided the opportunity to provide a written response to the alleged violation. In the written response, the licensee may address the specifics of the violation, as well as provide any mitigatory information that the licensee wishes to have included in any investigation report and/or a corrective action plan.

If the “Order of Correction” is for minor violations, and the inspector is satisfied with the pharmacy’s compliance, the “Order of Correction” may be the only action taken. If this is the case and the pharmacy doesn’t contest the order, then the licensee must maintain on the pharmacy premises a copy of the order of correction and corrective action plan for at least three years from the date the order was issued.

After the inspection or investigation is completed and there is a determination that the law was violated, the case is referred to a supervising inspector for review. If the supervising inspector determines that there was no violation or that the violation was so minor that the only action to take would be the issuance of the “Order of Correction”, then the case may be closed and the matter goes no further.

If, after review by the supervising inspector, it is determined that action may be warranted, the case is referred to the executive officer. The executive officer, with the assistance of the supervising inspector, reviews the matter and determines the appropriate course of action. In making this determination, the following factors may be taken in consideration:

- Gravity of the violation.
- Good or bad faith of the cited person or entity.
- History of previous violations.
- Evidence that the violations were or were not willful.
- Recognition by the licensee of his/her wrongdoing and demonstration of corrective action to prevent recurrence, e.g., new policies and procedures, protocol, hiring of additional staff, etc.
- Extent to which the cited person or entity has cooperated with the Board’s investigation and other law enforcement or regulatory agencies.
- Extent to which the cited person or entity has mitigated or attempted to mitigate any damage or injury caused by the violation.
- If the violation involved multiple licensees, the relative degree of culpability of
each licensee should be considered. In the case where a staff pharmacist may
have failed to consult, the pharmacist-in-charge and the pharmacy may also be
issued a citation and fine, if warranted by the circumstances.
• Any other relevant matters that may be appropriate to consider.

The type of potential action include:

• **Further Investigation**
The executive officer may decide that there is insufficient evidence to determine if a violation
occurred or if any action is warranted. The executive officer may then send the matter back for
further investigation.

• **Case Closure – No Further Action**
The executive officer may decide that no action is now warranted. This may occur when the
executive officer determines that there was no violation, that the violation was so minor as to not
merit an action, or that the mitigating circumstances were such that it would be best not to pursue
an action. The matter will then not be taken any further. (The final resolution would be the
“Order of Correction”.)

• **Letter of Admonishment**
The executive officer may decide to issue a letter of admonishment. This may occur when the
executive officer determines that there was a minor violation, or a violation that mitigating
circumstances were such that a letter of admonishment was appropriate. The licensee would be
directed to come into compliance within 30 days by submitting a corrective action plan to the
executive officer documenting compliance, or the licensee can contest the letter of
admonishment to the executive office for an office conference.

If an office conference is not requested, compliance with the letter of admonishment does not
constitute an admission of the violation noted in the letter of admonishment. The licensee must
maintain on the licensed premises a copy of the letter of admonishment and corrective action
plan for at least three years from the date the letter was issued. The letter of admonishment
would be considered a public record for purposes of disclosure.

• **Citation and Fine**
The executive officer may issue a citation, with or without a fine. The citation will be issued to
the licensee and will include a reference to the statute or regulation violated. It will also include
a description of the nature and facts of the violation, as well as a notice to the licensee of the
appeal rights. It may or may not include an order of abatement either requesting documentation
of the licensee’s compliance, or directing the licensee to come into compliance and specifying
how that must be done.

• **Disciplinary Action**
The executive officer may determine that the violation is substantial and warrants discipline of
the license. The matter is then referred to the Attorney General’s Office, where, if appropriate to
do so, an accusation is prepared, which identifies the alleged violations of pharmacy law.
Attachment I
Memorandum

To: Enforcement Committee
From: Patricia F. Harris
      Executive Officer
      Board of Pharmacy

Subject: Implementation of SB 151

Senate Bill 151 (Burton) repeals the triplicate prescription requirement for Schedule II controlled substance prescriptions and substantially revises California law regarding the prescribing of controlled substances generally. This memo will outline the changes contained in this legislation. Generally, this bill repeals the triplicate and replaces it with a tamper resistant prescription form that may be obtained from approved printers. This new form will be required for all controlled substance prescriptions after the phase-in period. The bill also will require pharmacies to report Schedule III controlled substance prescriptions to the CURES system.

**EFFECTIVE JANUARY 1, 2005**

- Triplicate prescription forms are no longer valid.
- All written controlled substance prescriptions (oral and fax orders for Schedules III-V are still permitted) shall be on the new controlled substance prescription forms.
- Pharmacies must report Schedule III controlled substance prescription information to the CURES system.
- Prescribers dispensing Schedule III controlled substances must report those prescriptions to the CURES system.
- The exemption for Schedule II prescriptions for the terminally ill remains in effect (H&S Code 11159.2)

**IMPLEMENTATION PHASE I**

January 1, 2004 – June 30, 2004

- The Board of Pharmacy (board) and the Department of Justice (Department) may approve security printers to produce the new controlled substance prescription forms.
• California mail order pharmacies can apply the prescription requirements of the state in which the patient resides when filling schedule II prescriptions.

• Controlled substance prescriptions (Schedules II-V) are valid for six-months.

• Makes CURES permanent and requires all pharmacies to report Schedule II controlled substance prescriptions to the Department of Justice.

• Prescribers only need to sign and date Schedule III-IV controlled substance prescriptions (consistent with current Schedule II prescription requirements).

• New controlled substance prescription forms may be acquired from approved security printers.

• Requires the new controlled substance prescription forms to have the following features:
  1. Latent "void" protection so that if a prescription is scanned or photocopied, the word "void" shall appear in a pattern across the entire front of the prescription.
  2. Watermark with the text "California Security Prescription" printed on the back of the prescription.
  3. Chemical void protection that prevents alteration by chemical washing.
  4. Feature printed in thermo-chromic ink (the ink changes color when exposed to heat).
  5. Feature using micro printing (the text becomes a line if the prescription is copied or scanned).
  6. Description of the security features included on each prescription form.
  7. Quantity check off boxes printed on the form in the following quantities: 1-24, 25-49, 50-74, 75-100, 101-150, 151 and over.
  8. Either of the following statements:
     (a) "Prescription is void if more than one controlled substance prescription is written per blank" or
     (b) Contain a space for the prescriber to specify the number of drugs prescribed on the prescription and a statement printed on the bottom of the prescription blank that the "Prescription is void if the number of drugs prescribed is not noted."
  9. The preprinted name, category of licensure, license number, and federal controlled substance registration number of the prescribing practitioner.
  10. A check box indicating the prescriber's order not to substitute.
  11. Each batch of controlled substance prescription forms shall have the lot number printed on the form and each form within that batch shall be numbered sequentially beginning with the numeral one.

**IMPLEMENTATION PHASE II**
*July 1, 2004 – December 31, 2004*

• The Department of Justice no longer will produce or distribute triplicate prescription forms. However, prescribers can continue to use the triplicate prescription forms to prescribe Schedule II controlled substances.
• Prescribers may use the new controlled substance prescription forms for Schedule II controlled substance prescriptions.

• Oral and electronic orders for Schedule II controlled substance prescriptions for patients in skilled nursing facilities, intermediate care facilities, home health care programs, and hospice programs are permitted and must be reduced to a hard copy form of the pharmacy’s design and signed by the pharmacist.

• Prescribers that dispense Schedule II controlled substances must report those prescriptions to the CURES system.
Written Controlled Substance Prescriptions

- Written Controlled Substance Prescriptions that are less than 6 months old (January 1, 2005)
- Is it on a triplicate form?
  - Yes: Proceed with normal controlled substance dispensing practices
  - No: Is it signed and dated by the prescriber?
    - Yes: Retain original security prescription for 3 years
    - No: Not a valid prescription
- Not a valid prescription

Revised 12/2/2003
Written Controlled Substance Prescriptions

1. Written Controlled Substance Prescriptions less than 6 months old (July 1, 2004 to January 1, 2005)

2. Is it for a Schedule II drug?
   - No
   - Yes

   a. Is it designated as a 11159.2 exemption?
      - No
      - Yes

      b. Is it on a security prescription form or a triplicate form?
         - No
         - Yes

         c. Is it signed and dated by the prescriber?
            - No
            - Yes

            d. Proceed with normal controlled substance dispensing practices

3. Proceed with normal controlled substance dispensing practices

   a. Retain original security form or regular prescription form for 3 yrs.
   b. Send original triplicate form to DOJ

Revised 12/2/2003
Oral, Fax, and Electronic Controlled Substance Prescriptions

Oral, Fax, & Electronic Rx’s not allowed for any other Schedule II Rx’s

Is it from:
- Skilled Nursing Facility
- Intermediate Care Facility
- Hospice Home Health Care?

Yes
- RPH reduces to hard copy
- RPH signs and dates

Yes
Proceed with normal controlled substance dispensing practices

No

Is it a Schedule II drug?

Yes
RPH reduces to hard copy

No

Is it for a Schedule III, IV, or V drug?

Yes
RPH reduces to hard copy

No

Non-Controlled Substance Proceed with normal dispensing practices

Retain original prescription record for 3 years

Fax, Oral, or Electronic Controlled Substance Prescriptions
Less than 6 Months Old (July 1, 2004 to January 1, 2005)

NOTE: Faxied prescriptions on new security form will come through as "VOID", the pharmacist must institute procedures for verifying authenticity prior to dispensing.
Attachment J
ENFORCEMENT COMMITTEE MEETING

Meeting Summary
December 10, 2003

Department of Consumer Affairs
400 R Street, Suite 4070
Sacramento, CA 95814

Present: John Jones, Chair and Board President
Bill Powers, Board Member
Patricia Harris, Executive Officer
Virginia Herold, Assistant Executive Officer
Robert Ratcliff, Supervising Inspector
Judi Nurse, Supervising Inspector
Dennis Ming, Supervising Inspector
Joan Coyne, Supervising Inspector
Board of Pharmacy Inspectors
Joshua Room, Deputy Attorney General
Enforcement Staff

Call to Order

Enforcement Committee Chair John Jones called the meeting to order at 9:30 a.m.

Reimportation of Prescription Drugs from Canada

Committee Chair John Jones reported that the board has been discussing and has sought comments on the issue of prescription drug importation from outside of the United States. This has been a sensitive and controversial issue. The board has been tasked with balancing consumer access to affordable prescriptions against the safety and effectiveness of drugs obtained from foreign sources. The board has heard from many interested parties on this issue during its committee meetings and at its quarterly board meetings.

During its October meeting, the board decided to hold a summit on prescription drug importation. The plan is to invite leaders representing all sides of the issue in an effort to fully discuss the health care policy concerns inherent with this topic.

Mr. Jones stated that on November 6th, the United States District Court for the Northern District of Oklahoma ruled that Rx Depot/Rx Canada violated federal law by causing the importation of prescriptions drugs from Canadian pharmacies. Rx Depot/Rx Canada assists individuals in procuring prescription medications from pharmacies in Canada. Each location has one or two
employees who accept prescriptions from U.S. customers. Customers are asked to fill out a medical history form and other forms provided by Rx Depot/Rx Canada. Customers can deliver these documents to Rx Depot/Rx Canada’s stores in person, or can mail or fax them to the nearest Rx Depot/Rx Canada store.

Once a Rx Depot/Rx Canada customer has submitted the required forms and prescriptions, the papers and the customer’s credit card information or a certified check are transmitted to an operating pharmacy in Canada. A Canadian doctor rewrites the prescription, and the Canadian pharmacy fills the prescription, ships the prescription drugs directly to the U.S. customer, and bills the U.S customer’s credit card. Rx Depot/Rx Canada receives a 10 to 12 percent commission for each sale they facilitate for the Canadian pharmacies. They also receive commissions for refill orders, which generally are arranged directly between customers and the Canadian pharmacies. It was noted that Rx Depot/Rx Canada stores are essentially commissioned sales agents for Canadian pharmacies.

The decision called for immediate closing of the 88 nationwide Rx Depot/Rx Canada affiliates, including 17 California locations. Rx Depot/Rx Canada appealed the decision. On November 21st, the 10th Circuit Court of Appeals decision denied the motion from Rx Depot to stay the District Courts ruling.

Proposed Citation and Fine Statute for Wholesale Violations and Proposals Regarding Wholesale Drug Transactions

Committee Chair John Jones commented that the Enforcement Committee has been engaged in a process of developing rules designed to strengthen the regulation of drug wholesalers. The committee has considered a number of different proposals. Based on discussions at prior committee meetings and discussion at the October 2003 board meeting, staff developed a legislative proposal for the committee’s consideration. The proposal includes elements that have been considered previously, most notably expanded citation and fine authority for certain violations, and elements drawn from recent legislation passed in Florida. The recent Florida legislation focused on preventing the introduction of counterfeit drugs into the system by implementing stricter licensing requirements for drug wholesalers, increasing the criminal sanctions for counterfeiting prescription drugs, and requiring pedigrees.

The proposal is designed to address challenges presented by the existing distribution system for prescription drugs. The proposal also includes changes to wholesale licensing requirements approved by the board at its October 2003 meeting. The principal elements were described as follows:

- Require pedigrees for all drug shipments beginning January 1, 2006.
- Generally prohibits the wholesaling of prescription drugs by pharmacies.
- Require wholesalers to obtain a $100,000 bond to secure payment of administrative fines and penalties.
- Permit the board to issue fines on a per occurrence basis for specified violations (e.g., sale of counterfeit drugs, sale of outdated drugs, failure to preserve records, etc.)
• Defines “closed door pharmacy” as one serving skilled nursing and intermediate care facilities and prohibits the owners of a closed-door pharmacy from owning a wholesale facility.

There was considerable discussion regarding the proposals. Many supported better screening procedures prior to the issuance of a wholesale license that would enhance product safety. There was reference to the Healthcare Distribution Management Association’s (HDMA) guidelines to assure integrity of the pharmaceutical distribution system to strengthen efforts to prevent the counterfeiting of products. The HDMA guidelines recommend that distributors conduct due diligence, background checks, on-site inspections and ongoing reviews of suppliers and purchasers to ensure compliance with federal and state laws pertaining to prescription drugs.

Comments were made regarding the proposed pedigree requirement. It was discussed that electronic tracking capabilities will significantly prevent counterfeiting. However, the technology will not be available until the middle of 2004. Meanwhile, Florida requires a paper pedigree for “high risk” drugs and then in 2006, will require pedigrees for all drugs. It was argued that a pedigree requirement would slow down the distribution of drugs and restrict commerce.

Concern was expressed that there should be uniformity among the 50 states. It was recommended that the FDA strengthen the PDMA guidelines to establish uniform national licensing standards and electronic tracking guidelines for qualified pharmaceutical distributors. Additionally, there should be stronger criminal and administrative penalties and enforcement actions against product counterfeiting.

The committee recommended that board support the statutory proposals. Committee Chair John Jones advised the public that the proposals would be discussed at the January board meeting and encouraged the interested parties to submit written comments and language modifications for board consideration.

Medical Board of California (MBC)/Board of Pharmacy Joint Task Force on Prescriber Dispensing

Committee Chair John Jones reported that the Medical Board of California (MBC) and the Board of Pharmacy held a joint task force meeting on the issue of prescriber dispensing. The meeting was held on May 27, 2003, and the task force reached consensus on the following: (1) Under current law, an individual prescriber can own his/her own prescription stock and dispense to his or her own patients as specified and such practice should be allowed to continue with the goal of strengthening and educating prescribers regarding the record keeping requirements; (2) Allow a medical group to dispense prescription medications pursuant to a special permit issued by the Board of Pharmacy and specified conditions that require one physician from the medical group to be responsible and accountable for the security of the prescription medications, record keeping requirements, and a consultant pharmacist reviews the dispensing process; (3) Establish the authority for a pharmacy to place an automated dispensing device in a prescriber’s office; and (4) Provide for joint oversight by the appropriate licensing agencies.
The task force agreed that staff from the two boards would work together to draft language for each board to consider as a possible joint legislative proposal for 2004. Draft language was developed and the Medical Board task force members provided comments on the draft. The language was reworked to address their comments. The proposal would require a special clinic licensure for these group practices, which would have a significant fiscal impact to the board.

The language was first provided to the Enforcement Committee at its September meeting. However, it was requested that the committee postpone its discussion until the interested parties had more time to review the proposal and submit comments. The Enforcement Committee agreed to discuss the issue at its December meeting.

There was considerable discussion that the legislative proposal would authorize the Board of Pharmacy to issue a clinic permit to a medical group and this was not in the best interest of the public. Moreover, it was argued that it was contrary to current law, which prohibits prescribers from owning pharmacies. There was also concern about the proposed amendment to Business and Professions Code section 4170(a) that would allow a registered nurse to hand to a patient the medication that is dispensed by the prescriber. Although there is an Attorney General Opinion (57 Op. Att’y Gen. 93 (1974)) that states that a nurse may assist, at the prescriber’s direction, in the dispensing of such drugs, including handing them to the patient, it was noted that this opinion was prior to the most recent amendments to section 4170 that took place over 10 years ago.

The committee did not take any action and referred the matter to the board for its consideration at the January meeting.

**Implementation of Enforcement Provisions from SB 361 (Chapter 539, Statutes of 2003)**

Executive Officer Patricia Harris reported that SB 361 (Figueroa) was the legislative vehicle for the Board of Pharmacy sunset extension and contained statutory recommendations approved by the Joint Legislative Sunset Review Committee. The following compliance provisions will be added to California Pharmacy Law effective January 1, 2004.

- **Add Section 4083 – Order of Correction**
  Will allow an inspector to issue an order of correction to a licensee directing the licensee to comply with pharmacy law within 30 days by submitting a corrective action plan to the inspector, or the licensee can contest the order of correction to the executive officer for an office conference. If an office conference is not requested, compliance with the order does not constitute an admission of the violation noted in the order of correction and the order of correction is not considered a public record for purposes of disclosure. A copy of the order of correction and corrective action plan must be maintained on the license premise for at least three years from the date the order was issued.

- **Add Section 4315 – Letter of Admonishment**
  Will authorize the executive officer to issue a letter of admonishment to a licensee for failure to comply with pharmacy law and directs the licensee to come into compliance within 30 days by
submitting a corrective action plan to the executive officer documenting compliance, or the licensee can contest the letter of admonishment to the executive office for an office conference. If an office conference is not requested, compliance with the letter of admonishment does not constitute an admission of the violation noted in the letter of admonishment. The licensee must maintain on the licensed premises a copy of the letter of admonishment and corrective action plan for at least three years from the date the letter was issued. The letter of admonishment will be considered a public record for purposes of disclosure.

- **Add Section 4314 – Issuance of Citations**

  Will allow the board to issue an order of abatement that will require a person or entity to whom a citation has been issued to demonstrate how future compliance with the pharmacy law will be accomplished and provides that such demonstration may include, but not be limited to, submission of a corrective action plan, as well as requiring the completion of up to six hours of continuing education courses in subject matter specified in the order of abatement.

The committee discussed how these new changes will be incorporated into the board’s investigation process.

**Implementation of SB 151 (Chapter 406, Statutes of 2003) – New Prescription Requirements for Controlled Substances and the Elimination of the Triplicate**

Committee Chair John Jones reported that Senate Bill 151 (Burton) repeals the triplicate prescription requirement for Schedule II controlled substance prescriptions and substantially revises California law regarding the prescribing of controlled substances generally. The committee was given a memorandum that outlined the changes contained in the legislation. Flow charts were provided that displayed the prescription dispensing process for controlled substance prescriptions.

It was stated that generally, SB 151 repeals the triplicate and replaces it with a tamper resistant prescription form that may be obtained from approved printers. This new form will be required for all controlled substance prescriptions after the phase-in period. The bill also will require pharmacies to report Schedule III controlled substance prescriptions to the CURES system.

The committee discussed the phase in of the legislation and responded to questions regarding implementation. Mr. Jones explained the extensive educational efforts that the board plans to undertake and added that information on the bill will be placed on the board’s Website in January.

**Review of the Quality Assurance Program**

Ms. Harris reported that in January 2002, the quality assurance regulation became effective and the board began its implementation. During the first six months of implementation (until July 1, 2002), the principal focus of the board’s enforcement efforts was to educate pharmacists about the new regulation. If during this first six months, the pharmacy didn’t have a quality assurance program, the inspector noted that on the inspection report and the pharmacy was requested to
come into compliance. After July 1, 2002, failure to have a quality assurance program in place and/or failure to complete a quality assurance review would have resulted in notification to the licensee, with a possible referral for additional action by the board such as the issuance of a citation and fine.

In July 2003, the board approved a proposed modification of CCR section 1711 to clarify the pharmacist’s responsibility when notifying the patient and prescriber of a prescription error. This modification was at the request of the professional associations. The modification allows for the pharmacist’s professional judgment when situations do not require immediate notification of the prescriber when a prescription error has occurred, and when the patient has not taken the wrong medication. This proposed regulation change is awaiting formal notification of the rulemaking process.

Ms. Harris provided overall statistics regarding the implementation of the program and there was a discussion on the board’s efforts to achieve compliance through the citation and fine program. There weren’t any recommendations for program changes.

**Overview of the Pharmacists Recovery Program (PRP) and Probation Monitoring Program**

Supervising Inspector Joan Coyne and PRP Manager Anne Sodergren provided an overview on the PRP and probation monitoring programs. They reported that the PRP has been in place for 13 years and the law requires the board to seek ways and means to identify and rehabilitate pharmacists whose competency may be impaired due to the abuse of alcohol or other drugs, or due to mental illness, so that pharmacists and interns so afflicted may be treated and returned to the practice of pharmacy in a manner which will not endanger the public health and safety. The law requires the board to contract with one or more employee assistance programs to administer the PRP and to contract with a pharmacist’s professional association to perform outreach and promote voluntary access to the program.

The program serves two distinct functions. The PRP serves as a diversion program to which the board may refer licentiates, where appropriate, either in lieu of or in addition to disciplinary action. The PRP is also a confidential source of treatment for pharmacists who enter the program on a voluntary basis and without the knowledge of the board. Irrespective of the type of referral into the program, all participants are afforded the same treatment opportunities in the PRP.

Currently the board contracts with Maximus to administer the PRP. Ms. Coyne stated that a licensed clinician evaluates all participants entering the PRP. The initial evaluation identifies the nature and severity of the problem. Initial recommendations are made regarding the treatment and an initial treatment contract is established based on the recommendations.

Treatment plans for a chemically dependent participant typically include total abstinence from alcohol or other mood altering chemicals, inpatient or outpatient treatment, documented attendance 3-5 self-help groups such as Alcoholics Anonymous (AA) and/or Narcotics Anonymous (NA) per week and at least 1-2 support groups. The support groups are conducted
under the guidance of a licensed clinician and are comprised of health care professionals in recovery. These support groups serve as a forum for health care professional to discuss their recovery and may be used to confront a participant who may be acting inappropriately or who is not embracing recovery. A random body fluid testing scheduled is established usually averaging between 24 – 36 urines screens a year (depending on the length of sobriety and severity of the addiction). Failure to maintain sobriety results in the immediate suspension from practice and usually requires at least a 30 - 90 day stay in residential treatment. Upon completion of this residential treatment, outpatient treatment is typically required in addition to support group attendance and attendance at AA and/or NA meetings.

PRP participation is usually a three to five year commitment depending on the severity of the drug abuse or mental illness. The mandatory length of participation must be at minimum one year unless two separate assessments are completed, both of which must conclude that the licensee is not appropriate for diversion. A transition phase, which may begin after at least 24 consecutive months of recovery and a minimum of 24 negative random body fluid tests allows the participant the opportunity to be responsible for his or her own recovery while still in the PRP. A participant who meets all the criteria for completion and who has demonstrated that he or she is a rehabilitated will be successfully completed from the PRP after completing this transition phase and a negative hair test.

Ms. Sodergren reported that since the program began, 539 pharmacists and interns have received services from the program and 472 participants have been closed out of the program. Approximately 50% of the licensees enrolled in the program are either self-referrals or board informal referrals. Of the participants closed from the program, 109 participants were closed out for either non-compliance or failure to derive benefit. In all circumstances where a participant has been mandated into the program and fails to successfully complete the program, the board will pursue additional disciplinary action. If a participant was a self-referral, the board will also complete an investigation and take appropriate action if the licensee was identified by the contractor as posing a threat to the health and safety of the public.

During the last fiscal year the age of new participants ranged between 35 – 54 years. Practice settings at the time of enrollment for these new participants included 42% in the retail pharmacy, 30% in the hospital pharmacy and the balance working in an assortment of other work settings. Alcohol was the highest reported drug used by these new participants in the previous 12 months prior to enrollment. The other most frequently reported drugs used included Tussionex® (or the generic equivalent), Soma®, Valium®, Heroine®, Hydrocodone, Hydromorphone, Morphine.

**Probation Program**

Enforcement Analyst Susan Cappello explained that the probation requirements for licensees are found in the California Code of Regulations sections 1773 and 1774. The Probation/PRP Team is responsible for monitoring probationers and participants in the PRP.

When a licensee is placed on probation, within 30 days of the effective date, an interview is scheduled for the probationer with the supervising inspector and another member of the
probation team. The purpose of this interview is to review the terms and conditions of probation to ensure the probationer understands what is expected during the probation period.

Each month, the board’s probation monitoring coordinator reviews each probation record to ascertain compliance with the terms and conditions. If a probationer is found to be non-compliant with any of the terms and conditions of probation, a letter is sent requesting compliance within 15 days. Continued non-compliance may result in either the probationer being scheduled for a probation office conference or being referred to the Attorney General’s Office with a request to file a petition to revoke probation. Additionally, the board may cite and fine a probationer for non-compliance in lieu of being referred to the Attorney General’s Office for formal action.

The board monitors approximately 129 pharmacists, 21 pharmacies and 24 other licensees on probation each year. Within the last three years, 14 probationers were referred to the Attorney General’s Office for preparation of a petition to revoke probation due to either a serious non-compliance with the terms of probation or for continued non-compliance with the monitoring aspects of probation.

Meeting Dates for 2004

The committee set the meeting dates for 2004. They are: March 18th, June 23rd, September 29th and December 2nd.

Adjournment

Committee Chair John Jones adjourned the meeting at 12:30 p.m.
Attachment K
Enforcement Team Meeting  
December 10, 2003  
2:00 p.m. – 3:30 p.m.  

Present:  
Committee Chair and Board Member John Jones  
Executive Staff  
Supervising Inspectors  
Inspectors  
Enforcement Staff  

Announcements/Introductions  
Committee Chair John Jones called the meeting to order at 2:00 p.m.  

Quality Improvement Efforts  
Supervising Inspector Dennis Ming reported that 1,101 routine inspections have been performed since July 1, 2003, which resulted in 61 investigations. Since the program’s inception in July 2001, the board has completed 5,553 inspections.  

The supervising inspectors reported on the many significant inspector accomplishments since the last meeting. Supervising Inspector Robert Ratcliff reported on the status of completed cases. He presented the workload for each team and their significant progress. There are 902 pending complaints/investigations. Supervising Inspector Ratcliff acknowledged efforts to complete cases that were over the targeted time frames for closure and reiterated that inspectors need to focus on closing the older cases first.  

Discussion of Enforcement Committee Meeting  
The Enforcement Team discussed the agenda items from the Enforcement Committee meeting.  

Adjournment  
Committee Chair John Jones adjourned the meeting at 3:30 p.m.
Attachment L
# Board of Pharmacy Enforcement Statistics

## Fiscal Year 2003/2004

### Workload Statistics

<table>
<thead>
<tr>
<th></th>
<th>July-Sept</th>
<th>Oct-Dec</th>
<th>Jan-Mar</th>
<th>Apr-June</th>
<th>Total 03/04</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Complaints/Investigations</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Initiated</td>
<td>372</td>
<td>337</td>
<td></td>
<td></td>
<td>709</td>
</tr>
<tr>
<td>Closed</td>
<td>430</td>
<td>469</td>
<td></td>
<td></td>
<td>899</td>
</tr>
<tr>
<td>Pending (at the end of quarter)</td>
<td>935</td>
<td>867</td>
<td></td>
<td></td>
<td>867</td>
</tr>
</tbody>
</table>

### Cases Assigned & Pending (by Team) as reported December 10, 2003

<table>
<thead>
<tr>
<th>Team</th>
<th>July-Sept</th>
<th>Oct-Dec</th>
<th>Jan-Mar</th>
<th>Apr-June</th>
<th>Total 03/04</th>
</tr>
</thead>
<tbody>
<tr>
<td>Compliance Team</td>
<td>89</td>
<td>82</td>
<td></td>
<td></td>
<td>82</td>
</tr>
<tr>
<td>Drug Diversion/Fraud</td>
<td>67</td>
<td>69</td>
<td></td>
<td></td>
<td>69</td>
</tr>
<tr>
<td>Mediation Team</td>
<td>71</td>
<td>78</td>
<td></td>
<td></td>
<td>78</td>
</tr>
<tr>
<td>Probation/PRP</td>
<td>45</td>
<td>28</td>
<td></td>
<td></td>
<td>28</td>
</tr>
<tr>
<td>Enforcement</td>
<td>194</td>
<td>164</td>
<td></td>
<td></td>
<td>164</td>
</tr>
</tbody>
</table>

### Application Investigations

<table>
<thead>
<tr>
<th></th>
<th>July-Sept</th>
<th>Oct-Dec</th>
<th>Jan-Mar</th>
<th>Apr-June</th>
<th>Total 03/04</th>
</tr>
</thead>
<tbody>
<tr>
<td>Initiated</td>
<td>82</td>
<td>21</td>
<td></td>
<td></td>
<td>103</td>
</tr>
</tbody>
</table>

|                  |           |         |         |          |             |
| Closed Approved  | 122       | 42      |         |          | 164         |
| Closed Denied    | 5         | 2       |         |          | 7           |
| Total*           | 139       | 57      |         |          | 196         |

Pending (at the end of quarter) | 73 | 33 | 33 |

### Citation & Fine

<table>
<thead>
<tr>
<th></th>
<th>July-Sept</th>
<th>Oct-Dec</th>
<th>Jan-Mar</th>
<th>Apr-June</th>
<th>Total 03/04</th>
</tr>
</thead>
<tbody>
<tr>
<td>Issued</td>
<td>359</td>
<td>281</td>
<td></td>
<td></td>
<td>640</td>
</tr>
<tr>
<td>Abated</td>
<td>231</td>
<td>73</td>
<td></td>
<td></td>
<td>304</td>
</tr>
</tbody>
</table>

Total Fines Collected: $93,425.00 $377,200.00 $470,625.00

* This figure includes withdrawn applications.

** Fines collected and reports in previous fiscal year.
## Workload Statistics

<table>
<thead>
<tr>
<th>Administrative Cases (by effective date of decision)</th>
<th>July-Sept</th>
<th>Oct-Dec</th>
<th>Jan-Mar</th>
<th>Apr-June</th>
<th>Total 03/04</th>
</tr>
</thead>
<tbody>
<tr>
<td>Referred to AG's Office*</td>
<td>50</td>
<td>42</td>
<td></td>
<td></td>
<td>92</td>
</tr>
<tr>
<td>Pleadings Filed</td>
<td>24</td>
<td>26</td>
<td></td>
<td></td>
<td>50</td>
</tr>
<tr>
<td>Pending</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Pre-accusation</td>
<td>85</td>
<td>97</td>
<td></td>
<td></td>
<td>97</td>
</tr>
<tr>
<td>Post Accusation</td>
<td>67</td>
<td>76</td>
<td></td>
<td></td>
<td>76</td>
</tr>
<tr>
<td>Total</td>
<td>153</td>
<td>179</td>
<td></td>
<td></td>
<td>179</td>
</tr>
<tr>
<td>Closed**</td>
<td>26</td>
<td>22</td>
<td></td>
<td></td>
<td>48</td>
</tr>
<tr>
<td>Revocation</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Pharmacist</td>
<td>3</td>
<td>6</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Pharmacy</td>
<td>2</td>
<td>2</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Other</td>
<td>4</td>
<td>3</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Revocation, stayed; suspension/probation</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Pharmacist</td>
<td>1</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Pharmacy</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Other</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Revocation, stayed; probation</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Pharmacist</td>
<td>4</td>
<td>3</td>
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<tr>
<td>Pharmacy</td>
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<td></td>
<td></td>
</tr>
<tr>
<td>Other</td>
<td>1</td>
<td>2</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Suspension, stayed; probation</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
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<tr>
<td>Pharmacist</td>
<td></td>
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<td>Pharmacy</td>
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<tr>
<td>Other</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Surrender/Voluntary Surrender</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Pharmacist</td>
<td>2</td>
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<tr>
<td>Pharmacy</td>
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<td></td>
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<tr>
<td>Other</td>
<td>2</td>
<td>1</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Public Reproval/Reprimand</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Pharmacist</td>
<td></td>
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</tr>
<tr>
<td>Pharmacy</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Other</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Cost Recovery Requested</td>
<td>$42,992.25</td>
<td>$68,512.50</td>
<td></td>
<td></td>
<td>$111,504.75</td>
</tr>
<tr>
<td>Cost Recovery Collected</td>
<td>$36,714.86</td>
<td>$47,847.87</td>
<td></td>
<td></td>
<td>$84,562.73</td>
</tr>
</tbody>
</table>

* This figure includes Citation Appeals
### Board of Pharmacy Enforcement Statistics
#### Fiscal Year 2003/2004

<table>
<thead>
<tr>
<th>Workload Statistics</th>
<th>July-Sept</th>
<th>Oct-Dec</th>
<th>Jan-Mar</th>
<th>Apr-June</th>
<th>Total 03/04</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

** This figure includes cases withdrawn
Board of Pharmacy Enforcement Statistics  
Fiscal Year 2003/2004

Workload Statistics  
July-Sept  Oct-Dec  Jan-Mar  Apr-June  Total 03/04

Probation Statistics

<table>
<thead>
<tr>
<th>Probation Office Conferences</th>
<th>8</th>
<th>5</th>
</tr>
</thead>
<tbody>
<tr>
<td>Probation Site Inspections</td>
<td>35</td>
<td>17</td>
</tr>
<tr>
<td>Probationers Referred to AG for non-compliance</td>
<td>1</td>
<td>7</td>
</tr>
</tbody>
</table>

As part of probation monitoring, the board requires licensees to appear before the lead inspector at probation office conferences. These conferences are used as 1) an orientation to probation and the specific requirements of probation at the onset, 2) to address areas of non-compliance when other efforts such as letters have failed, and 3) when a licensee is scheduled to end probation.

Pharmacists Recovery Program (as of June 30, 2003)

<table>
<thead>
<tr>
<th>Program Statistics</th>
<th>July-Sept</th>
<th>Oct-Dec</th>
<th>Jan-Mar</th>
<th>Apr-June</th>
<th>Total 03/04</th>
</tr>
</thead>
<tbody>
<tr>
<td>In lieu of discipline</td>
<td>0</td>
<td>1</td>
<td>0</td>
<td>0</td>
<td>1</td>
</tr>
<tr>
<td>In addition to probation</td>
<td>1</td>
<td>3</td>
<td>1</td>
<td>5</td>
<td>10</td>
</tr>
<tr>
<td>Closed, successful</td>
<td>3</td>
<td>0</td>
<td>3</td>
<td>3</td>
<td>9</td>
</tr>
<tr>
<td>Closed, non-compliant</td>
<td>2</td>
<td>3</td>
<td>5</td>
<td>4</td>
<td>10</td>
</tr>
<tr>
<td>Closed, other</td>
<td>0</td>
<td>0</td>
<td>1</td>
<td>0</td>
<td>1</td>
</tr>
<tr>
<td>Total Board mandated Participants</td>
<td>50</td>
<td>50</td>
<td>49</td>
<td>50</td>
<td>50</td>
</tr>
<tr>
<td>Total Self-Referred Participants*</td>
<td>15</td>
<td>15</td>
<td>15</td>
<td>15</td>
<td>15</td>
</tr>
<tr>
<td>PRP Site Inspections**</td>
<td>29</td>
<td>1</td>
<td>6</td>
<td>8</td>
<td>44</td>
</tr>
<tr>
<td>Treatment Contracts Reviewed</td>
<td>31</td>
<td>37</td>
<td>26</td>
<td>23</td>
<td>26</td>
</tr>
</tbody>
</table>

Monthly the board meets with the clinical case manager to review treatment contracts for scheduled board mandated participants. During these monthly meetings, treatment contracts and participant compliance is reviewed by the PRP case manager, enforcement coordinator and lead inspector and appropriate changes are made at that time and approved by the executive officer. Additionally, non-compliance is also addressed on a needed basis e.g., all positive urines screens are reported to the board immediately and appropriate action is taken.

* By law, no other data is reported to the board other than the fact that the pharmacists and interns are enrolled in the program.

**Some PRP Participant Inspections are included in the Probation Site Inspections total.

As of December 31, 2003.
Attachment M
## Enforcement Committee

### Goal 1: Exercise oversight on all pharmacy activities.

**Outcome:** Improve consumer protection.

<table>
<thead>
<tr>
<th>Objective 1.1:</th>
<th>To achieve 100 percent closure or referral on all cases within 6 months by June 30, 2005:</th>
</tr>
</thead>
<tbody>
<tr>
<td>Measure:</td>
<td>Percentage of cases closed or referred within 6 months (Based on 435 completed mediations/investigations sent to SI for review)</td>
</tr>
<tr>
<td>Tasks:</td>
<td></td>
</tr>
</tbody>
</table>

1. Mediate all consumer complaints within 90 days.

   - 0-90 Days 29 (7%)
   - 91-180 Days 53 (12%)
   - 181-365 Days 30 (7%)
   - 366-730 Days 1 (0%)

2. Investigate all other cases within 120 days.

   - 0-90 Days 157 (36%)
   - 91-180 Days 85 (20%)
   - 181-365 Days 72 (17%)
   - 365-730 Days 8 (2%)

   (Based on 463 closed investigations/mediations)

3. Close (e.g. issue citation and fine, refer to the AG’s Office) all board investigations and mediations within 180 days.

   - 0-90 Days 138 (30%)
   - 91-180 Days 67 (14%)
   - 181-365 Days 186 (40%)
   - 366-730 Days 67 (14%)
   - 731+ 5 (1%)

4. Seek legislation to grant authority to the executive officer to issue a 30-day Cease and Decease Order to any board-licensed facility when the operations of the facility poses an immediate threat to the public.
<table>
<thead>
<tr>
<th>Objective 1.1, cont’d</th>
<th>5. Integrate data obtained from computerized reports into drug diversion prevention programs and investigations (CURES, 1782 reports, DEA 106 loss reports).</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Board staff continues to work with BNE fine-tuning the new CURES database and resolving data errors and pharmacy non-compliance. Board staff developed additional reports including pharmacy transactions by drug, patient profiles, pharmacy by status code, pharmacies dispensing over a specified threshold, non-reporting pharmacies, and doctor profile. The Board has requested the addition of several critical date fields to the CURES system to ensure meaningful and accurate reports. For example, staff asked to have the date CURES was last updated by DOJ.</td>
</tr>
<tr>
<td></td>
<td>11 CURES reports were provided to supervising inspectors and/or inspectors this quarter to aid in an investigation or inspection.</td>
</tr>
<tr>
<td></td>
<td>DEA 106 Theft/Loss Report database is ready with the exception of a few minor programming modifications. Staff developed and implemented procedures to include CURES pharmacy transaction reports and CURES pharmacy drug profile reports when opening a complaint investigation for a theft or loss.</td>
</tr>
<tr>
<td></td>
<td>47 CURES reports were provided to staff this quarter for investigations involving theft or loss.</td>
</tr>
<tr>
<td></td>
<td>6. Re-establish the CURES workgroup that includes other regulatory and law enforcement agencies to identify potential controlled substance violations and coordinate investigations.</td>
</tr>
<tr>
<td></td>
<td>▪ Board plans to meet with the CURES workgroup and BNE in January 2004 to work on pharmacy non-compliance and data error issues.</td>
</tr>
<tr>
<td></td>
<td>▪ Board met with representatives of BNE in November and in December, with those agencies impacted by SB 151 to discuss the implementation of the Security Printer program. Security printer draft application completed and to Legal for review.</td>
</tr>
<tr>
<td></td>
<td>Inspector and supervising inspector continue to participate on</td>
</tr>
<tr>
<td>Objective 1.1, cont’d</td>
<td>Tasks</td>
</tr>
<tr>
<td>----------------------</td>
<td>-------</td>
</tr>
<tr>
<td><strong>Tasks</strong></td>
<td>the monthly diversion task force meetings regarding the importation of dangerous drugs, repackaging and distribution in the U.S.; monthly Oxycontin task force meetings in Ventura; FBI task force meetings; and diversion task force meetings in San Diego. Additionally, an inspector, supervising inspector and the CURES analyst attended FBI diversion training in October 2003.</td>
</tr>
<tr>
<td></td>
<td>7. Secure sufficient staffing for a complaint mediation team and to support an 800 number for the public.</td>
</tr>
<tr>
<td></td>
<td>8. Improve public service of the Consumer Inquiry and Complaint Unit.</td>
</tr>
<tr>
<td></td>
<td>- Board staffed and attended two consumer health fair this quarter. Consumer brochures and Health Notes are taken to these fairs for distribution and a “Notice to Consumer” is displayed.</td>
</tr>
<tr>
<td></td>
<td>9. Automate processes to ensure better operations and integrate technology into the board’s investigative and inspection activities.</td>
</tr>
<tr>
<td></td>
<td>- No changes to automated reports for case management.</td>
</tr>
<tr>
<td></td>
<td>- Revisions made to the automated inspection system this quarter include:</td>
</tr>
<tr>
<td></td>
<td>o Modified the inspector program to include CURES data when an inspector displays inspection assignments. With the click of a button next to the pharmacy name, a pop-up window displays that pharmacy’s total number of CURES transactions for the previous 3 months and breaks the data down by drug.</td>
</tr>
<tr>
<td></td>
<td>- Installed program modifications to Inspector computers in December 2003.</td>
</tr>
<tr>
<td></td>
<td>o Developed and implemented a data scrub program to import raw Cures data into Access format.</td>
</tr>
<tr>
<td></td>
<td>o Developed and implemented a program to integrate zero-fill CURES data into the inspector program.</td>
</tr>
<tr>
<td></td>
<td>o Developed and implemented several modifications to inspector data program to improve functionality for</td>
</tr>
</tbody>
</table>
the end-user through point and click menus and automated data transmission.

- Developed and implemented a program that allows office staff and inspectors easy access to inspection reports on the server.

- Developed and implemented a behind-the-scenes weekly email delivery of an assigned versus completed inspection report to the supervising inspector. This is a weekly status report that shows inspections assignments completed and inspections assignments yet to be completed for each inspector.

**Inspection assignment status reports are sent weekly to supervising inspectors.**

- Automated evidence database – Revisions made to the database during this quarter include:
  - Further defined data fields to specify type of evidence such as drug or paper and further define drug evidence as liquid, glass, syringe, needle, etc.
  - Developed evidence inventory data form.
  - Linked Teale CAS closure data to evidence database.

- Automated sterile compounding database – Staff developed and implemented a monthly automated scrub update program for updating the licensing data extracted from Teale CAS licensing system.

- New Security Printer Database – SB 151 requires the board to approve security printers in advance of producing controlled substances prescription forms for Schedule II drugs beginning July 1, 2004. In December 2003, staff began development of a database that will track security printer applications. Plans for this database include programming for the automated generation of letters and automated updates to the list of “approved printers to the board’s website.

<table>
<thead>
<tr>
<th>Objective 1.2:</th>
</tr>
</thead>
<tbody>
<tr>
<td>To achieve 100 percent closure on all administrative cases within one year by June 30, 2005.</td>
</tr>
</tbody>
</table>
### Measure:

Percentage closure on administrative cases within 1 year

<table>
<thead>
<tr>
<th>Tasks:</th>
</tr>
</thead>
</table>
| 1. Pursue permanent funding to increase Attorney General expenditures for the prosecution of board administrative cases.  
  - A BCP was not submitted for funding due to a July 2003 Finance Budget Letter directing agencies to offset any increase in expenditures through redirection of existing funds.  
  2. Aggressively manage cases, draft accusations and stipulations and monitor AG billings and case costs.  
    - Case management and review of pending cases is a continuous process. **Status memos sent this quarter:** 25.  
    - Disciplinary cases closed this quarter:  
      - 0-365 days: 9 (40.9%)  
      - 366+ days: 13 (59.1%)  
    - Disciplinary cases reviewed this quarter:  
      - Accusations reviewed: 36  
      - Accusations needing revision: 5  
      - Accusations filed: 40  
      - Stipulations/proposed decisions reviewed: 12  
      - Cases reviewed for costs: 21  
  3. Establish a disciplinary cause of action for fraud convictions similar to current cash compromise provisions related to controlled substances.  
  4. Automate processes to ensure better operations and integrate technology into the board’s investigative and inspection activities.  
    - Administrative Case Management Database Program – no changes this quarter.  
  5. Review and update disciplinary guidelines.  
    - Board staff identified the “examination” term as needing revision for consistency with the new pharmacist exam requirements. |

<table>
<thead>
<tr>
<th>Objective 1.2 cont’d.</th>
</tr>
</thead>
</table>

<table>
<thead>
<tr>
<th>Objective 1.3:</th>
<th>Inspect 100 percent of all licensed facilities once every 3 years by June 30, 2004.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Measure:</td>
<td>Percentage of licensed facilities inspected once every 3 years</td>
</tr>
</tbody>
</table>
| Tasks:         | 1. Automate processes to ensure better operations and integrate technology into the board’s investigative and inspection activities.  
|                | ‣ See response to Objective 1.1, Task #9.                                       |
|                | 2. Inspect licensed premises to educate licensees proactively about legal requirements and practice standards to prevent serious violations that could harm the public.  
|                | For this quarter:                                                                |
|                | Total number of inspections to be completed by July 2004 is 2,339.               |
|                | Total number of inspections completed this quarter: 590  
|                | (This is all inspections combined i.e., routine, diversion, probation/PRP, sterile compounding, status 3 (delinquent), CURES, inspections as a result of a complaint investigation, etc)  
|                | Of those inspections, there were:                                                |
|                | Total Sterile Compounding Inspections: 15  
|                | Total Status 3 (delinquent) inspections: 7  
<p>|                | Total routine inspections resulting in a complaint investigation: 25             |
|                | 3. Seek legislation to mandate that periodic inspections be done on all board-licensed facilities. |</p>
<table>
<thead>
<tr>
<th>Objective 1.4:</th>
<th>Develop 4 communication venues in addition to the inspection program to educate board licensees by June 30, 2005.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Measure:</td>
<td>Number of communication venues (excluding inspection program)</td>
</tr>
<tr>
<td>Tasks:</td>
<td>1. Develop the board’s website as the primary board-to-licensee source of information.</td>
</tr>
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<td></td>
<td>- The availability of disciplinary history on licensees is in the final stages of development and test.</td>
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<td></td>
<td>- Once completed, employers will be able to query disciplinary status of a licensee.</td>
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<td></td>
<td>- During this quarter website revisions included:</td>
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<tr>
<td></td>
<td>- Update on California licensure exam requirements.</td>
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<td>- Update on new pharmacy technician program requirements.</td>
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<tr>
<td></td>
<td>- Addition of new pharmacy technician application.</td>
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<tr>
<td></td>
<td>- Addition of new pharmacist exam application.</td>
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<td></td>
<td>- Availability of board committee packets for download.</td>
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<td>- Regulation Updates</td>
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<td>- Lawbook Updates</td>
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<td>2. Prepare two annual <em>The Scripts</em> to advise licensee of pharmacy law and interpretations.</td>
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<td>- Articles for January 2004 Script written and submitted for review.</td>
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### Objective 1.4, cont’d.

   - Being reviewed by Legislation/Regulation Committee.

4. Develop board-sponsored continuing education programs for pharmacists in the area of pharmacy law and the expectations of the pharmacist-in-charge and coordinate presentations at local and annual professional association meetings throughout California.
   - C/E presentations given this quarter:
     - October – CSHP’s Seminar 2003
     - December – Coachella Chapter of CPhA
   - Held public Enforcement Committee meeting attended by licensee professional association representatives. Topics included the reimportation of prescription drugs, review of the quality assurance program, implementation of SB 151 and 361, wholesale violations, task force on prescriber dispensing and an overview of the Pharmacist Recovery Program, Probation Monitoring Program and the disciplinary penalty petition process. Meeting agenda and materials available for download from the Web.

### Objective 1.5:

**Measure:**
To monitor alternative enforcement programs for 100 percent compliance with program requirements by June 30, 2005.

**Percentage compliance with program requirements**

**Tasks:**

1. Administer effective alternative enforcement programs to ensure public protection (Pharmacists Recovery Program, probation monitoring program, citation and fine program).
   - Pharmacists Recovery Program: As of December 2003, there were 65 participants in the PRP. During this quarter the board referred 2 pharmacists to the program. Statistics for closures are not yet available.
   - Probation Monitoring Program: As of this quarter there are 122 pharmacists, 21 pharmacies and 23 other individual licensees (technicians, interns, exempees) on probation with the board. Four new probationers were added during this quarter, seven investigations for petitions to revoke probation for non-compliance were completed, and two non-compliance letters were sent.
   - Citation and Fine Program:
     - October through December 2003: 202 citations issued. Total fines: $174,425.00
| Objective 1.5, cont’d. | § In December, reviewed compliance provisions of SB 361 for implementation – order of correction, letter of admonishment and revisions to the citation and fine program.  

2. Automate processes to ensure better operations and integrate technology into the board’s investigative and inspection activities.  

§ Citation and Fine Database Program – No changes this quarter. The database is scheduled for modification next quarter. |

| Objective 1.6: | Respond to 95 percent of all public information requests within 10 days by June 30, 2005.  

Measure: | Percentage response to public information requests within 10 days |

| Tasks: | 1. Activate public inquiry screens to expand public information. Establish web look-up for disciplinary and administrative (citation) actions.  

§ Teale Public Disclosure Screen – In this quarter an estimated 100% of the board’s probationers were entered into the database and currently completed disciplinary actions are entered into the database on a going-basis.  

§ Web Enforcement Look-Up – Test records for “web look-up” have been designed and data imported into these records. Testing of program will be completed in January 2004.  

2. Establish on-line address of record information on all board licensees.  

§ Licensee address of record information became available on-line to the public in December.  

3. Respond to specialized information requests from other agencies about board programs, licensees (e.g. subpoenas) and Public Record Act requests.  

§ In the last quarter the board responded to:  

38 public records requests –71% within 10 days; 29% over 10 days.  

14 requests from licensees – 86% within 10 days; 14% over 10 days. |
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<tr>
<td>23 requests from other agencies</td>
<td>78% within 10-day response time; 22% over 10 days.</td>
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<tr>
<td>178 written license verifications</td>
<td>60% within a 10 days; 40% over 10 days.</td>
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<tr>
<td>3 subpoenas</td>
<td>100% responded to within 5 days.</td>
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