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STATE AND CONSUMER SERVICES AGENCY
DEPARTMENT OF CONSUMER AFFAIRS
ARNOLD SCHWARZENEGGER, GOVERNOR

Enforcement Committee Report

William Powers, Public Member, Chair
Marian Balay, Public Member
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Report of December 7, 2005

Because the Enforcement Committee did not have a quorum, a subcommittee meeting was held instead. The following are not recommendations from the Enforcement Committee but are action items for board consideration. A motion will be required for each action item.

FOR ACTION

ACTION ITEM 1

That the Board of Pharmacy consider a request to form an ad hoc committee to address the implementation of the electronic pedigree requirement that becomes effective January 1, 2007, for wholesalers and January 1, 2008, for pharmacies.

Discussion
In 2004, the Board of Pharmacy sponsored SB 1307 (Figueroa), which was signed by Governor Schwarzenegger and became law on January 1, 2005. The bill made various changes to the wholesaler requirements and distribution of dangerous drugs. Most of the changes strengthened and clarified the requirements for the distribution of dangerous drugs and dangerous devices in California.

The Enforcement Committee has been monitoring the implementation of this legislation especially the implementation of the pedigree requirement. The bill requires an electronic pedigree by January 1, 2007 and gives the board the authority to extend the compliance date for wholesalers to January 1, 2008. The Legislature may extend the compliance date for pharmacies to January 1, 2009. The purpose of the pedigree is to maintain the integrity of the pharmaceutical supply chain in the United States.

The industry anticipates that Radio Frequency Identification technology (RFID) will be the method used to track a drug's pedigree. The manufacturer would tag the drug with a small chip and antenna. When the tag is in close proximity of a reader, it would receive a low-powered radio signal and interact with a

reader exchanging identification data and other information. Once the reader receives data, it would be sent to a computer for processing.

During the last year, the Board of Pharmacy and the Enforcement Committee has had presentations from various companies displaying their electronic pedigree solutions. The first presentation was by T3Ci, an application software company that provides drug counterfeit, diversion detection and electronic drug pedigree for the pharmaceutical market. They demonstrated their technology solution for the electronic pedigree. The next presentations were by SupplyScape and Acerity Corporation. SupplyScape presented its electronic pedigree software program that enables a safe and secure pharmaceutical supply chain that complies with federal and state regulations to prevent counterfeit drugs. Acerity Corporation presented its security software program, which is an electronic authentication process. This system employs a cryptography techniques in conjunction with RFID forming a multiplayer secure process, which provides numerous advantages and allows versatile applications.

At the September Enforcement Committee meeting, Lew Kontnik, Director of Brand Protection/Business Continuity for Amgen presented to the committee the challenges that Amgen has encountered in developing an electronic pedigree for its manufactured products. He stated that Amgen, a billion dollar company that is headquartered in California, is the leading human therapeutics company in the biotechnology industry. He demonstrated the challenges that their company is facing in the implementation of RFID technology to track the electronic pedigree of its liquid products. Primarily he showed how the placement of the radio frequency tag on the products have resulted with inconsistent and inaccurate readings by the scanner unless the scanner is in close proximity of the tagged item, which is not conducive to tracking large quantities of distributed product. He also stated that whatever mechanism is used to generate the electronic pedigree, it must be incompliance with good manufacturing practices (GMPs), which is regulated by the federal Food and Drug Administration (FDA).

Upon conclusion of his presentation, Mr. Kontnik presented his company's position that it will be extremely difficult to meet the January 1, 2007 deadline to implement an electronic pedigree for its manufactured drug products.

The Board also has been participating in the Uniform Drug Pedigree meetings. This is a group of participants that represents manufacturers, wholesalers, and regulators. The purpose of these meetings is to provide a cooperative effort to develop uniform standards and regulations regarding electronic pedigrees. As result of the board's participation with this group and others, a list of questions and answers were developed on the implementation of California's pedigree requirement. The questions and answers were provided in advance of this Enforcement Committee meeting. **(Attachment A)**

As a result of the question and answer document additional clarification was sought and the suggestion made that an ad hoc committee or workgroup be formed to address the implementation of the electronic pedigree requirement and provide additional clarification. The Board has taken a similar approach when it addressed various issues regarding compounding. A workgroup group of the Licensing Committee was formed that invited all interested parties to participate at the table. The Board took a similar approach this year when it addressed pharmacy practice issues (see the Licensing Committee Report). A special subcommittee was not formed, but as part of the Licensing Committee meetings, the committee developed a proposal to update the definition of pharmacy, nonresident pharmacy and pharmacist practice. Again all interested parties were invited to the table to participate.

While the Enforcement Committee has been addressing the implementation of the electronic pedigree requirement over the last year, one option is to continue to do so as part of the Enforcement Committee

but extend the length of the meeting and the format – invite all participants to the table to discuss the implementation and to determine the appropriate means to clarify issues. Another option is to form a separate workgroup (similar to the Compounding Workgroup) that would meet in the same format but separately from the Enforcement Committee, but on the same day in the afternoon.

In January, the Federal Food and Drug Administration (FDA) announced a public workshop and vendor display on the use of radio-frequency identification (RFID) to combat counterfeit drugs. The meeting is scheduled for February 8 and 9, 2006, in Maryland. The goals of the meeting are to: (1) Identify incentives and obstacles for widespread adoption of RFID throughout the United States drug supply chain, and to discuss ways of overcoming any impediments; (2) Solicit comment on the implementation of the pedigree requirements of the Prescription Drug Marketing Act (PDMA) and the use of e-pedigree; (3) Learn about the state of technology development related to electronic "track and trace" and e-pedigree technology solutions. **(Attachment B)**

ACTION ITEM 2

That the Board of Pharmacy consider a proposal to amend B&P § 4040(c) to allow a pharmacy to accept a fax prescription from a patient.

Discussion
The Committee discussed a proposal to amend B&P § 4040(c) to allow a pharmacy to accept a fax prescription from a patient provided that the pharmacy has the original prescription before dispensing the prescription medication to the patient. The proposal came from a consumer as a result of a complaint. Current law only authorizes a pharmacy to accept a fax prescription from a prescriber. In the specific complaint, the pharmacy was accepting a fax from the patient; however, the pharmacy stopped the practice because of the law and the consumer was not happy that he could no longer fax the prescription.

The proposal is an option for pharmacies to implement. Concern was expressed that patients would fax their prescriptions (especially a controlled substance prescription) to various pharmacies to have it filled. There was also concern that accepting a fax from a patient would disrupt a pharmacy's workflow. It was discussed that this proposal is an option for pharmacies to implement as a service to patients if it chose to do so. Also, it would be incumbent on the pharmacy to obtain the original prescription prior to dispensing the medication to the patient to prevent the patient from having the same prescription filled at several different pharmacies. There was also discussion that the patient would more than likely forget to bring in the original prescription when picking up the dispensed medication. It was stated that the patient would have to return with the original prescription. The decision to allow for a patient to fax a prescription would be a customer service decision that each pharmacy would need to make.
(Attachment C)

ACTION ITEM 3

That the Board of Pharmacy consider a proposal to amend B & P § 4073(b) to indicate the prohibition of generic substitution by a prescriber on an "Electronic Data Prescription."

Discussion
The Committee discussed a proposed amendment to B&P § 4073(b) to update pharmacy law regarding the prohibition of generic substitution by a prescriber on an electronic data transmission prescription. Current law requires the physician to personally indicate either orally or on the prescription "Do Not

Substitute" or words of similar meaning. If a prescriber checks a box indicating no substitution, then he/she must initial the box or checkmark.

The purpose of the amendment is to clarify that a physician is not required to manually initial an electronic data transmission prescription in order to prohibit generic substitution. It is presumed that prescriber is already electronically verified for the data transmission prescription and there is no additional need for the handwritten initial. Concern was expressed that software programs would automatically default to "Do Not Substitute."

The Centers for Medicare and Medicaid Services (CMS) issued its final rule on November 7, 2005, that covers transactions involving the electronic transmission of prescriptions and certain other information for covered Part D drugs prescribed for Part D eligible individuals. Essentially CMS has interpreted the federal law to preempt all contrary State laws that are applicable to a prescription that is transmitted electronically not only for those individuals who are enrolled in Part D, but for all Part D eligible individuals. Categories that are anticipated by CMS include state laws prohibiting e-prescribing, state laws prohibiting transmissions through intermediaries, state laws requiring certain language if not consistent with the federal Act and state laws requiring handwritten signatures. Therefore, this proposal is consistent with the final rule issued by CMS. **(Attachment D)**

NO ACTION

Importation of Prescription Drugs

The importation of prescription drugs is an ongoing agenda item for the Enforcement Committee and Board of Pharmacy meetings for the last three years. 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. The board's mandate is to protect the public, which includes patient access to "safe and affordable" prescription medications.

Attached are articles regarding recent developments on the issue of drug importation including a letter from Governor Schwarzenegger to Congressional leaders calling for a change in federal law to allow consumers to safely import prescription drugs from other countries. **(Attachment E)**

Enforcement Committee Meeting Summary of December 7, 2005 (Attachment F)

Enforcement Team Meeting Summary of December 7, 2005 (Attachment G)

Report on Enforcement Actions (Attachment H)

Quarterly Status Report on Committee Strategic Objectives for 2005/2006 (Attachment I)

ATTACHMENT A

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PRESCIPTION DRUG PEDIGREE

Preamble
In 2004, the California State Board of Pharmacy sponsored legislation that made comprehensive changes to the wholesale distribution system to protect against counterfeit drugs.

The Center for Medicines in the Public Interest projects that the number of counterfeit drug sales will reach $75 billion by 2010, a 92 per cent increase from 2005. The board's statutes require the development of a "pedigree" that tracks each prescription drug through the distribution system beginning January 1, 2007. The statutes also require licensure of out-of-state wholesalers, the posting of a $100,000 surety bond (or equivalent security), and authorize the board to embargo drugs when the board suspects drugs are adulterated or counterfeit.

The following are questions that the Board of Pharmacy has received regarding the implementation of the pedigree requirement and proposed answers.

QUESTIONS AND ANSWERS

General Questions

Q1 What is a pedigree?

A pedigree is an electronic record containing information regarding each transaction resulting in a change of ownership of a prescription drug (dangerous drug) from the sale by the manufacturer through each acquisition and sale of the drug until the final sale to a pharmacy or prescriber who will furnish, administer or dispense the prescription drug to a patient. (B & P § 4034(a))

Q2 What are the requirements for a pedigree in California?

Source of the Prescription Drugs
At each stage or link in the distribution chain down to the end user, a pedigree must contain information on each source/prior owner of the prescription drug. Information regarding the source will include the manufacturer, wholesaler and in some instances, the pharmacy from which the prescription drug was acquired and/or through whose ownership the prescription drug passed. It is any entity that is selling, trading or transferring the prescription drug. The pedigree must include each source's name and principal address and California license number if available.

Prescription Drugs and Transaction Information
The pedigree shall include the name of the prescription drug, its quantity, its dosage form and strength, the date of each transaction in its distribution to that point, the sales invoice number(s) associated with each such transaction, the container size(s) for each transaction, the number of containers for each transaction, the expiration dates and the lot number(s).

Prescription Drug Ownership Information
The business name, address, and if appropriate, the state license number, including a California license number if available, of each owner of the prescription drug, and the prescription drug shipping information, including the name and address, of each person certifying to delivery and receipt of the prescription drug.

A California license is required to authorize an entity to possess, acquire, sell or transfer prescription drugs in California.

Certification of Transaction Authenticity
A certification under penalty of perjury from a responsible party of the source of the prescription drug that the information contained in the pedigree is true and accurate. (B & P § 4034(b))

Q3 When does the pedigree requirement become effective? (B & P § 4034(e))

The pedigree requirement becomes effective January 1, 2007.

Q4 What types of drugs require a pedigree?

All prescription drugs (dangerous drugs), including controlled substances, require a pedigree.

Q5 Does prescription drugs include prescription drugs for animals?

The definition of "dangerous drug" means any drug unsafe for self-use in humans or animals and includes any drug bearing the legend: "Caution: federal law prohibits the dispensing without prescription, "Rx only," or words of similar import. (B & P § 4022)

Q6 When is a pedigree required?

Beginning January 1, 2007, a California licensed wholesaler or pharmacy may not acquire a prescription drug (dangerous drug) without a pedigree. A California licensed wholesaler or pharmacy also may not sell, trade or transfer a prescription drug at wholesale without providing a pedigree.

Q7 Who creates or starts a pedigree?

The pedigree must reflect every change of ownership of the prescription drug beginning with sale by a manufacturer. The manufacturer initiates the pedigree.

Q8 When does the required information need to be recorded on the pedigree? When there is movement of the prescription drug or a change of ownership of the prescription drug?

Any change of ownership of the prescription drug requires documentation of the transaction information on the pedigree.

Q 9 When are additional entries made on the pedigree?

Each time that the ownership of the prescription drug changes, the required transaction information must be recorded on the pedigree. The responsible party of the source who is selling, trading or transferring the prescription drug must certify that the pedigree is true and accurate and thereby authenticate the transaction information.

Q10 What types of "change of ownership" transactions require documentation on the pedigree?

The following transactions require documentation on the pedigree (not a comprehensive list):

- Any sale, trade, or transfer of prescription drugs between a manufacturer and wholesaler
- Any wholesale sale to a pharmacy, other wholesaler, clinic or prescriber (This would include "wholesale brokering" where the wholesaler doesn't take possession of the prescription drug but makes arrangements for the delivery of the prescription drug and processes the paperwork.)
- Drop ship deliveries for a manufacturer, wholesaler or pharmacy
- Consignment transactions
- Third party logistics transactions
- Pharmacy sales to another pharmacy as authorized by B&P § 4126.5
- Pharmacy returns to the wholesaler or manufacturer from whom the prescription drugs were originally purchased
- Pharmacy sales to a prescriber or other licensed entities authorized to receive drugs
- Pharmacy or wholesale transfers to a reverse distributor.

Q11 What transactions are not required to be recorded on the pedigree?

The following transactions do not require a pedigree entry:

- Any transfer of a prescription drug between individuals or entities that does not constitute or result in a change of ownership of the prescription drug.
- Complimentary prescription drug samples ordered by a prescriber from a manufacturer and delivered to the prescriber for future dispensing to a patient at no charge

- Any transaction of dangerous devices
- Any transaction of non-prescription drugs (over-the-counter drugs)
- Prescription drugs provided as a part of a manufacturer's patient assistance program, i.e., where the prescriber requests the prescription drugs from a drug manufacturer and the prescription drugs are delivered to the prescriber by the manufacturer, to be dispensed to the prescriber's patient.

Q12 What other types of transactions are not considered a change of ownership and therefore would not require documentation on the pedigree?

Prescription drugs distributed or transferred between, within or among a licensed health care services plan, a hospital organization, and one or more physicians organizations having an exclusive contractual relationships to provide health care services, are not deemed to have changed ownership. (B&P § 4034(c))

Q 13 When does the pedigree need to be verified and authenticated?

The pedigree needs to be verified and authenticated when any recipient in the chain of distribution (e.g., wholesaler, pharmacy, prescriber) receives the prescription drug and the pedigree.

Manufacturer/Wholesaler Questions

Q Where in the supply chain does the pedigree start?

The pedigree starts at the manufacturer.

Q Does a wholesaler or pharmacy have to use the pedigree it receives or can it create a different pedigree?

A wholesaler or pharmacy must use the pedigree in the form that it is received. The wholesaler or pharmacy cannot create a different pedigree.

Q If a pharmacy returns prescription drugs to the manufacturer or wholesaler from which the prescription drugs were purchased, does this transaction need to be recorded on the pedigree? If the prescription drugs are sold to a pharmacy and the pharmacy returns the prescription drugs within 7 days, is that transaction exempt from documentation on the pedigree?

Any returns to a manufacturer or wholesaler, or any other change of ownership, requires documentation on the pedigree. There is no exemption from the pedigree for prescription drugs that are returned within 7 days. All prescription drug returns require a pedigree.

Q Do wholesalers who only broker prescription drugs have to receive a pedigree when making arrangements for shipment of prescription drugs, and do wholesalers in such transaction have to provide a pedigree when the prescription drugs are sold?

Yes, a wholesaler who brokers prescription drugs must receive a pedigree and provide a pedigree to the individual or entity receiving the prescription drugs.

Q Would a third party logistics provider that receives a prescription drug from the manufacturer and ships the prescription drug to the wholesaler be considered a manufacturer and therefore be required to start the pedigree?

The manufacturer is required to start the pedigree. If the manufacturer ships the prescription drug to the third party logistics provider, that third party provider must be licensed as a wholesaler and the transaction must be recorded on the pedigree that started with the manufacturer.

Each licensed wholesaler that receives the prescription drug and ships the prescription drug would be required to be on the pedigree if the prescription drug is changing ownership.

Q Do wholesalers who only store and ship consigned prescription drugs have to receive a pedigree when they receive the prescription drugs? Would a pedigree be required when the prescription drugs are distributed?

Yes, wholesalers who receive consigned prescription drugs and then deliver the prescriptions drugs upon request of the consignor must receive a pedigree upon receipt of the prescription drugs and must issue a pedigree to the individual or entity to whom or which the prescription drugs are delivered.

Another example is where a manufacturer or wholesaler owns the prescription drugs, but the prescription drugs reside at another licensed wholesale facility and are billed by the original manufacturer or wholesaler at the time of sale, while they are delivered by the wholesaler storing the prescription drugs. A pedigree would be required that documents each change of ownership, including the transaction from the manufacturer to the wholesaler where the prescription drugs reside, as well as the subsequent sale and delivery.

Q Do manufacturers or wholesalers who have another wholesaler drop ship a prescription drug have to receive a pedigree when arranging for the drop shipment and issue a pedigree when distributing the prescription drug?

Yes, a drop shipment requires a pedigree entry.

Q What does a wholesaler do with prescription drugs in their possession on January 1, 2007 that do not have a pedigree?

A licensed wholesaler may create a pedigree with the wholesaler listed as the original creator of the pedigree only for those prescription drugs in its possession on January 1, 2007. The wholesaler (creating the pedigree) should retain purchase invoices or other documentation confirming the date of purchase and receipt of any prescription drugs in its possession before January 1, 2007 for which a pedigree is created until all prescription drug stock held on January 1, 2007 is sold, traded or transferred or 3 years whichever is longer.

Q Is the shipping address required on the pedigree? If so, does that mean the corporate office or the actual location from where the prescription drug was shipped?

The shipping address is the address of the location **from** which the prescription drug was actually shipped or the actual address **to** which the prescription drug was shipped and delivered.

Q What is a sales invoice number?

A sales invoice number is a unique number created by each manufacturer or wholesaler in the chain of distribution and used by each manufacturer or wholesaler to identify the invoice that documents the sale transaction of a prescription drug. The sale transaction would include any purchase, trade or transfer of a prescription drug resulting in a change of ownership.

Q The pedigree requires the "source" of the drug. What is the source?

The source is the entity or entities selling, trading or transferring the prescription drug. Depending on the transaction, the "entity" may be the manufacturer, wholesaler, pharmacy, and/or prescriber.

Q What happens to a pedigree when a licensed repackager repackages a prescription drug?

In California, an entity that repackages prescription drugs must be licensed as a manufacturer. When a prescription drug is repackaged, it will acquire a new NDC number, lot number and perhaps expiration date. The repackager must receive a pedigree with the prescription drug and the new pedigree information (new NDC number, etc.) must be documented on the original pedigree and continue with the newly repackaged prescription drug.

Q Is a pedigree required for an intra-company transfer between manufacturer and wholesaler?

A pedigree is required to contain information regarding each transaction resulting in a change of ownership of a given prescription drug.

Q Is a pedigree required for an intra-company transfer of drugs between pharmacies?

A pedigree is required to contain information regarding each transaction resulting in the change of ownership of a given prescription drug. Any transfer from or by a pharmacy must be in compliance with B& P § 4126.5.

Q What are the pedigree requirements for prescription drugs that are shipped into California?

Prescription drugs that are shipped into California are required to have documentation of each transaction from the manufacturer, to acquisition and sale by a wholesaler until final sale to the pharmacy. Only those transactions that result in a change of ownership of the prescription drug are required to be documented on the pedigree.

Q Is it possible for a wholesaler or pharmacy to update its inventory before a pedigree is authenticated?

If a wholesaler or pharmacy receives delivery of a prescription drug but has not authenticated the pedigree, the prescription drugs may be stored under secure conditions for a brief period of time, separated from the regular inventory, until the pedigree may be verified. Any such unverified prescription drugs may not be stored with regular inventory or be available for sale until the pedigree is authenticated.

Q Is it acceptable to list multiple prescription drugs, which were all purchased from the same manufacturer at different times on a single pedigree as long as the date of purchase and associated invoice number(s) are listed with each drug?

It is expected that the required pedigree elements will be kept at all times in a readily retrievable form at the facility or pharmacy from which, by which, or to which prescription drugs are distributed. The statues do not specify how the pedigree data is stored.

Q Would it be acceptable to post pedigree information on a secure site for customers to access? There is concern about the amount of paper recipients of pedigrees at the pharmacy and wholesalers would need to manage, as well as the funds they would have to invest to secure their own pedigree solution. With this approach, all they would need to invest in would be an Internet access to their supplier's existing infrastructure?

It is expected that the required pedigree elements will be kept at all times in a readily retrievable form at the facility or pharmacy for which, by which, or to which prescription drugs are distributed. The statutes do not specify how the pedigree data is stored.

Pharmacy Questions

Q Are pharmacies required to obtain a pedigree when buying prescription drugs?

Effective January 1, 2007, a pharmacy may not acquire any prescription drugs (dangerous drugs) without obtaining a certified pedigree at the time the drugs are acquired.

Q Are pharmacies ever required to provide a pedigree?

A pharmacy is required to provide a pedigree as part of any transaction resulting in a change of ownership of a given prescription drug, including but not limited to when the pharmacy returns a prescription drug to the wholesaler or manufacturer from which the prescription drug was obtained, when the pharmacy wholesales the prescription drug to another pharmacy to alleviate a temporary shortage, when the pharmacy transfers the prescription drug to a health care provider authorized to purchase prescription drugs, or when the pharmacy sends a prescription drug to a reverse distributor. The pharmacy is required to provide a pedigree at the time of any sale, trade or transfer of a prescription drug resulting in a change of ownership.

A pedigree is not required if the transaction does not result in the change in ownership of the prescription drug. However, the transaction must be one of the transactions authorized by B& P § 4126.5.

Q To whom can a pharmacy furnish prescription drugs? (B& P § 4126.5)

- A wholesaler owned or under common control by the wholesaler from which the prescription drug was acquired.
- The pharmaceutical manufacturer from which the prescription drug was acquired.
- A licensed wholesaler acting as a reverse distributor.
- Another pharmacy or wholesaler to alleviate a temporary shortage of a dangerous drug that could result in the denial of health care. Only a quantity sufficient to alleviate the temporary shortage may be furnished.
- A patient or another pharmacy pursuant to a prescription or as otherwise authorized by law.
- A health care provider that is not a pharmacy but that is authorized to purchase dangerous drugs.
- To another pharmacy under common control.

Q What does under "common control" mean?

Common control means the power to direct or cause the direction of the management and policies of another person whether by ownership, by voting rights, by contract, or by other means.

Prescriber Questions

Q Are prescribers required to receive a pedigree when they purchase prescription drugs?

Yes, beginning January 1, 2007, a prescriber may not **purchase** prescription drugs without a pedigree. A pedigree is not required for transactions that do not result in a change of ownership, e.g., when a prescriber requests and receives prescription drug samples from the manufacturer for dispensing without charge to his/her own patients, or prescription drugs are provided to a prescriber as part of a manufacturer's patient assistance program.

Q Are prescribers required to provide a pedigree?

If a prescriber returns prescription drugs to the manufacturer, wholesaler or pharmacy from which the prescription drugs were obtained, then the prescriber must provide a pedigree at the time the prescription drugs are returned. There is no provision in California law for a prescriber to sell, trade or transfer prescription drugs, or otherwise transfer ownership, except to the end user (his or her own patient), so presumably there would be no other instance when a prescriber would provide a pedigree.

General Technology Questions

Q What type of technology is required?

The only requirement is that the pedigree be electronic; no specific technology is required.

California wholesalers, pharmacies and other healthcare providers that sell, trade, transfer or receive prescription drugs must ensure the authenticity, integrity, and non-repudiation of the electronic pedigree.

Authentication means ensuring that the person certifying the delivery or receipt of the drug and the responsible person that is certifying the accuracy of the information in the electronic pedigree is the person he or she purports to be. Integrity means that both the electronic document and the signature(s) of the person(s) providing the certifications have not been altered. Non-repudiation means ensuring that the parties to the transactions cannot later disclaim it.

The California Board of Pharmacy does not provide specific directions or technological requirements on how to ensure the authenticity, integrity and non-repudiation of the electronic

pedigree. It is the responsibility of the involved parties to meet these requirements in whatever way best suits the circumstances in question.

Q Can the wholesaler and pharmacy maintain the pedigree record electronically?

California law requires that records of the manufacture, sale, acquisition and distribution of prescription drugs be available on the licensed premises for three years from the date of making (B&P § 4081, 4105, and 4333.) The pedigree record may be kept electronically so long as a hard copy and an electronic copy can during that period always be produced (B&P § 4105.)

Q Can a manufacturer or wholesaler provide a database containing more information than required by California as long as the electronic pedigree requirements for California are part of the data?

As long as the required pedigree data is provided and is readily retrievable upon inspection or otherwise, additional data may also be collected.

Q Is the lot number of a drug required on the pedigree? Can multiple lot numbers be on the pedigree document?

The lot number is required. Multiple lot numbers can be on the pedigree as long as the wholesaler or pharmacy can readily retrieve the lot number upon request without having to do a manual search for the required lot number.

Q Is Radio Frequency Identification (RFID) technology required?

No, RFID is not required.

Q If a California wholesaler or pharmacy ships out of state, how will the out of state entity receive the pedigree if they do not have the appropriate software?

If another state requires a pedigree, then the California wholesaler or pharmacy must comply with the receiving state's pedigree requirement as well as California's requirements. If the state does not require a pedigree, the California wholesaler or pharmacy would still be required to document the transaction on the electronic pedigree and provide it to the receiving entity. If the receiving entity does not have the software to read the pedigree, it would be advisable for the California business selling the prescription drug to provide a printed hard copy of the electronic pedigree. In order to be shipped back into or received in California, the prescription drug would have to have a complete electronic pedigree.

Q Is there a clearinghouse for the transaction data for electronic pedigrees?

At the current time, there is no clearinghouse for pedigree data.

Q Is there a hotline to verify pedigree data provided by the wholesaler?

At the current time there is no hotline to verify the authenticity of data provided in a pedigree.

Q To read and accept an electronic pedigree, is a wholesaler required to provide software to its customer pharmacies or will pharmacies have to procure the needed software?

There is no requirement for a manufacturer or wholesaler to provide the necessary software to read an electronic pedigree.

Q Will everyone need a scanner or other hardware to comply with the pedigree requirement?

The type of technology used will determine the hardware and software needs of a business. There is no requirement for a particular type of technology.

Regulatory Questions

Q Is any additional legislation regarding the pedigree being considered in California?

No further legislation is pending or proposed at this time.

Q California law provides for an extension to implement the pedigree requirement until January 1, 2008, if the Board of Pharmacy determines that manufacturers or wholesalers require additional time to implement electronic technologies to track prescription drugs within California. How would the board grant this extension?

The Board of Pharmacy would have to grant the request at a public meeting upon the request of manufacturers and/or wholesalers. A written request to extend the implementation date for the pedigree would need to be sent to the attention of the Executive Officer Patricia Harris, at 1625 N. Market Blvd. Ste N219, Sacramento, CA 95834.

The Enforcement Committee would first review the request and make a recommendation. The full board would then consider the request and make a decision.

Q Does a manufacturer have to be licensed in California to sell prescription drugs in California?

No, if the manufacturer only sells the prescription drugs it actually manufactures, and the prescription drugs are distributed solely from the premises of the licensed manufacturer.

Q How will the Board of Pharmacy be enforcing the pedigree requirement for pharmacies and wholesalers?

Compliance will be confirmed through board inspections and complaint investigations.

Q How will the board's inspector know if a pedigree has been provided to a pharmacy or wholesaler for a specific drug?

As a part of an inspection or investigation of a California wholesaler or pharmacy, the inspector would verify the receipt and verification of pedigree documents and the procedure for providing a pedigree when drugs are sold, traded or transferred.

Strategies to avoid Counterfeit, Misbranded or Adulterated Drugs

1. Know your supplier. Deal only with trustworthy, reputable wholesalers. Just because a wholesaler has a license does not necessarily mean it is trustworthy.
2. Be careful of the "good deal." If something appears to be too good to be true, be careful, especially with a new supplier. Due diligence is needed to check on suppliers.
3. Be careful of fax and email deals you receive.
4. Look for signs of removed labels – look for a tacky adhesive residue on or near the label.
5. Look for discolored labels. The solvent used to remove original print may discolor the label.
6. Look for slight differences in bottle or container size
7. Listen to patients – many drug counterfeits are caught by patients
8. Look for changes in lab/test values; a worsening in the patient may be due to an ineffective and/or counterfeit medication.
9. Ask the patient if they are using drugs purchased from foreign sources
10. If you suspect something is wrong contact the FDA at hhtp://www.fda/gove/medwatch or 1-800-FDA-1088 , contact the manufacturer, contact the State Board of Pharmacy

Related Pharmacy Law

Effective January 1, 2007

4034. (a) "Pedigree" means a record, in electronic form, containing information regarding each transaction resulting in a change of ownership of a given dangerous drug, from sale by a manufacturer, through acquisition and sale by a wholesaler, until final sale to a pharmacy or other person furnishing, administering, or dispensing the dangerous drug.

(b) A pedigree shall include all of the following information:

(1) The source of the dangerous drug, including the name, state license number, including California license number if available, and principal address of the source.

(2) The quantity of the dangerous drug, its dosage form and strength, the date of the transaction, the sales invoice number, the container size, the number of containers, the expiration dates, and the lot numbers.

(3) The business name, address, and if appropriate, the state license number, including a California license number if available, of each owner of the dangerous drug, and the dangerous drug shipping information, including the name and address of each person certifying delivery or receipt of the dangerous drug.

(4) A certification under penalty of perjury from a responsible party of the source of the dangerous drug that the information contained in the pedigree is true and accurate.

(c) If a licensed health care service plan, hospital organization, and one or more physician organizations have exclusive contractual relationships to provide health care services, drugs distributed between these persons shall be deemed not to have changed ownership.

(d) The application of the pedigree requirement in pharmacies shall be subject to review during the board's sunset review to be conducted as described in subdivision (f) of Section 4001.

(e) This section shall become operative on January 1, 2007.

4126.5. (a) A pharmacy may furnish dangerous drugs only to the following:

(1) A wholesaler owned or under common control by the wholesaler from whom the dangerous drug was acquired.

(2) The pharmaceutical manufacturer from whom the dangerous drug was acquired.

(3) A licensed wholesaler acting as a reverse distributor.

(4) Another pharmacy or wholesaler to alleviate a temporary shortage of a dangerous drug that could result in the denial of health care. A pharmacy furnishing dangerous drugs pursuant to this paragraph may only furnish a quantity sufficient to alleviate the temporary shortage.

(5) A patient or to another pharmacy pursuant to a prescription or as otherwise authorized by law.

(6) A health care provider that is not a pharmacy but that is authorized to purchase dangerous drugs.

(7) To another pharmacy under common control.

(b) Notwithstanding any other provision of law, a violation of this section by either a pharmacy whose primary or sole business is filling prescriptions for patients of long-term care facilities or a person engaged in a prohibited transaction with a pharmacy whose primary or sole business is filling prescriptions for patients of long-term care facilities may subject the persons who 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) Amounts due from any person under this section on or after January 1, 2005, shall be offset as provided under Section 12419.5 of the Government Code. Amounts received by the board under this section shall be deposited into the Pharmacy Board Contingent Fund.

(d) For purposes of this section, "common control" means the power to direct or cause the direction of the management and policies of another person whether by ownership, by voting rights, by contract, or by other means.
(e) For purposes of subdivision (b) of this section and subdivision (s) of Section 4301, "long-term care facility" shall have the same meaning given the term in Section 1418 of the Health and Safety Code.

Effective January 1, 2007
4163. (a) A manufacturer or wholesaler may not furnish a dangerous drug or dangerous device to an unauthorized person.
(b) Dangerous drugs or dangerous devices shall be acquired from a person authorized by law to possess or furnish dangerous drugs or dangerous devices. When the person acquiring the dangerous drugs or dangerous devices is a wholesaler, the obligation of the wholesaler shall be limited to obtaining confirmation of licensure of those sources from whom it has not previously acquired dangerous drugs or dangerous devices.
(c) A wholesaler or pharmacy may not sell, trade, or transfer a dangerous drug at wholesale without providing a pedigree.
(d) A wholesaler or pharmacy may not acquire a dangerous drug without receiving a pedigree.
(e) This section shall become operative on January 1, 2007.

4163.5. The board may extend the date for compliance with the requirement for a pedigree set forth in Section 4163 until January 1, 2008, if it determines that manufacturers or wholesalers require additional time to implement electronic technologies to track the distribution of dangerous drugs within the state. A determination by the board to extend the deadline for providing pedigrees shall not be subject to the requirements of Chapter 3.5 (commencing with Section 11340) of Part 1 of Division 3 of Title 2 of the Government Code.

4163.6. If the Legislature determines that it is not yet economically and technically feasible for pharmacies to implement electronic technologies to track the distribution of dangerous drugs within the state, the Legislature may extend the date for compliance with the requirement for a pedigree for pharmacies set forth in Section 4163 until January 1, 2009.

ATTACHMENT B

Press Office
Food and Drug Administration
U.S. Department of Health and Human Services

NOTE TO CORRESPONDENTS
January 9, 2006

Media Inquiries: Rae Jones
(301) 827-6242
Consumer Inquiries: 888-INFO-FDA

FDA Announces Workshop to Promote Adoption of New Technology to Protect Patients from Counterfeit Drugs

The Food and Drug Administration (FDA) will hold a public workshop and vendor display on the use of radio-frequency identification (RFID) to combat counterfeit drugs. The meeting will be held on February 8 and 9, 2006, from 9:00 a.m. to 5:00 p.m. at the Holiday Inn Select Bethesda, 8120 Wisconsin Ave, Bethesda, Maryland.

"Drug counterfeiting is a worldwide problem and the growing sophistication of those who make their trade in this illegal business should be a concern to all of us," said Deputy Commissioner for Medical and Scientific Affairs Scott Gottlieb, MD. "Despite this widespread activity, the United States has a very safe prescription drug supply and FDA is working hard to keep it that way. FDA believes meetings like this are essential to foster and cultivate the necessary cooperation to continue to keep our drugs safe."

RFID offers the most promising technology to protect patients from counterfeit drugs because it could potentially provide reliable electronic records ("e-pedigrees") that track prescription drugs from the manufacturer to the pharmacist. RFID also could provide for rapid location and distribution of drugs in case of national emergencies, such as in the event of a pandemic influenza situation.

Successful adoption of electronic track and trace technologies like RFID will require unusually high levels of cooperation among all stakeholders in the manufacture and distribution of medical products. Without cooperation among stakeholders, the full promise of RFID cannot be realized. While investments in some RFID technology may well make sense for some individual companies, the net benefits that all stakeholders will enjoy from RFID will be maximized if independent organizations adopt common standards and compatible approaches.

The goals of the meeting are to:

(1) Identify incentives and obstacles for widespread adoption of RFID throughout the United States drug supply chain, and to discuss ways of overcoming any impediments;

(2) Solicit comment on the implementation of the pedigree requirements of the Prescription Drug Marketing Act (PDMA) and the use of e-pedigree;

(3) Learn about the state of technology development related to electronic "track and trace" and e-pedigree technology solutions.

FDA will accept written comments on the RFID, PDMA, and e-pedigree issues until February 24, 2006. Comments may be submitted electronically at http://www.fda.gov/dockets/ecomments or mailed to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Room 1061, Rockville, MD, 20852. All comments should be identified with Docket Number 2005N-0510, Anti-Counterfeit Drug Initiative Workshop and Vendor Display (Notice). Meeting registration information can be found at http://www.fda.gov/RFIDmeeting.html.

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Cracks in the Pharmaceutical Supply Chain
By Susannah Patton, CIO
BioITWorld.com
January 18, 2006

As an undercover agent with the Drug Enforcement Administration and the Food and Drug Administration, Aaron Graham saw firsthand how counterfeit drugs can slip into the pharmaceutical supply chain. Graham, now VP and chief security officer for Purdue Pharma, once posed as the manager of an "institutional pharmacy" selling drugs at a discount to secondary wholesalers who were then supposed to sell them to nursing homes. Soon after he began, his phone started ringing. Dozens of smaller pharmaceutical wholesale companies were calling, desperate to buy his drugs. These secondary or "gray market" wholesalers scour the country and the world for low-price drugs they can sell back to major wholesalers for a profit. In addition to trawling for institutional pharmacies, some secondary wholesalers have been known to purchase counterfeit drugs from criminal organizations in places such as China, Thailand or Colombia.

Graham, who was part of a two-year FDA sting operation known as "operation gray pill," helped expose a system in which large and small wholesalers were taking advantage of multitiered pricing in the industry. Prescription drugs are sold at discounts to subsidized groups such as nursing homes and also exported at lower prices. Graham and his colleagues found that these lower-priced drugs are sometimes smuggled back into the country and sold to large wholesalers for a profit. These multiple steps, in which a drug can bounce back and forth from distributor to distributor, create a supply chain that is complex, convoluted and, at times, vulnerable. The more frequently a drug changes hands, the greater the chance that counterfeit or diverted drugs can enter the legitimate supply chain.

Such a porous supply chain poses hazards to patients -- thousands of people worldwide die every year from ingesting fake drugs -- and it costs the pharmaceutical industry an estimated US$46 billion a year in lost profits. The World Health Organization (WHO) in a recent study said that counterfeit drugs represent more than 10 percent of global sales. And in 2004, the FDA reported that the number of its investigations of counterfeit drugs rose by 150 percent from the previous year as a growing number of criminal groups take advantage of high profits and penalties that are less severe than those for selling illegal narcotics such as heroin or cocaine.

"Prescription drugs pass through so many hands before they reach the pharmacy, there is no way to know where they all come from," says Graham, who came to Purdue in 2002. "Laws on the books today are not effective in keeping counterfeit drugs out of the supply chain."

To fix the problem, pharmaceutical companies are under increasing pressure to plug holes in their supply chain, particularly in the distribution network that runs from manufacturer to customer. For instance, several states are now mandating that companies confirm the authenticity of their product by creating a "pedigree" that vouches for a medication's origin and who else has handled it. The FDA has recommended that pharmaceutical companies start using radio frequency identification technology (RFID) as a means of better tracking drugs. As a result, most pharmaceutical companies are experimenting with RFID, or at least using bar codes or other technologies such as Web portals that can help track and authenticate the drugs.

Purdue, along with several pharmaceutical giants, including Pfizer and GlaxoSmithKline, has started tagging some of its most popular drugs with RFID chips as part of a pilot program designed to track drugs from the manufacturer to the consumer. None of the technologies or

techniques now being tested is trouble free, and most demand a hefty investment in infrastructure and IT. Tagging drug bottles with RFID and collecting data on drug sales also raises privacy and security issues that have yet to be resolved. But those drug manufacturers not yet on the bandwagon can't wait for questions of standards or privacy regulations to be decided. With the help of their CIOs, who will design the IT infrastructure to support the new processes, they need to start pilot projects now to get ready for further mandates or risk getting left in the dust as the industry gears up to fight a dangerous global scourge. "Drug companies need to be seen doing everything they can to secure their supply chains," says Daniel W. Engels, director of the health-care research initiative at MIT.

Now You See It, Now You Don't

The pharmaceutical industry operates one of the world's most complex and opaque supply chains. The industry is heavily regulated, but the rules vary from country to country, as do the prices, generating a web of legitimate, quasi-legitimate and illegitimate trade. Although there are three main drug wholesalers in the United States -- Cardinal Health, McKesson and AmerisourceBergen, which collectively control 90 percent of the prescription drug business -- hundreds of smaller, secondary wholesalers also buy and sell excess inventory from the large wholesalers. A prescription drug commonly moves from manufacturer to several distributors and even "repackagers" before it lands at a pharmacy. Many of these small wholesalers are legitimate businesses that can help the supply chain run smoothly by efficiently finding buyers for prescription drugs. But they also add an extra layer that reduces visibility and creates opportunities for counterfeit drugs (including products with the wrong active ingredient or fake packaging) to enter the distribution network.

Each year, thousands of people around the world die from taking counterfeit medication, much of which has been produced in squalid conditions. And developed countries are not immune. In 2003, 18 million tablets of the cholesterol-lowering drug Lipitor, the world's best-selling prescription drug in 2004, were recalled by Pfizer in the United States after fake pills were found in pharmacies. In 2004, fake Cialis, an erectile dysfunction drug, was found in the United Kingdom supply chain; and this year 120,000 packets of Lipitor were recalled in the United Kingdom after 73 counterfeit packets were found.

To prevent such abuses, federal and state law enforcement are devoting more resources to investigating criminal networks and enforcing anticounterfeit laws. At the same time, the states of Florida and California have taken the lead in passing legislation that will push the industry to come up with a way to authenticate their products. Florida's law, effective in July of this year, requires drug wholesalers to provide a paper "pedigree," or record of where drugs originated from. California's law, set to take effect in January 2007, will require an electronic pedigree or serial number for all prescription drugs sold in the state. Initially, drug wholesalers will be responsible for creating the pedigree, whether it is paper or electronic, although manufacturers will need to comply in the future as well. Some are skeptical that the industry will be able to meet these mandates, given the current state of technology adoption. "We move so many products that it is a challenge to do what Florida is requiring," says Ron Bone, senior vice president for distribution support at McKesson. Bone, however, says his company already won't buy drugs without a pedigree when purchasing them from an "alternate source" or secondary wholesaler.

Different Ways to Track and Trace

Drug companies are working on an array of techniques to prevent counterfeit and mispriced drugs from slipping into the supply chain. Many are experimenting with holograms, color-shifting inks and watermarks that can help them authenticate the package and actual pills. Genzyme, which does the bulk of its business making specialty drugs to treat genetic diseases, is looking at using inks or dyes and is already using tamper-resistant packaging tape on some of its products. Genzyme is beginning to see some counterfeiting and price manipulation of its drugs to treat kidney disease and arthritis, says Jim Shuman, Genzyme's VP for materials management. For instance, wholesalers will sometimes buy drugs in one country where the government has negotiated a certain rate from pharmaceutical companies and then export the drugs to another country, where they can sell them at a higher price. "We now have products showing up in countries where they have never been sold," Shuman adds.

To better track its drugs around the world, Genzyme is testing a Web-based system, working with United Parcel Service (UPS) in Europe, to follow products distributed from its facilities in the United Kingdom and Ireland. Those at Genzyme who order the drug can visit the website to track a product delivery and follow the process using a traffic light system. If they see a green code, they know the delivery is on schedule, while yellow indicates a delay and red signals a problem. Shuman says that Genzyme is considering expanding the Web-based system with UPS to include more geographic areas.

Other pharmaceutical companies are working to create electronic pedigrees for their drugs through track and trace technologies such as bar coding or RFID. Bar-coding technology, which has matured over the past 20 years, is cheaper to implement than RFID, but it can be more expensive to maintain because it requires someone to read the package at each stage of the supply chain. Passive RFID tags, on the other hand, can be read automatically as unopened boxes pass by electronic readers in a warehouse. Paul Chang, associate partner at IBM Business Consulting Services, says that companies will be able to comply with the new state pedigree legislation using bar codes as well as RFID to authenticate their products. He predicts that these two technologies will coexist for years to come.

Pfizer and Purdue are ahead of the pack with RFID tagging pilots, if only because these companies produce Viagra and Oxycontin respectively -- two drugs that have been more vulnerable to theft and counterfeit because of their popularity. These companies are trying out RFID because paper pedigrees are expensive to produce and can be forged and lost. "RFID is interesting because it's not just a bar code replacement," says MIT's Engels. "You can put sensors on it or log the product's temperature history and create a database on the products." Knowing the temperature is important because some drugs need a certain amount of refrigeration in order to remain active.

The Oxycontin Story

Even before the FDA came out with its statement in favor of RFID, supply chain executives at Purdue Pharma were working to meet a 2004 mandate from Wal-Mart that all shipments of "Class 2" narcotics, including the highly addictive Oxycontin, be labeled with RFID tags. While Purdue executives were wrestling with the new technology, they saw that it could also help them in the battle against counterfeit drugs in the supply chain.

Mike Celantano, Purdue's associate director of supply chain systems and RFID, says that when his group first started to investigate RFID tagging, the technology was immature and there were few examples to follow. "Wal-Mart specified the frequency and the type of tags it wanted, and it was up to us to find a solution," Celantano says. Purdue figured out a way to tag the product as

it moved along a high-speed production line before it ended up in cases that each contain 48 bottles of Oxycontin. Purdue met Wal-Mart's mandate and at the same time was able to gain experience with data collection and RFID's track-and-trace capabilities. Celantano used SAP's Aii middleware software to collect the information from the RFID labels.

Starting earlier this year, Purdue began testing an electronic drug pedigree using RFID tags to match each bottle of Oxycontin with a corresponding record that shows the drug's movement through the distribution chain. The idea, says Celantano, was to look at ways to pass along data from the manufacturer to the distributor and eventually to a hospital or pharmacy.

Before shipping a case of Oxycontin to its distributor, H.D. Smith, Purdue scans the shipment and records data that includes a unique electronic product code as well as a batch or lot number and expiration date. So, when H.D. Smith receives a shipment of Oxycontin from Purdue, the distributor can authenticate it, certify the pedigree and make sure its serial number -- the electronic product code number -- for each bottle of medication matches the corresponding number on the bottle's RFID tag. Celantano says the pilot shows that it's possible to create an electronic pedigree using RFID. In the future, he says, the process could extend beyond the distributor down to the retailer.

"The potential is tremendous from both an efficiency and a safety standpoint because you're introducing that ability to manage the product supply chain at a level of granularity that has never been seen before," Celantano says. When you can track and manage each case of pills, he says, it will be easier to match document cases as they flow through the supply chain. And distributors will no longer be able to disguise where the product comes from.

The Problem with RFID

Celantano acknowledges that anyone trying out RFID in the pharmaceutical industry is facing some serious challenges. "RFID is one way to tighten the supply chain, but it's not a panacea," he says. First of all, compared with the consumer packaged-goods industry, which is using RFID to tag cases and pallets, pharmaceutical companies need to label each bottle to create a system that will allow for authentication. There are also questions about how radio frequency will affect biological products. According to McKesson's Bone, the industry still needs to be reassured that their liquid and biological medications won't be affected by RFID tags, although tests have shown that solid medications aren't damaged by the radio waves.

The cost of building the infrastructure needed for RFID and the lack of agreed-upon industry standards are also holding back mass RFID adoption. But Graham and Celantano say they are encouraged by the results of their initial trials. "At this point, no one knows the durability of the tags," Graham says. But he says that once the tags have been applied to the bottles, the tags are tested and if found defective removed before issued to the packaging line. As a result, the failure rate is low; only seven out of 200,000 RFID tags have failed inside the plant. (Purdue pays Symbol Technologies between 30 cents and 35 cents a tag and each tag is applied to a bottle containing 100 tablets.) Graham says they could scale up at any time if more in the industry decided to invest in RFID infrastructure and technology. But if more distributors and retailers don't sign on, there will be very few distributors able to read the tags.

Graham adds that electronic pedigree technologies like the one they are testing with H.D. Smith, Unisys and SupplyScape would "wipe out" a significant number of "gray market" wholesalers, thus tightening the supply chain. If manufacturers are able to track their drugs

through the supply chain, then the smaller wholesalers will no longer be able to sell drugs they have purchased illegally.

While Purdue and other large drug manufacturers are experimenting with RFID, other companies are waiting to see what standards will be developed and how feasible the technology is. "I believe that the pharmaceutical industry as a whole is waiting for proof that RFID can work," says Dennis Kim, senior manager of supply chain operations at Tap Pharmaceuticals. At Tap, Kim says supply chain and IT leaders are working to understand how the technology can be applied and are reviewing pilot opportunities so they will be ready if they need to be. "RFID is expensive and the technology is becoming more robust, but it's not quite there yet," Kim says. "Most people are saying they're not going to commercial deployment until they have to."

Robert Cowie, CIO at biotech company Genzyme, says he believes RFID is a good idea for improving efficiency in the consumer product supply chain. However, he also does not think the technology is mature enough for his company to start using it. "The cost of the unit and its level of reliability doesn't make RFID economical for us right now," Cowie says. Forrester Research VP Laura Ramos agrees that most pharmaceutical companies should wait on RFID until the technology matures. Typical tag failure rates are not uncommon, and placing tags near certain metals and liquids can cause reader interference rates to climb higher, Ramos notes.

For now, companies that are taking the lead with RFID are those that sell either high-profile or very expensive drugs. Whereas it may not be economically feasible to buy a 30-cent RFID tag for a bottle of Tylenol, it would be more appealing for a $50 or $100 prescription.

The Big Brother Issue

Privacy concerns relating to RFID could also cloud the picture for the technology's easy adoption. Privacy groups such as the American Civil Liberties Union and Consumers Against Supermarket Privacy Invasion and Numbering, or CASPIAN, have raised concern over RFID use in the retail sector, fearing a loss of privacy if the technology is used to track what people buy and bring into their own homes. In the pharmaceutical industry so far, RFID tags are placed on the large bottles that pharmacies buy, but not on the bottles of pills that consumers take away from the pharmacies. Still, "privacy could be the killer issue that seriously limits the potential value of RFID in product tracking," says Forrester's Ramos.

Examples from outside the United States underscore how collecting data from medication down to the vial could raise concerns from privacy advocates. In Italy, for example, a law requires that each vial of a prescription drug have a unique ID. The vials, marked with bar codes, are read at each stage of the supply chain until they reach the pharmacy or hospital. Italian law requires that the data captured go directly to a central government database. While such an intrusion of privacy by the government would probably not be permitted in the United States, pharmaceutical companies have already gained access to individual prescription information from some pharmacy chains, and RFID tags on individual medications could accelerate that trend. (Under pressure from a recent class-action lawsuit, CVS was forced to stop its practice of sharing patient prescription information with major pharmaceutical companies.)

"Security and privacy will have to be addressed more fully than they have been, because when we create a network information system that spans the globe -- as the pharmaceutical supply chain does -- the data won't always be protected by VPNs or other secure networks," Engels says.

Despite such issues, Purdue's Graham believes that tracking and tracing technology represents the best chance so far to solve the problems he helped expose back in 1995. "Operation gray pill" ultimately led to more than 100 convictions and $25 million in fines from drug wholesalers. An executive at the country's fourth-largest wholesaler at the time, Bindley Western, pled guilty to two federal felony and fraud charges after the sting operation revealed he had been directing people to buy from Graham and his colleagues so they could get a discount themselves. Ten years later, however, such fraudulent practices remain common.

"The system hasn't changed, and the loopholes remain in place," Graham says. "That's why track-and-trace accountability is so important."

THE WALL STREET JOURNAL. ONLINE

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January 6, 2006 2:29 p.m. EST

Pfizer Uses ID Tags to Ship Viagra, Combat Counterfeiting

By NICOLE URBANOWICZ
DOW JONES NEWSWIRES
January 6, 2006 2:29 p.m.

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NEW YORK -- **Pfizer** Inc. has begun to ship Viagra with radio frequency identification tags to prevent counterfeiting.

Pfizer, which has invested several million dollars to date in the RFID technology, said Viagra was selected to launch this project because the erectile dysfunction treatment has been a major target for counterfeiters.

Pfizer said it is the first pharmaceutical company to establish a comprehensive program of this type focused on electronic product code authentication as a method to deter drug counterfeiters.

In a news release Friday, Pfizer said the RFID tags that are incorporated into each package, case and pallet of Viagra will enable pharmacies and wholesalers to verify the unique electronic product code, or EPC, on Viagra packaging. The technology allows pharmacists and wholesalers to use specially designed electronic scanners that communicate the code over the Internet to a secure Pfizer Web site.

However, Pfizer's application of RFID isn't yet capable of tracking and tracing medicine through the distribution system. "Track and trace" requires that all parts of the supply chain invest in compatible technology and agree to capture and share information about product movement.

Pfizer plans to continue to explore the uses of this technology, including "track and trace," during the coming year. The drug company's application of RFID doesn't collect any patient information.

The company expects it will take several years before RFID is applied broadly throughout the pharmaceutical industry, and said cost will be a significant consideration, as well as the readability and reliability of RFID tags. Pfizer also said standards must be developed to govern the technology and data exchange.

Write to Nicole Urbanowicz at nicole.urbanowicz@dowjones.com[1]

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HDMA
Healthcare Distribution
Management Association

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December 22, 2005

Ms. Patricia Harris
Executive Director
California State Board of Pharmacy
400 R Street
Suite 4070
Sacramento, CA 95814-5784

Dear Ms. Harris:

On behalf of the Healthcare Distribution Management Association (HDMA) and our distributor members, I am pleased to inform you of the recent launch of a new initiative for the federal licensure of prescription drug distributors. In this era of increasingly sophisticated threats to the integrity of the nation's drug supply, the time has come for uniform federal licensing of pharmaceutical distributors, and I hope you will support this important endeavor.

HDMA commends your efforts to protect the citizens of California from the threat of counterfeit drugs through commitment to strong enforcement and oversight of the prescription drug supply chain. We appreciate the cooperative spirit that state regulators have shared with HDMA during this past year. Protecting the nation's drug supply is a responsibility shared by distributors, manufacturers, pharmacies and government. We look forward to continuing a productive ongoing relationship that will help to further secure the drug supply and ensure patient safety.

As I am sure you will agree, however, there is much work to be done. Since the enactment of PDMA in 1988, a patchwork of regulatory standards has evolved across the states, resulting in inconsistencies and contradictions. In part, this may be due to resource constraints in some states and the challenges of regulating a distribution system that is increasingly dependent upon interstate commerce. As a result, opportunities exist for unethical, criminal entities to avoid strict regulation by taking advantage of regulatory gaps and enforcement problems created by a state-by-state approach.

HDMA is supportive of national licensure because maintaining the integrity of the United States' prescription drug supply is a compelling national priority. Our goal is to secure Congressional support for a uniform federal standard for the licensure of pharmaceutical distributors and provide the Food and Drug Administration (FDA) with the authority to issue licenses according to uniform, tough, federal standards. We believe it is also important to maintain an optional role for states to inspect facilities as well as the ability to petition the federal government for increased regulatory authority in unique circumstances. HDMA pledges to work with lawmakers and regulators at the national and state levels to ensure that the resulting regulatory framework provides enhanced supply chain security while maintaining a reliable and efficient supply of prescription drug products for consumers.

For your information and review, I have enclosed a copy of HDMA's policy statement regarding federal licensure, and my staff is available to discuss this important initiative. Please contact Elizabeth Gallenagh, Director, State Government Affairs at 703-885-0234 for more information.

Sincerely,

John M. Gray
President and CEO

901 North Glebe Road • Suite 1000 • Arlington, VA 22203
(703) 787-0000 • (703) 935-3200 (Fax) • www.HealthcareDistribution.org

HDMA
Healthcare Distribution
Management Association

HDMA Policy Statement

The Time is Now for Uniform Federal Licensing of Prescription Drug Distributors:

Protecting the Integrity of the Supply Chain for Patient Safety

A Policy Statement Approved by the Healthcare Distribution Management Association Board of Directors

October 2005

Healthcare Distribution Management Association (HDMA)

901 North Glebe Rd.
Suite 1000
Arlington, VA 22203

For more than 125 years, HDMA has worked with its members to secure a safe, efficient and reliable healthcare distribution system that provides life-saving health products and services. HDMA members ensure that billions of units of medication are delivered safely and efficiently to tens of thousands of retail pharmacies, hospitals, nursing homes, clinics and other provider sites in all 50 states. HDMA members are a vital link in the healthcare system, providing highest quality solutions that save money and empower providers to deliver care more effectively. Through our advocacy activities, HDMA operates at the forefront of health care, and ensures that members' perspectives and businesses are understood and addressed in legislative and regulatory arenas. For more information on HDMA, please visit www.HealthcareDistribution.org.

HDMA Policy Statement

The time has come for uniform federal licensing of prescription drug distributors. In an era of increasingly sophisticated domestic and international threats to the integrity of the nation's prescription drug supply, the Healthcare Distribution Management Association (HDMA) believes the current state-by-state licensing structure cannot provide the strong and consistent regulation of pharmaceutical distribution necessary to further secure the supply chain and protect the safety of the public. Maintaining the integrity of the United States' prescription drug supply is a compelling national priority that requires a national solution involving business and government. A uniform federal standard for the licensure of pharmaceutical distributors is necessary to enhance the protection of the public health. The time to act is now.

HDMA believes it is essential to provide the U.S. Food and Drug Administration (FDA) with authority to license prescription drug distributors according to uniform, tough, national standards and to maintain an optional role for states to inspect facilities. HDMA pledges to work with lawmakers and regulators at the national and state levels to ensure that the resulting regulatory framework provides enhanced supply chain security while maintaining a reliable and efficient supply of prescription drug products for patients.

Background: The 1980s System in the 21st Century

The Prescription Drug Marketing Act (PDMA) was enacted in 1988 to provide additional assurance to American consumers that their prescription drugs were safe and effective, and had been handled and stored appropriately. At that time, Congress found that "American consumers cannot purchase prescription drugs with the certainty that the products are safe and effective" and that "the integrity of the distribution system for prescription drugs is insufficient to prevent the introduction and eventual retail sale of substandard, ineffective, or even counterfeit drugs."

Prior to the enactment of the PDMA, the licensing of pharmaceutical distributors was solely a function of state government. The PDMA established minimum federal standards for the licensing of prescription drug distributors. States, however, continued to be responsible for establishing their own licensing requirements, consistent with the minimum federal standards, and to be responsible for licensing and inspection of pharmaceutical distributors.

Since the enactment of PDMA, states have enacted a patchwork of regulatory standards that is inconsistent and often contradictory. In part, this is because of resource constraints within various states and the challenges of regulating a distribution system that is increasingly dependent upon interstate commerce. The resulting regulatory patchwork provides opportunities for unethical and criminal entities to avoid consistently strict regulation by taking advantage of the regulatory voids that exist state-by-state.

The Evolution of Licensure

The U.S. healthcare supply chain has evolved over time, and there have been important changes in the nearly two decades since Congress enacted the PDMA. It should be no surprise that a regulatory system crafted in the 1980s now would face very different challenges that require very different solutions.

The following factors demand a new approach to licensure:

1. The increasing frequency and sophistication of pharmaceutical counterfeiting
2. The increasing threat of terrorism
3. Consolidation of the domestic distribution industry and the significant reliance upon interstate shipment of prescription drug products
4. The difficulty of states effectively licensing and regulating out-of-state distributors
5. The enactment of an inconsistent patchwork of state licensing standards and great variability in the state commitment to fund and enforce those standards.

These factors combine to point to the urgent need for an updated regulatory approach that is uniform across the states and reaches across the entire supply chain. It is now clear that the only truly effective response is for the federal government to establish uniform national standards for the licensing and inspection of prescription drug distributors.

The current state-based regulatory system is ill-equipped to deal with these emerging realities, and may actually impede the adoption across the supply chain of such advanced technologies such as electronic product code (EPC) and radio frequency identification (RFID). This technology provides enhanced ability to track the path of pharmaceutical products moving through the supply chain. It can significantly enhance the ability of the industry and government to further secure product integrity, but it cannot be implemented if state requirements are inconsistent and contradictory.

HDMA has a consistent and long track record of working with state and federal policymakers and regulators to address the challenges in our state-based regulatory system. HDMA has testified in the states and before Congress, and has a strong record of submitting formal comments and recommendations in response to state and federal proposals. The association is committed to uniform, strong national licensure standards.

The Case for Reform

It is critical to address this national priority without further delay. Counterfeiters and other criminals are becoming increasingly sophisticated in their methods and capabilities. This 21st Century problem cannot be addressed through 1980s approaches, whether at the level of individual business practices or at the level of government regulation. A comprehensive response must include stricter regulation, adoption of best business practices and the utilization of new and advancing technologies, including EPC/RFID.

American consumers expect their medicines to be safe and readily available in their pharmacies, 24 hours a day, 7 days a week. To meet this requirement, pharmaceutical distributor licensing requirements must be modernized and uniform throughout the country. This can only be accomplished by establishing uniform federal standards. Licensing standards, by their very nature, demand a consistent and coordinated approach. HDMA believes this can only be accomplished by providing the FDA with the authority to establish such uniform federal standards and to empower them to issue licenses and establish a system for consistent regulation and inspection.

Conclusion

The system under which prescription drug distributors are licensed and regulated must be modernized to address increasingly sophisticated threats to the domestic supply chain. HDMA believes there is compelling and urgent need to consider a national, uniform approach to distributor licensing. HDMA and its primary, full-service distributor members stand ready to work--with government and with all supply chain partners--on these next critical steps for the safety and security of the nation's healthcare system.

In considering how best to make decisions about a national, uniform prescription drug licensing system, HDMA suggests three guiding principles:

- First, any national licensing endeavor must be guided by the priorities of patient safety and supply chain integrity.
- Second, supply chain oversight from manufacture to consumption must be based on best practices, including interim and promising new technologies such as Electronic Product Code/Radio Frequency Identification (EPC/RFID). We must be able to flexibly allocate research, business and regulatory resources in order to be cost-effective and to maximize efficiencies. In these times of scarce resources, it is critical to align these resources with the most pressing needs.
- Third, it will take an ongoing industry and government commitment to monitor and employ all state-of-the-industry processes and security measures across the system. This cannot be achieved by an individual partner in the supply chain or an individual agency in the government. Although the current system is in need of reform to meet the current and future challenges, it is still the standard of excellence, and it will take consistent and coordinated efforts to continue to improve upon that high standard.

# # #

U.S. Food and Drug Administration

Speech before

NACDS/HDMA RFID Healthcare Adoption Summit

Remarks by

Randall Lutter, Ph.D.
Associate Commissioner
Food and Drug Administration

November 14 , 2005

This text contains Dr. Lutter's prepared remarks. It should be used with the understanding that some material may have been added or deleted during actual delivery.

Introduction

- I am very pleased to have this opportunity to speak at the first, and hopefully not the last NACDS and HDMA Summit on the adoption of Radio Frequency Identification technology in health care. We at FDA congratulate HDMA and NACDS for organizing this meeting and greatly appreciate your ongoing commitment and work to advance current and emerging technology and business solutions--such as RFID--to combat counterfeit drugs and thereby improve the integrity and safety of the U.S. drug supply.
- RFID is more than just a means to control counterfeit drugs. In the broader scheme it is a 21st century technology to ensure patient safety. As makers, distributors, and dispensers of drug products, you have an obligation to maintain and guarantee the integrity of the drug products that you sell. RFID can both help you to meet this obligation and help us ensure that all drugs are safe and effective.
- I am here to tell you that FDA shares your hopes about the promise that RFID brings for the distribution and delivery of health care products into the 21st Century. We also share some of your concerns about the need for coordinated action to overcome obstacles in implementing this technology.
- Dr. Andy von Eschenbach, our Acting Commissioner is engaged, knowledgeable, interested, and supportive of RFID.
- Successful adoption of electronic track and trace technologies like RFID will require unusually high levels of cooperation among all stakeholders in the manufacture and distribution of medical products. Meetings like this are essential to foster and cultivate the necessary cooperation. Without cooperation among stakeholders the full promise of RFID can not be realized. While investments in some RFID technology may well make sense for some individual companies, the net benefits that all stakeholders will enjoy from RFID will be maximized only if independent organizations adopt common standards and compatible approaches.
- Today I would like first to discuss the policy problem that electronic track and trace technologies such as RFID can help solve, at least from the perspective of FDA. Increasingly sophisticated counterfeit drug organizations have posed an increasing threat to the integrity of the drug supply in the U.S. Lack of information in the drug distribution system is hindering efforts to ensure that each patient gets the right drug in the right amount at the right time.
- Second, I would like to summarize for you the steps that FDA has taken recently to remedy this problem. These include the February 2004 Report on Combating

Counterfeit Drugs, and our efforts to encourage the voluntary adoption of RFID during the stay until December 2006, of the pedigree regulations issued under the Prescription Drug Marketing Act.

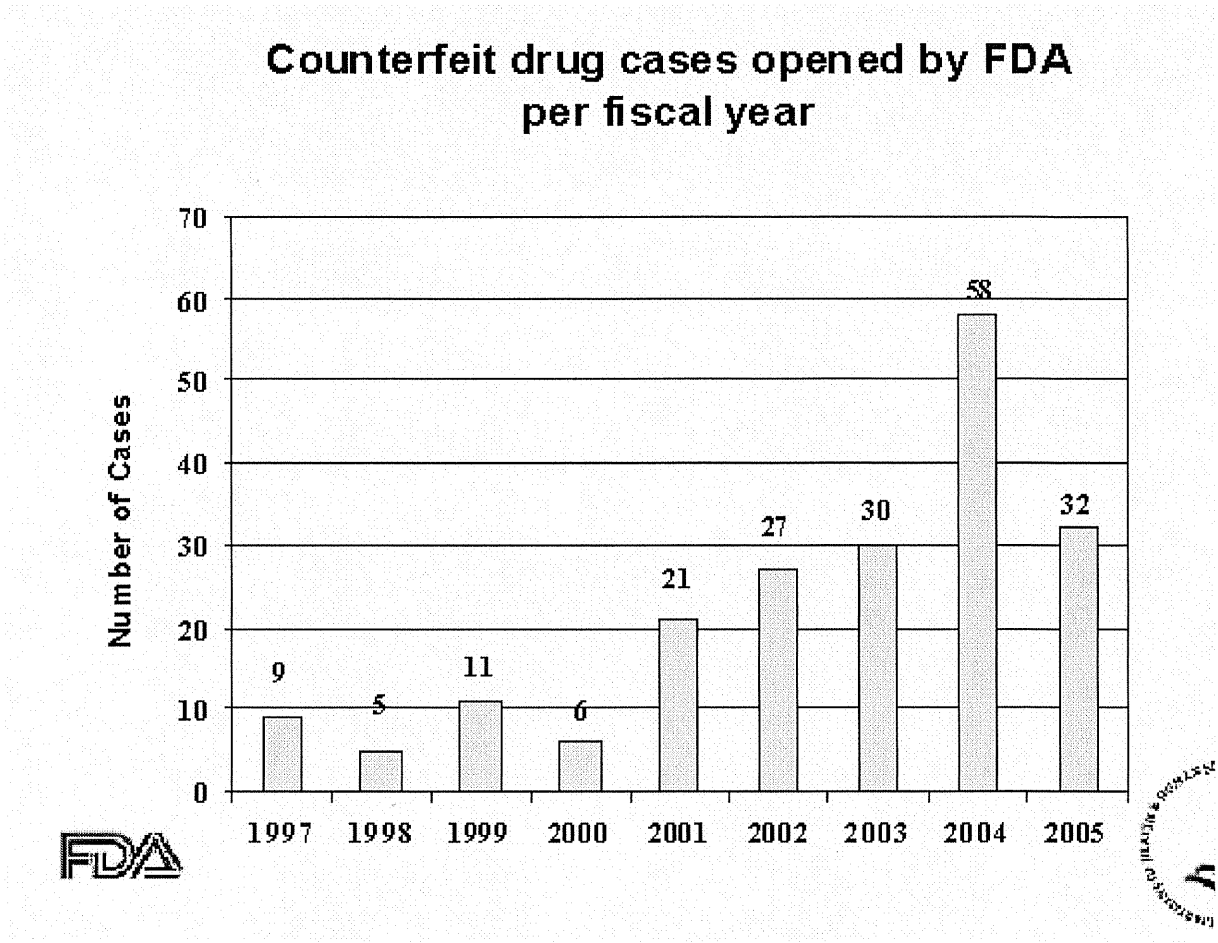
- And finally, I will tell you what our plans are for helping drive adoption of an electronic pedigree and RFID and ensuring that Americans have the greatest possible assurance that their medications are safe and effective.
- But before proceeding, let me share with you a vision about how the distribution of medical products could occur in the near future, if we take the right steps today.
    - We at FDA envision a world where devious would-be peddlers of diverted or fake medicines are thwarted and unable to sell to unsuspecting U.S. wholesalers, pharmacists and, most importantly, patients.
    - We envision pharmacists at drug stores and hospitals being certain of the safety and efficacy of drugs they are dispensing, including their appropriateness for particular patients.
    - This certainty comes not merely because the label conveys FDA approval but because an up-to-date electronic database confirms that the particular package contains the genuine authentic product--it was tracked at each stage of the distribution chain, from the FDA-approved manufacturing facility, to the dispensing pharmacist.
    - Further, the electronic track and trace system that will provide this certainty, offers such savings to private firms that the benefits of greater certainty about safety and efficacy are realized without any untoward increase in the costs of medications at a retail level.
    - This final point is important. While fighting counterfeit drugs is a key part of FDA's mission to ensure drug safety, we acknowledge important public concerns about the cost of medications and the implications of high costs for access to drugs. Based on discussions with some drug companies and retailers, we believe that RFID can offer significant savings in the form of better inventory management to manufacturers, wholesalers and retailers alike. Other savings would stem from reduction in theft and product loss, improved recalls, and reduction in paperwork burdens. While desire for these cost savings is understandably the key motivation for your pursuit of RFID, our interests overlap. Thoughtful adoption of RFID, while helping you financially, will also offer a lower cost way of ensuring authenticity of drugs thereby providing key support for our fight against diversion and counterfeiting.
- Let me elaborate why implementing this vision is important to combating the problem of counterfeit drugs.

The Counterfeit Drug Problem

- But before describing the counterfeit drug problem, let me make a general comment: While we are here to discuss steps to improve the integrity of the U.S. drug supply it is important to note how good it already is. Counterfeit drugs in the U.S. are quite rare.
    - While we have no direct quantitative evidence about the prevalence of counterfeit drugs, because they so successfully mimic genuine products and by all accounts are rare, we are confident that the overwhelming majority of prescription drugs sold in the U.S. are products genuinely approved by FDA.
    - We believe counterfeit drugs represent significantly less than one percent of the total U.S. drug supply.
- The high confidence that we and the public have about the distribution system for U.S. drug products stems from an intricate web of federal and state laws. These laws require drugs to be treated as potentially dangerous consumer goods that require regulations and oversight by health professionals in order to protect the public health.
- Despite this high confidence, FDA has been concerned that the drug supply is under increasing threat of attack from ever more sophisticated counterfeiters. This disturbing trend is evident in the increased efforts to introduce counterfeit drugs into the U.S. market.
- The Agency has witnessed an increase in counterfeiting activities and a greater capacity to introduce finished dosage form counterfeits into legitimate drug distribution channels.

Illicit wholesale drug diverters and others in the supply chain provide the window through which most counterfeit drugs have historically entered legitimate distribution channels.

- As you can see from Slide 1, the number of newly initiated counterfeit drug cases has risen sharply from just a few years ago, although preliminary data from fiscal year 2005 suggest a decline relative to the peak reported for fiscal year 2004. In fiscal year 2004, FDA's Office of Criminal Investigations (OCI) initiated 58 counterfeit drug cases, a significant increase from the 30 cases initiated in FY 2003.



D

- Let me stress that these are estimates of the number of newly initiated counterfeit drug cases being investigated. Since these are ongoing cases, we have no estimate of the volume of counterfeit drugs involved in each case--it could vary from dozens to thousands.
- We believe that the unusually high number of cases in FY2003 is in part due to an increased awareness and vigilance at all levels of the drug distribution chain. One factor contributing to this increased awareness and vigilance is the Counterfeit Drug Report that FDA issued in February 2004. A second is increased referrals from, and coordination with other state and federal law-enforcement agencies, and communications with drug manufacturers.
- The decline from 58 cases in 2004 to 32 new cases in 2005 may be due partly to a positive deterrent effect of the new 2004 cases on the level of counterfeiting in 2005. But the decline may also exist because some new cases, after further research, are found to relate to the large number of existing ones. In reality we can not identify the exact causes of changes in the number of new counterfeit drug cases opened each year.
- Fortunately, most of the counterfeit drugs at issue did not reach consumers because we focused our resources and developed proactive investigations. We believe that this strategy enabled us to identify components of counterfeit products and interdict finished counterfeit drug products before they entered retail distribution.

including privacy, standards, technology and policy.

- In our February 2004 report, we took an essentially voluntary approach toward widespread adoption of electronic track and trace. Supply chain stakeholders assured us that there would be considerable movement toward implementation of RFID and that widespread adoption could be done in 2007. We believed at that time regulatory intervention might stifle innovation and progress in adopting this emerging technology. Yet from our vantage point today, it appears a voluntary approach may not be enough.
- In an annual update in May of this year we said that "stakeholders have made tremendous progress in the development and implementation of EPC/RFID [(electronic product code for unit serialization)]. This is a huge endeavor that requires close collaboration among all constituents of the pharmaceutical distribution system. "
    - We also said that "we are pleased with the progress stakeholders, standard setting bodies, and software and hardware companies have made thus far toward implementing an electronic pedigree for drug products. We realize that there have been, and continue to be, challenges along the way. However, we are optimistic that this progress will continue in an expeditious manner toward meeting our 2007 goal. If it appears that his goal will not be met, we plan to consider the options regarding implementation of the PDMA provisions that are the subject of the stay."
- At this point we have become concerned about the slow or inadequate progress implementing an electronic pedigree. We are concerned that widespread adoption may not be realized by December 2006, when the PDMA stay expires.

Next Steps

- Let me turn now to our plans to renew and reinvigorate our support for RFID so as to accelerate its adoption.
- First, FDA, given its responsibilities for drug safety, must ensure that radio-frequency exposure does not impact the quality, safety, or efficacy of drug and biologic products.
    - We asked stakeholders to share data and information regarding the effects of RF on drug and biologic products. We haven't received significant amount of data to date.
    - We believe, based on preliminary information and hypothesis, that RF does not have a significant thermal effect on solid dosage forms.
    - An FDA CDRH lab has done some preliminary research looking at the heating effect of 915 MHz RFID fields on a placebo, simulating a pharmaceutical. The research showed a very modest rise in temperature, of unknown significance.
    - This small bit of information shows that we are just beginning to know the impact of RF on certain products. This has given us the impetus to develop and conduct our own studies to determine the impact of RF on a range of products.
    - We are developing protocols for further research, but we intend to look at RF effects on various types of drug, biologics, and various types of packaging materials under a variety of conditions. Effects we will consider will include
        - Thermal effects (the impact of heat), and
        - Non-thermal effects (the impact on molecular bonds).
    - We expect to share the results in spring or summer 2006.
- Second, I am pleased to announce here that the FDA Counterfeit Drug Task Force is going to hold a Public Workshop in January or February 2006.
    - The new chairpersons of the Task Force are Maggie Glavin, Associate Commissioner for Regulatory Affairs and me. The purpose of the meeting is to --
        - Facilitate RFID standard-setting and coordination of issues,
        - Discuss PDMA/pedigree issues related to the stay, and
        - Reaffirm our commitment to facilitate and drive adoption of electronic track/trace technology.
    - Our general interest is in identifying the current barriers to adoption and finding ways these barriers can be overcome. We haven't yet set the agenda, but I can sketch here some issues that we've heard merit further public discussion. These

- It is important to note that the number of cases that OCI has opened is NOT an indication of the prevalence of drug counterfeiting in the U.S. Almost 4 billion prescriptions were filled last year. That means a very large volume of drugs is moving through the supply chain. The sophistication and precision of counterfeit copies make a reliable estimate of the number impossible. However, we believe that existing regulations and the commitments by most supply chain stakeholders to comply with these rules, keep very low the prevalence of drug counterfeiting in the U.S.
- Unfortunately, not everyone abides by the rules. Counterfeit, stolen, and otherwise fraudulently obtained pharmaceutical drugs can enter legitimate channels through pre-existing illicit diversion networks. OCI's enforcement efforts targeting these diverters also have resulted in detection and dismantling of counterfeit schemes. Without the intimate knowledge of diversion borne of extensive investigative experience it would be difficult, if not impossible, to effectively combat pharmaceutical counterfeiting.
- Counterfeit drugs in other countries are a much bigger threat than in the U.S. Strong enforcement efforts are the key to keeping counterfeits off the U.S. market.

FDA's Recent Activities

- FDA has tried to implement the Prescription Drug Marketing Act while encouraging the voluntary adoption of anti-counterfeiting technologies and practices.
- For those of you who are not familiar with PDMA, the Prescription Drug Marketing Act is a law passed in 1987 in response to a number of counterfeit drug incidents in the U.S. where patients received counterfeit drugs.
    - PDMA requires State licensing of wholesale distributors of prescription drugs and requires unauthorized wholesale distributors to provide purchasers a statement (also called a pedigree) identifying each prior sale of the drug. FDA issued final regulations implementing the PDMA in 1999.
    - Shortly thereafter, the agency received comments raising a number of concerns related to the pedigree provisions. Many of the concerns suggested that there would be an adverse economic impact on wholesalers who have to provide pedigrees. Comments noted the high costs of using paper pedigrees--the best technology then available—and the inability of wholesalers would be unable to get complete pedigrees from sellers, even for legitimate transactions. As a result, FDA stayed certain provisions of the final rule, and has continued to stay these provisions. The current stay, which expires in December 2006, was issued in part to give stakeholders time to implement an electronic track and trace technology solution.
- Our statements to stakeholders in the February 2004 report were
    - Adoption and common use of reliable track and trace technology would be feasible in 2007, and would help secure the integrity of the drug supply chain by providing an accurate drug "pedigree".
    - RFID is the most promising approach to provide reliable and timely track and trace information.
    - Adoption of electronic track and trace technology would help stakeholders meet and surpass the goals of PDMA.
- Since February 2004 we have engaged in a variety of efforts to cultivate RFID implementation/adoption.
    - We are working closely with individual companies and supply chain partnerships who are implementing or piloting RFID, including several companies that are here today.
    - EPCglobal has kindly welcomed FDA to meetings of its Health and Life Sciences Business Action Group, where much of the standard setting work is being done. We are pleased by the progress that they are making in this area.
    - We have led an FDA RFID working group, in which all FDA centers are represented, information is shared within the agency, and consistent approaches are identified and pursued.
    - We have also served on an inter-governmental RFID Council, coordinated by the Department of Defense. We participate in 4 sub-working groups on this panel,

include:

- What type of number should be used as the unique identifier: the embedded NDC number or a randomly generated number to protect privacy and mask product identity;
- Should all of the transaction information be stored and accessible at a single central database or a distributed network of information. Does it really matter if it's one or the other?
- What common fields/information should be included in an electronic pedigree?
- What incentives are needed for more rapid and widespread adoption?
- What can FDA do to further facilitate/drive adoption across the supply chain?

- In the coming weeks, we will put out an invitation for people to testify on these and other issues and we expect to publish more information about this meeting in the near future both in the Federal Register and posted on FDA's website.

- We have been advocating the adoption and widespread use of electronic track and trace technologies for almost 2 years now. We know that many of you have been involved in exploring RFID technology for significantly longer than that. With our February 2004 report, we gave this technology a big push for use in the pharma sector. Let me be clear that this continues to be an Agency priority and we are prepared to give this another big push to keep the momentum moving quickly.
- I believe that the steps that I have shared with you today—the public workshop and any follow up from that and the RFID research that we will be conducting, as well as our continued interactions and discussions with you and your companies, demonstrate our commitment to push this forward.
- We want this to succeed and we continue to believe that widespread adoption is feasible in the very near future

Thanks again for giving me this opportunity to speak. I have a few minutes for questions.

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ATTACHMENT C

4040. (a) "Prescription" means an oral, written, or electronic transmission order that is both of the following:

(1) Given individually for the person or persons for whom ordered that includes all of the following:

(A) The name or names and address of the patient or patients.

(B) The name and quantity of the drug or device prescribed and the directions for use.

(C) The date of issue.

(D) Either rubber stamped, typed, or printed by hand or typeset, the name, address, and telephone number of the prescriber, his or her license classification, and his or her federal registry number, if a controlled substance is prescribed.

(E) A legible, clear notice of the condition for which the drug is being prescribed, if requested by the patient or patients.

(F) If in writing, signed by the prescriber issuing the order, or the certified nurse-midwife, nurse practitioner, or physician assistant who issues a drug order pursuant to Section 2746.51, 2836.1, or 3502.1, respectively, or the pharmacist who issues a drug order pursuant to either subparagraph (D) of paragraph (4) of, or clause (iv) of subparagraph (A) of paragraph (5) of, subdivision (a) of Section 4052.

(2) Issued by a physician, dentist, optometrist, podiatrist, or veterinarian or, if a drug order is issued pursuant to Section 2746.51, 2836.1, or 3502.1, by a certified nurse-midwife, nurse practitioner, or physician assistant licensed in this state, or pursuant to either subparagraph (D) of paragraph (4) of, or clause (iv) of subparagraph (A) of paragraph (5) of, subdivision (a) of
Section 4052 by a pharmacist licensed in this state.

(b) Notwithstanding subdivision (a), a written order of the prescriber for a dangerous drug, except for any Schedule II controlled substance, that contains at least the name and signature of the prescriber, the name and address of the patient in a manner consistent with paragraph (3) of subdivision (b) of Section 11164 of the Health and Safety Code, the name and quantity of the drug prescribed, directions for use, and the date of issue may be treated as a prescription by the dispensing pharmacist as long as any additional information required by subdivision (a) is readily retrievable in the pharmacy. In the event of a conflict between this subdivision and Section 11164 of the Health and Safety Code, Section 11164 of the Health and Safety Code shall prevail.

(c) "Electronic transmission prescription" includes both image and data prescriptions. "Electronic image transmission prescription" means any prescription order for which a facsimile of the order is received by a pharmacy from a licensed prescriber. <u>A pharmacy may also receive a facsimile of a prescription order from a patient provided that the pharmacy has the original prescription before dispensing the prescription medication to the patient.</u> "Electronic data transmission prescription" means any prescription order, other than an electronic image transmission prescription, that is electronically transmitted from a licensed prescriber to a pharmacy.

(d) The use of commonly used abbreviations shall not invalidate an otherwise valid prescription.

(e) Nothing in the amendments made to this section (formerly Section 4036) at the 1969 Regular Session of the Legislature shall be construed as expanding or limiting the right that a chiropractor, while acting within the scope of his or her license, may have to prescribe a device.

ATTACHMENT D

4073. (a) A pharmacist filling a prescription order for a drug product prescribed by its trade or brand name may select another drug product with the same active chemical ingredients of the same strength, quantity, and dosage form, and of the same generic drug name as determined by the United States Adopted Names (USAN) and accepted by the federal Food and Drug Administration (FDA), of those drug products having the same active chemical ingredients.

(b) In no case shall a selection be made pursuant to this section if the prescriber personally indicates, either orally or in his or her own handwriting, "Do not substitute," or words of similar meaning. Nothing in this subdivision shall prohibit a prescriber from checking a box on a prescription marked "Do not substitute"; provided that the prescriber personally initials the box or checkmark. To indicate that a selection shall not be made pursuant to this section for an electronic data transmission prescription as defined in Section 4040 (c), a prescriber may indicate "Do not substitute," or words of similar meaning, in the prescription as transmitted by electronic data, or may check a box marked on the prescription "Do not substitute." In either instance, it shall not be required that the prohibition on substitution be manually initialed by the prescriber."

(c) Selection pursuant to this section is within the discretion of the pharmacist, except as provided in subdivision (b). The person who selects the drug product to be dispensed pursuant to this section shall assume the same responsibility for selecting the dispensed drug product as would be incurred in filling a prescription for a drug product prescribed by generic name. There shall be no liability on the prescriber for an act or omission by a pharmacist in selecting, preparing, or dispensing a drug product pursuant to this section. In no case shall the pharmacist select a drug product pursuant to this section unless the drug product selected costs the patient less than the prescribed drug product. Cost, as used in this subdivision, is defined to include any professional fee that may be charged by the pharmacist.

(d) This section shall apply to all prescriptions, including those presented by or on behalf of persons receiving assistance from the federal government or pursuant to the California Medical Assistance Program set forth in Chapter 7 (commencing with Section 14000) of Part 3 of Division 9 of the Welfare and Institutions Code.

(e) When a substitution is made pursuant to this section, the use of the cost-saving drug product dispensed shall be communicated to the patient and the name of the dispensed drug product shall be indicated on the prescription label, except where the prescriber orders otherwise.

Camino Medical Group

A Division of the Palo Alto Medical Foundation

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West Valley/Cupertino Clinic
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San Jose, CA 95129
408-366-0595

Web Site
caminomedical.org

October 23, 2005

To: California Board of Pharmacy
400 R Street, Suite 4070
Sacramento, CA 95814

From: Steven E. Carlson, M.D
Camino Medical Group
301 Old San Francisco Road
Sunnyvale, CA 94086

The Camino Medical Group has been striving for the past few years to implement a clinic wide electronic prescribing system in order to provide a safer, more efficient prescribing process. This effort has been very successful to date except for certain instances in which the prescribing system is not able to ensure complete compliance with California State Pharmacy Law.

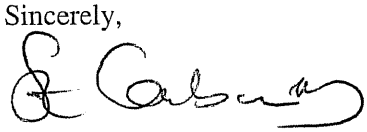
According to Section 4073 (b) of California Pharmacy Law: "In no case shall a selection be made pursuant to this section if the prescriber personally indicates, either orally or in his or her own handwriting, 'Do not substitute,' or words of a similar meaning. Nothing in this subdivision shall prohibit a prescriber from checking a box on a prescription marked 'Do not substitute'; provided that the prescriber personally initials the box or checkmark.

In the circumstance described by 4073 (b), compliance to this regulation is very difficult in the context of electronic prescription submission. Pharmacists receiving electronically transmitted prescriptions intended for DNS can still substitute generically since there is no method of providing the prescriber's initials, e.g. Levoxyl vs. levothyroxine, coumadin vs. warfarin, etc. The electronic prescribing program which has been implemented by Camino Medical Group does contain a default area 'box' for DNS or DAW which can be populated with either 'yes' or 'no'. However, even if the prescriber indicates a 'yes' in the designated default area, it is nearly impossible to guarantee that his patient will get a branded prescription as desired since the dispensing pharmacist is allowed to substitute because there is no method for the physician/prescriber to initial an electronically transmitted prescription DNS area. This becomes an extremely critical medical issue and can lead to potential toxicity for drugs with a narrow therapeutic window.

We would like to enlist your support in helping us to provide a solution to this problem. If none seems possible, we would like to advocate the provision of a regulation which would exempt prescribers from initialing electronically transmitted prescriptions.

Thank you for your cooperation and we look forward to your response and proposed resolution to this issue.

Sincerely,



Steven E. Carlson, M.D.

ATTACHMENT E

FDA News

FOR IMMEDIATE RELEASE
P06-04
January 11, 2006

Media Inquiries:
Catherine McDermott, 301-827-6242
Consumer Inquiries:
888-INFO-FDA

FDA Cautions Consumers Against Filling U.S. Prescriptions Abroad

Drugs With Same or Similar Names May Contain Different Active Ingredients Than in U.S. and Pose Health Risks

The U.S. Food and Drug Administration (FDA) is warning healthcare professionals and consumers that filling their prescriptions abroad may have adverse health consequences because of confusion with drug brand names that could inadvertently lead consumers to take the wrong medication for their condition. An FDA investigation has found that many foreign medications, although marketed under the same or similar-sounding brand names as those in the United States, contain different active ingredients than in the United States. Taking a different active ingredient may not help, and may even harm, the user.

"Consumers who fill U.S. prescriptions abroad, either when traveling or when shopping at foreign internet pharmacies, need to be aware of this potential health hazard," said Dr. Murray Lumpkin, Deputy Commissioner for International and Special Programs. "The name of a drug bought from another country may be identical or similar to the name on the U.S. prescription, but the active ingredient in the medicine may be different and not provide the right treatment."

FDA's investigation illustrates this health risk inherent in filling U.S. prescriptions abroad and highlights the lack of standardization of drug trade names internationally. For example, in the United States, "Flomax" is a brand name for tamsulosin, a treatment for an enlarged prostate, while in Italy, the active ingredient in the product called "Flomax" is morniflumate, an anti-inflammatory drug. In the United States, "Norpramin" is the brand name for an anti-depression drug containing desipramine but, in Spain, the same brand name, "Norpramin," is used for a drug that contains omeprazole, a treatment for stomach ulcers. While some of the identical brand names have different active ingredients appropriate for the same health condition, even these products should not be substituted without the guidance of a healthcare professional because of the potential for different doses, side effects, allergies, and interactions with other drugs.

FDA also has found 105 U.S. brand names that have foreign counterparts that look or sound so similar that consumers who fill such prescriptions abroad may receive a drug with the wrong active ingredient. For example, in the United Kingdom, "Amyben," a brand name for a drug product containing amiodarone, used to treat abnormal heart rhythms, could be mistaken for "Ambien," a U.S. brand name for a sleeping pill. Using Amyben instead of Ambien could have a serious adverse outcome.

For more information, see FDA's Public Health Advisory at www.fda.gov/oc/opacom/reports/confusingnames.html.

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Press Release

OFFICE OF THE GOVERNOR

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01/02/2006

Governor Schwarzenegger Calls on Federal Government to Allow Consumers to Safely Import Prescription Drugs

Governor Arnold Schwarzenegger will send the following letter to Congressional leaders on January 3, 2006, calling for a change in federal law to allow consumers to safely import prescription drugs from other countries. The Governor will also reiterate his call for federal action on this issue during his upcoming State of the State address. Below is the full text of the letter.

January 3, 2006

The Honorable Bill Frist
Majority Leader
United States Senate
Washington, DC 20510

The Honorable Harry Reid
Minority Leader
United States Senate
Washington, DC 20510

The Honorable J. Dennis Hastert
Speaker of the House
U.S. House of Representatives
Washington, DC 20515

The Honorable Nancy Pelosi
Minority Leader
U.S. House of Representatives
Washington, DC 20515

Dear Senator Frist, Senator Reid, Speaker Hastert and Minority Leader Pelosi,

As you begin work on developing the agenda for the upcoming 2006 congressional session I urge you to make passage of legislation that will allow American consumers to import safe prescription drugs from other countries a top priority.

I am concerned by the continuous and steady rise in the cost of prescription drugs and have sponsored legislation to make prescription drugs more affordable for lower income uninsured Californians. While state approaches such as I have proposed are a necessary near term action, they are insufficient. Rather, federal action is necessary to address this increasingly difficult situation for our citizens, employers and governments. I recognize that Congress has already begun the process of reducing prescription drug costs for millions of senior citizens across the country under the new Medicare Part D benefit that went into effect just a few days ago. However, this development does not address the problems facing more than 45 million uninsured Americans (nearly 7 million in California) who have limited access to affordable prescription drugs.

As you know, prescription drug costs continue to grow faster than any other category of health care expenditures. The

result is that millions of Americans, small businesses, and governments are forced to devote an ever-increasing percentage of their incomes to pay for prescription drugs. Conversely, residents of Canada, the European Union, and millions of others around the world pay less for their prescription drugs because their governments impose price controls that effectively shift the financial burden of research and development to the United States. As I wrote to then-Secretary of Health and Human Services Tommy Thompson last year, it is unfair and inappropriate that American consumers bear a disproportionate share of the cost of developing new medicines that benefit the international community.

Since I became Governor, legislators and advocates have been encouraging me to enact legislation making it easier for Californians to import prescription drugs from other countries. I have consistently said I would not sign a bill that encourages foreign importation in violation of federal law. But in my letter to Secretary Thompson, I also urged the Bush Administration to aggressively pursue discussions with our trading partners to achieve fairer pricing of pharmaceuticals in the international marketplace and an equitable distribution of the costs of drug research and development. Sixteen months later, drug prices continue to escalate and there is no evidence that the federal government has been able to bring more equity to the global pharmaceutical marketplace. The Congress must act to allow Americans to import safe prescription drugs.

There are those in California and elsewhere who believe we should impose price controls on prescription drugs or use the importation issue as a covert way to import foreign price controls to the United States. I adamantly oppose efforts to impose price controls on prescription drugs because they will have a chilling effect on the research and development of life saving medicines and harm California's critical biotech industry.

I believe we have an opportunity to use free-market forces to create a more equitable international market and help millions of Americans pay less for their prescription drugs. First, the Congress should demand an end to price controls in foreign countries and vigorously support those pharmaceutical and biotech companies who refuse to sell their products to countries imposing price controls. Second, Congress must pass and send to the President legislation that allows Americans to import prescription drugs from other nations in a manner that protects patient safety and respects intellectual property rights. By simultaneously pushing to eliminate foreign price controls and giving Americans access to more affordable prescription drugs from those same countries, the federal government can promote more affordable medicines for American consumers and a more equitable distribution of the costs of developing the life-saving medicines that benefit us all.

I urge Congress to take action in 2006 to allow for the importation of safe, more affordable medicines. I look forward to working with you in this important effort.

Sincerely,

Arnold Schwarzenegger

cc: California Congressional Delegation
Health and Human Services Secretary Leavitt
United States Trade Representative Portman

Link to August 20, 2004 letter from Governor Schwarzenegger to U. S. Health and Human Services Secretary

Letter to Congressional Leadership 01/03/2006

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FDA: Forget Drug Authorization

By Dale J. Atkinson, JD

The contentious and complex issues surrounding the importation and re-importation of drugs from Canada was recently addressed by the United States District Court for the District of Vermont. On September 19, 2005, the Honorable William K. Sessions III, the chief judge, issued an opinion on a matter initiated by the State of Vermont, through its Vermont Agency of Administration (Vermont), against the secretary of Health and Human Services (HHS) and acting commissioner of Food and Drug Administration (FDA).

On August 19, 2004, Vermont filed a lawsuit challenging a decision by FDA that denied its citizen petition seeking allowance for the Vermont State Employee Medical Benefit Plan (Plan) to "establish a program for the orderly individual importation of prescription medications." Vermont claimed that the denial of the petition by FDA was arbitrary and capricious, and in violation of the Administrative Procedures Act.

Vermont also sought a declaratory judgment that the relevant section of the federal Food, Drug, and Cosmetic Act (FD&C) – implemented through the Medicare Prescription Drug, Improvement, and Modernization Act (MMA) – was unconstitutional as improperly delegating authority to the Executive Branch of the federal government. The statute in question empowers the secretary of HHS to promulgate regulations that facilitate the wholesale importation of prescription medications from Canada only after certification to Congress that implementation of such a program would pose no additional risk to the public health and safety and result in a significant reduction in the cost of drugs to the American consumer. To date, the current and previous secretaries of HHS have refused to recognize any such certification.

In its petition and lawsuit, Vermont explained that it wanted the authority to contract with providers to create a system under which its members would have the option of forwarding a prescription to a Canadian firm where the prescription would be reviewed by a physician familiar with the patient's medical history. The script would be rewritten by the Canadian prescriber as a Canadian prescription and forwarded to a licensed Canadian pharmacy to be filled and shipped by mail directly to the member in the US.

In the lawsuit, Vermont requested that FDA "issue regulations or otherwise commit to exercise its enforcement discretion to allow the [Plan] to establish a program for the orderly individual importation of prescription medications in a manner that promotes the safety and health of its members." Vermont also requested that FDA issue guidance that such a program would be lawful under the statutes and regulations enforced by the commissioner. Finally, Vermont requested that FDA promptly establish regulations to provide for the importation of prescription drugs from Canada into the US as provided by the MMA.

As one basis for the lawsuit, Vermont argued

that FDA is not currently committing resources to controlling importation by individuals for their own use of prescription medications from outside the US. Vermont also argued the close proximity of Canada to Vermont, price differentials, and the fact that the Plan gave control of what would otherwise be an ad hoc approach to importation with no controls over risks and intervention.

FDA argued that the denial of the Vermont petition was based upon the FD&C's closed system, which strictly limits the importation of prescription medications. Pursuant to FDA, the only importation permitted under the FD&C is the reimportation of prescription drugs that were originally manufactured in the US and only by the manufacturer of the reimported drugs. As one of its bases for denial of the original petition, FDA stated that it would be "extremely unlikely that the State of Vermont could ensure that all Canadian drugs that the [Plan] helped its members obtain were in full compliance with all laws and regulations applicable to FDA-approved drug products."

FDA also argued that the MMA calls for the issuance of regulations that facilitate the importation of prescription medications from Canada only if the secretary of HHS certifies the risk and cost issues. While conceding that FDA is studying the matter of the importation of drugs in accordance with the MMA and that it "will submit a comprehensive study to Congress on the importation of drugs" as set forth in that law, such does not constitute the certification by the secretary.

Based upon its position, FDA filed a Motion to Dismiss the Vermont litigation arguing that Vermont can prove no set of facts in support of its claim that would entitle it to relief. In considering the facts in light most favorable to Vermont (as required under the applicable Federal Rules of Civil Procedure), the court agreed with FDA and dismissed the lawsuit.

Addressing Vermont's "arbitrary and capricious" argument, the court held in favor of FDA agreeing that the FD&C creates a closed system of drug distribution in the US and prohibits the introduction of any adulterated drugs into interstate commerce. Under the FD&C, the court noted that no prescription drug may be imported into the US with two exceptions. First, if authorized by the secretary for an emergency; and second, if permitted under the MMA.

The court noted that the MMA authorizes the secretary to promulgate regulations permitting pharmacists and wholesalers to import drugs from Canada into the US. It also noted that the secretary may "grant to individuals, by regulation or on a case-by-case basis, a waiver . . . under conditions as the secretary determines appropriate." While the MMA contemplates both commercial and individual importation, these provisions of the MMA, according to the court, become effective only if the Secretary certifies to Congress that importation will be safe and cost effective. No such certification has ever been issued, either under the MMA or the Medicine Equity and Drug Safety Act of 2000, which preceded and has been pre-empted by the MMA.

The court clearly stated that the Vermont Plan would violate the FD&C, related to both prohibitions on reimportation and introduction of unapproved drugs into interstate commerce. Thus, the court addressed the issue of whether or not the Plan would violate the MMA.

(continued on page 198)

Attorney Dale J. Atkinson is a partner in the law firm of Atkinson & Atkinson, counsel for NABP.

Telepharmacy

(continued from page 195)

and has added approximately $12 million in economic development to the local rural economy."

North Dakota is not the only state to aggressively pursue a telepharmacy project. Many state boards have addressed or are addressing the issue of telepharmacy in some form or other.

Texas is another state that has been at the forefront of the telepharmacy movement. Legislation in that state was passed in 2001, permitting remote dispensing via audio and video links. In that state, specific restrictions were placed on the location of these remote sites; telepharmacy services are allowed only in medically underserved areas as defined by state or federal law. "Telemedicine and telepharmacy are not panaceas, they're tools," says then-state Senator (and bill sponsor) Mike Moncrief, currently mayor of Fort Worth. "They should complement, not replace, traditional hands-on, face-to-face consultations." Nonetheless, most public safety officials see telepharmacy as preferable to mail order when ensuring access to prescription medications.

Increasing Convenience

Yet another form of telepharmacy – perhaps more accurately referred to as remote dispensing and/or verification – is arising in the name of increased customer convenience as well as increased access. Often touted in the press as the pharmacy equivalent of an ATM, kiosks that accept prescriptions and others that dispense them are appearing in a number of states throughout the country. When placed in or around community pharmacies in areas of high urban concentration (for example, Southern California or New York City), they are touted specifically as a time-saving convenience for drug store customers. Proponents argue that they do not endanger the public health and, moreover, that they allow overextended pharmacists to spend more time with the patients who most need attention and counseling.

Two manufacturers, Asteres Inc and Distributed Delivery Networks Corp (DDN), are producing substantially similar kiosks. Typically, a customer must register to use the device. After the patient submits a refill request in the usual way, often by phone or computer, the pharmacist fills it as normal and, if no counseling is indicated, places the labeled package in the kiosk for a later pickup. When the patient arrives to pick up the prescription, he or she logs onto the system with a user name and password, swipes a credit or debit card to pay, and the appropriate prescription package drops into the bin for retrieval.

California has become the most widely publicized pioneer in the pharmacy kiosk area. The California State Board of Pharmacy granted a waiver in October 2004, to authorize Longs Drug Stores to install and use 24-hour prescription drop kiosks at its pharmacies. It also waived requirements that

Legal Briefs

(continued from page 193)

In agreeing with FDA, the court rejected the arguments of Vermont that the "certification" requirement of the MMA only applies to commercial importations, not individual importations. The court stated that the Vermont argument that the certification requirement was somehow bifurcated was "convoluted and implausible." The court held that the only plausible reading of the statute is to apply the certifications requirement to the whole applicable section of the MMA.

Similarly, the court rejected the argument of Vermont that the certification requirement improperly delegates legislative power to the Executive Branch. Vermont had asked the court to declare unconstitutional that section of the MMA and sever it from the statute. The state argued that if the certification section of the MMA were severed from the statute, it would authorize the commercial and individual importation from Canada.

The court held that the MMA establishes an "intelligible principle" to which the secretary of HHS is directed to conform in certifying safety and costs to Congress. As such, the MMA does not improperly delegate legislative authority. In addition, the court opined that the certification provisions of the MMA were vital to the act and, even if there was merit to Vermont's argument, such provisions could not be severed.

Based upon these and other findings, the court dismissed the Vermont complaint and closed the case on this matter. This opinion represents an essential recognition of the FD&C and its impact upon state initiatives that may not conform to the federal laws. More to come.

State of Vermont v Leavitt, Case No. 2:04-cv-206 United States District Court for the District of Vermont, decided September 19, 2005.

Newsday (New York)

December 30, 2005 Friday
BUSINESS & TECHNOLOGY; Pg. A52

Medicare drugs ace out Canada; AARP survey finds 5 of 6 commonly used pills cost less through Part D than by mail from northern neighbor

BY TAMI LUHBY. STAFF WRITER

Buying medicine under the new Medicare drug coverage may end up being cheaper than ordering it from Canadafor some people, a study has found.

Conducted by the AARP Bulletin, the analysis looked at the least expensive Medicare drug plan in 21 states for six commonly used medications under the plans' 90-day mail order option. It compared the prices under these Medicare Part D plans with those charged by Global DrugsDirect.com, which bills itself as a low-cost Canadian provider. The study took into account the plans' premiums, deductibles and co-payments.

It found that for many Americans, the Medicare plans can be a better deal because beneficiaries are charged only a co-payment for covered drugs, as opposed to paying the full price in Canada.

For instance, in New York, a three-month supply of Lipitor (20 mg) or Fosamax (70 mg) costs $413 each under the least expensive Medicare plan, but $516 from Canada. At an American pharmacy, the price balloons to $1,160 and $780, respectively. Among the drugs surveyed, only Toprol XL (50 mg) wound up costing consistently more under Medicare.

Of course, costs and savings depend on the drugs you take and the plan you pick because each plan covers only certain medications. Most senior citizens have to weigh dozens of insurance plans - there are 44 in New Yorkstate - to determine which is best for them.

"We were really surprised that so many of these Medicare drug plans had lower costs than the Canadians," said Susan Crowley, executive editor of AARP Bulletin, a monthly newspaper published by the advocacy group. "But this is not true across the board. People still have to do their homework. That's the only way you'll ever know if you've gotten the best deal."

Beneficiaries can get more information about the plans and the drugs covered at Medicare's Web site, www.medicare.gov, or by calling 800-633-4227. Coverage begins Jan. 1, but beneficiaries have until May 15 to sign up without penalty.

Other industry experts said they were not surprised by the survey's results, having heard similar anecdotal reports about particular medications.

"I think that holds up," said Alfred Chiplin Jr., a senior policy attorney at the Center for Medicare Advocacy, a health care rights organization in Washington, D.C.

Many people, however, may not select the cheapest plans and, therefore, may wind up paying a lot more even with the new Medicare coverage, experts said.

"The likelihood of someone picking the least expensive plan is remote," said Robert Hayes, president of the MedicareRightsCenter, a national consumer services group based in Manhattan. "Many people are taking a shot in the dark."

The costs at a glance

NY MAIL MAIL

MEDICARE ORDER, ORDER,

DRUG PURPOSE COST CANADAU.S.

Lipitor 20 mg Cholesterol reducer $413.04 $516.00 $1,159.96

PREVACID 30 mg Heartburn $595.70 $608.40 $1,487.88

preventative

ZOLOFT 50 mg Anti-depressant $413.04 $596.00 $887.88

TOPROL XL 50 mg High blood $304.63 $208.00 $275.88

Pressure

FOSAMAX 70 mg Osteoporosis $413.04 $516.00 $779.88

Preventative

PLAVIX 75 mg Heart attack $413.04 $849.60 $1,399.96

preventative

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Dec. 22, 2005, 7:09AM

Texas won't allow Canadian drugs after all

Import program patterned after one in Minnesota violated U.S. law, state's AG says

By CLAY ROBISON

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AUSTIN - A new state law intended to help Texas consumers buy less expensive prescription drugs from Canada was struck down Wednesday by Attorney General Greg Abbott, who ruled that it violated federal law.

The law, enacted by the Legislature last spring, had been put on hold pending Abbott's review.

The attorney general said the statute violates the federal Food, Drug and Cosmetic Act, which "makes it an offense not only to import, but to 'cause' the importation of prohibited medications."

The U.S. government has generally ignored the importation of small quantities for personal use.

The provision, part of a broader law re-creating the Texas State Board of Pharmacy, had directed the board to provide information on a Web site to assist consumers in ordering drugs from as many as 10 designated Canadian pharmacies. It also directed the board to

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inspect the pharmacies to assure they met both Canadian and U.S. safety standards.

The pharmacy board sought Abbott's opinion after the U.S. Food and Drug Administration objected to the law.

In a letter to Gov. Rick Perry in June, Randall W. Lutter, an acting associate commissioner with the FDA, expressed concerns about potential health and safety risks. "In our experience, many drugs obtained from foreign sources that purport and appear to be the same as U.S.-approved prescription drugs have been of unknown origin and quality," he said.

Perry, however, couldn't veto the provision from the larger bill, which was necessary to keep the pharmacy board in business.

"By 'designating' certain Canadian pharmacies, promoting them on its Web site and expressly permitting Texas consumers to import prescription drugs that cannot be imported under federal law, the Texas State Board of Pharmacy would violate the Federal Food, Drug and Cosmetic Act, as will Texas consumers and those Texas pharmacies that take part in such transactions," Abbott said.

State Rep. Scott Hochberg, D-Houston, who sponsored the provision, was unavailable for comment late Wednesday. But he noted previously that at least nine other states and the District of Columbia have had similar Web sites. He said the Texas program was patterned after one in Minnesota.

During House debate in May, he said brand-name drugs from Canada listed on Minnesota's Web site had prices that were between 23 percent and 75 percent lower than those listed by a major American retail pharmacy chain.

Hochberg also argued many Texans already are buying prescription drugs from Canada and Mexico, with no guarantees of safety or quality.

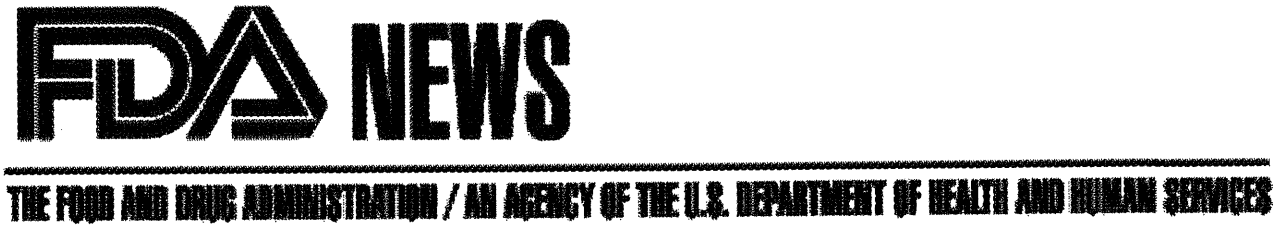
Abbott, whose jurisdiction covers only Texas law, said similar proposals in Maryland, Tennessee and Vermont have encountered legal challenges.

In seeking Abbott's opinion earlier this year, Gay Dodson, the pharmacy board's executive director, said the procedure set out in the new Texas law "would be equivalent to the board condoning, if not promoting, these Canadian pharmacies shipping prescription drugs into Texas."

The National Association of Boards of Pharmacy, the professional organization of state regulatory agencies, also wrote Perry in opposition to the Canadian drug provision.

Most of the nine members of the State Board of Pharmacy, all gubernatorial appointees, are pharmacists or have ties to the industry.

clay.robison@chron.com



FOR IMMEDIATE RELEASE
P05-102
December 16, 2005

Media Inquiries: **Catherine McDermott**
301-827-6242
Consumer Inquiries: **888-INFO-FDA**

FDA OPERATION REVEALS MANY DRUGS PROMOTED AS "CANADIAN" PRODUCTS REALLY ORIGINATE FROM OTHER COUNTRIES

An FDA operation found that nearly half of the imported drugs FDA intercepted from four selected countries were shipped to fill orders that consumers believed they were placing with "Canadian" pharmacies. Of the drugs being promoted as "Canadian," based on accompanying documentation, 85 percent actually came from 27 countries around the globe. A number of these products also were found to be counterfeit.

"This operation suggests that drugs ordered from so-called 'Canadian' Internet sites are not drugs of known safety and efficacy," said Dr. Andrew von Eschenbach, Acting FDA Commissioner. "These results make clear there are Internet sites that claim to be "Canadian" that, in fact, are peddling drugs of dubious origin, safety, and efficacy. We believe that these 'bait and switch' tactics—offering patients one thing and then giving them something else—are misleading to patients and potentially harmful to the public health."

FDA conducted its operation, named "Operation Bait and Switch," over a few days in August 2005 at JFK Airport in New York City, Miami International Airport, and Los Angeles International Airport. FDA examined all mail parcels suspected of containing pharmaceuticals sent from four countries—India, Israel, Costa Rica, and Vanuatu—that FDA had previously noticed were sources of drugs apparently ordered from pharmacies alleged to be Canadian in origin. Out of nearly 4,000 parcels examined, almost 1,700 or about 43 percent had been ordered from "Canadian" Internet pharmacies and were represented as being of Canadian origin.

However, only 15 percent of the "Canadian" drugs in the parcels examined actually originated in Canada. The remaining 85 percent were manufactured in 27 different countries. In addition to having been falsely promoted as being of Canadian origin, many of these drugs were not adequately labeled in English to help assure safe and effective use.

Thirty two of the pharmaceuticals sampled, representing three distinct drug products, have been determined to be counterfeit. FDA is working closely with the Canadian drug regulatory and law enforcement authorities on this matter. FDA will take appropriate action to keep these counterfeit products out of the U.S. drug supply and pursue actions against those responsible for attempting to defraud the American public.

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Administration News | President Bush Signs Spending Bill With Provision on Prescription Drug Reimportation
[Nov 28, 2005]

President Bush on Tuesday signed the appropriations bill (HR 2862) for the Commerce, Justice and State departments, which contains a provision regarding the purchase of lower-cost drugs from other nations, the AP/Baltimore *Sun* reports. The provision, which was sponsored by Sen. Debbie Stabenow (D-Mich.) and Rep. Anne Northup (R-Ky.), would bar the U.S. Trade Representative from creating trade agreements that prevent prescription drug reimportation for one year. Bush said he is considering the provision an "advisory," which leaves "open the question of whether it will be enforced and how," the *AP/Sun* reports. White House spokesperson Trent Duffy said Bush is "reserving the right to object" to the provision. He added, "Essentially, it means that the legislative branch has the ability to suggest things, but there are powers reserved by the constitution for the executive branch," to which the trade representative belongs. The office of current U.S. Trade Representative Rob Portman opposes the measure, saying that blocking the ability to create such trade agreements would infringe on the intellectual property rights of pharmaceutical companies. Terry Carmack, Northup chief of staff, said, "I suspect there will be many, many discussions with lawyers and committee staff to figure what the next step might be" (AP/Baltimore *Sun*, 11/25).

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VA, Canadian Pharmacies Will Offer Lower Prices Than Medicare Drug Benefit, Democratic Report Says

November 23, 2005

The Medicare prescription drug benefit does not offer medications at the lower prices available through the Department of Veterans Affairs, Canadian pharmacies or high-volume U.S. pharmacies, according to a report by the Democratic staff of the House Government Reform Committee, the *Washington Post* reports. The report, requested by Rep. Henry Waxman (D-Calif.), looks at the average prices of 10 popular drugs offered to Medicare beneficiaries through 10 "well-known insurance plans," the *Post* reports.

The report then compares those prices with the average prices offered to VA beneficiaries, Canadian consumers and customers at major pharmacies such as Costco or Drugstore.com. The average Medicare prices were 80% higher than VA prices, 60% higher than Canadian average prices and 3% higher than prices at major U.S. pharmacies.

The report states, "The prices offered by the Medicare drug plans are higher than all four benchmarks, in some cases significantly so. This increases costs to seniors and federal taxpayers and makes it doubtful that the complicated design of Medicare Part D provides any tangible benefit to anyone but drug manufacturers and insurers."

According to the *Post*, the report resulted from a disagreement among some Republicans and Democrats over how to obtain the lowest drug prices. Some Democrats maintained that lower prices would come from allowing the federal government to negotiate prices directly with drug companies, while many Republicans stated that lower prices would come from competition among drug plans.

CMS spokesperson Gary Karr said the report is "selective and misleading" and did not consider prices for generic medications, which generally are less expensive. He added, "The question really is whether this is indeed a true and accurate reflection of the plan choices that somebody would have if they pumped these drugs into the Medicare

California Hospitals
(in English and Spanish)

plan finder" (Lee, *Washington Post*, 11/23).

Additional information about the Medicare drug benefit also is available online.

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Prescription Drugs | U.S. Residents Increasingly Reimporting Prescription Drugs; Few Mechanisms Exist To Stop Practice, Study Says
[Nov 10, 2005]

U.S. consumers import a "substantial and increasing" amount of illegal prescription drugs, but "very limited" information exists to help federal regulators intercept shipments of addictive medications or other treatments that could have safety risks, according to a report released on Thursday by the Government Accountability Office, the *Washington Post* reports. Almost all prescription drugs purchased from pharmacies abroad are illegal under federal law because such pharmacies operate outside of U.S. regulations, but several state and local governments have enacted legislation that allows the practice. The report -- requested by Sen. Norm Coleman (R-Minn.), chair of the Senate Permanent Subcommittee on Investigations, and Rep. John Dingell (D-Mich.), ranking member of the House Energy and Commerce Committee -- said that millions of shipments of prescription drugs are imported into the U.S. annually, although the exact number remains undetermined. Estimates submitted to Congress have ranged from two million to 20 million shipments of prescription drugs imported into the U.S. annually, the *Post* reports. The effort to end shipments of prescription drugs into the U.S. is a "complex undertaking," and, although a task force formed last year by U.S. Customs and Border Protection to study the issue "appears to be a step in the right direction," more specific priorities and benchmarks are required, according to the report.

Comments
Coleman in a statement said that "efforts to work cooperatively between the various agencies and to engage the private sector have been lacking," which has led to a "virtual black market for controlled prescription drugs and bootleg pharmaceuticals" on the Internet. In

addition, Dingell said in a statement that, "while rogue Web sites continue to send their drugs into the U.S. with impunity, the agencies most responsible for stopping this chaos are completely out of ideas" (Flaherty, *Washington Post*, 11/10).

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GAO Faults Efforts on Drug Sales

Illegal Importation Of Prescriptions Up

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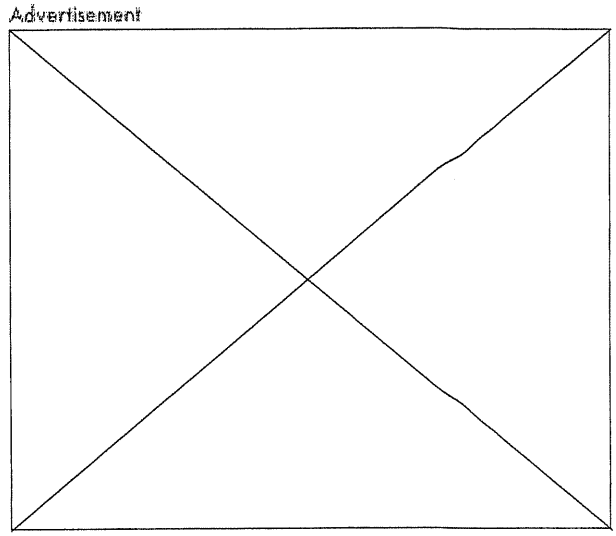

By Mary Pat Flaherty
Washington Post Staff Writer
Thursday, November 10, 2005; A07

Americans import a "substantial and increasing" number of illegal prescription drugs, but efforts to stop the sales remain scattershot, according to a federal report released today.

The report by the Government Accountability Office echoes criticisms raised since 1999 by various regulators, law enforcement agencies and congressional committees.

The report comes as some state and local governments, including that of Montgomery County, are allowing their employees to import medications to reduce drug costs.

Millions of packages of medications, including addictive painkillers, are shipped into the United States from foreign sellers every year, yet reliable data are lacking despite years of debate about the risks of Internet drug sales, the report says.

Estimates given to Congress range from 2 million to 20 million packages a year.

The "very limited" information prevents regulators from directing resources efficiently to prevent shipments of addictive substances or other medications that could be harmful, the report says. Virtually all prescription drug purchases from foreign pharmacies are illegal because the sellers operate outside U.S. rules that regulate drug distribution, labeling and safety.

Last year, U.S. Customs and Border Protection organized a drug-imports task force consisting of representatives from several federal agencies.

Both the Food and Drug Administration and the Drug Enforcement Administration have streamlined some procedures to make it easier to intercept packages containing illegal prescriptions. Stopping such imports is a "complex undertaking" and the task force "appears to be a step in the right direction," but clearer priorities and benchmarks are needed, the report says.

The report was sought by Sen. Norm Coleman (R-Minn.), chairman of the Senate Permanent Subcommittee on Investigations, and Rep. John D. Dingell (Mich.), ranking Democrat on the House Energy and Commerce Committee. Though noting some improvements, Coleman said in a statement that "efforts to work cooperatively between the various agencies and to engage the private sector have been lacking," leaving the Internet "a virtual black market for controlled prescription drugs and bootleg pharmaceuticals."

Dingell said in his own statement that "while rogue websites continue to send their drugs into the U.S. with impunity, the agencies most responsible for stopping this chaos are completely out of ideas."

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ATTACHMENT F

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www.pharmacy.ca.gov

STATE AND CONSUMER SERVICES AGENCY
DEPARTMENT OF CONSUMER AFFAIRS
Arnold Schwarzenegger, GOVERNOR

ENFORCEMENT COMMITTEE MEETING
Summary of Agenda Items Discussed – Not an Official Meeting

December 7, 2005
Holiday Inn Capitol Plaza
300 J Street
Sacramento, CA 958914

Present: William Powers, Chair, Board Member
Stan Goldenberg, R.Ph., Board President and Member

Staff: 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, Liaison Counsel, Deputy Attorney General
LaVonne Powell, Staff Counsel

Call to Order

Chair William Powers stated that committee members Marian Balay and David Fong were unable to attend due to previous commitments. Because the Enforcement Committee did not have a quorum, it would be operating as a subcommittee. All agenda items will be placed on the agenda for the February board meeting for discussion and action.

Implementation of the Electronic Pedigree Requirement for Prescription Drugs Effective January 1, 2007 – Questions and Answers on Implementation (SB 1307 -Chapter 857, Statutes of 2004)

Chair William Powers stated that in 2004, the Board of Pharmacy sponsored SB 1307 (Figueroa), which was signed by Governor Schwarzenegger and became law on January 1, 2005. The bill made various changes to the wholesaler requirements and distribution of dangerous drugs. Most of the changes strengthened and clarified the requirements for the distribution of dangerous drugs and dangerous devices in California.

The Enforcement Committee is monitoring the implementation of this legislation especially the implementation of the pedigree requirement. The bill requires an electronic pedigree by January 1, 2007 and gives the board the authority to extend the compliance date for wholesalers to January 1, 2008. The Legislature may extend the compliance date for pharmacies to January 1, 2009. The

purpose of the pedigree is to maintain the integrity of the pharmaceutical supply chain in the United States.

The industry anticipates that Radio Frequency Identification technology (RFID) will be the method used to track a drug's pedigree. The manufacturer would tag the drug with a small chip and antenna. When the tag is in close proximity of a reader, it would receive a low-powered radio signal and interact with a reader exchanging identification data and other information. Once the reader receives data, it would be sent to a computer for processing.

During the last year, the board and enforcement committee has had presentations from various companies displaying their electronic pedigree solutions. The first presentation was by T3Ci, an application software company that provides drug counterfeit, diversion detection and electronic drug pedigree for the pharmaceutical market. They demonstrated their technology solution for the electronic pedigree. The next presentations were by SupplyScape and Acerity Corporation. SupplyScape presented its electronic pedigree software program that enables a safe and secure pharmaceutical supply chain that complies with federal and state regulations to prevent counterfeit drugs. Acerity Corporation presented its security software program, which is an electronic authentication process. This system employs a cryptography techniques in conjunction with RFID forming a multiplayer secure process, which provides numerous advantages and allows versatile applications.

At the September Enforcement Committee meeting, Lew Kontnik, Director of Brand Protection/Business Continuity for Amgen presented to the committee the challenges that Amgen has encountered in developing an electronic pedigree for its manufactured products. He stated that Amgen, a billion dollar company that is headquartered in California, is the leading human therapeutics company in the biotechnology industry. He demonstrated the challenges that their company is facing in the implementation of RFID technology to track the electronic pedigree of its liquid products. Primarily he showed how the placement of the radio frequency tag on the products have resulted with inconsistent and inaccurate readings by the scanner unless the scanner is in close proximity of the tagged item, which is not conducive to tracking large quantities of distributed product. He also stated that whatever mechanism is used to generate the electronic pedigree, it must be incompliance with good manufacturing practices (GMPs), which is regulated by the federal Food and Drug Administration (FDA).

Upon conclusion of his presentation, Mr. Kontnik presented his company's position that it will be extremely difficult to meet the January 1, 2007 deadline to implement an electronic pedigree for its manufactured drug products.

The board also has been participating in the Uniform Drug Pedigree meetings. This is a group of participants that represents manufacturers, wholesalers, and regulators. The purpose of these meetings is to provide a cooperative effort to develop uniform standards and regulations regarding electronic pedigrees. As result of the board's participation with this group and others, a list of questions and answers were developed on the implementation of California's pedigree requirement. The questions and answers were provided in advance of this Enforcement Committee meeting.

Committee Chair Powers invited comments regarding the questions and answers. Clarification was sought regarding the definition of "change of ownership." The law requires that each time a change of ownership occur, the pedigree information must be documented. Some felt that there was an inconsistency with the definition because it included "third party logistics transactions." This means when a manufacturer sends a prescription drug to a "third party logistics" carrier to store and transport the prescription drug to the wholesaler and/or pharmacy, the transaction to the "third party logistics" carrier must be recorded on the pedigree. There was disagreement that this type of transaction constitutes a change of ownership. In some situations, the manufacturer is still the owner until the prescription drug reaches the wholesaler and/or pharmacy, in another example; the change in ownership of the prescription drug is immediate upon leaving the manufacturer and is transferred to the wholesaler and /or pharmacy.

During the discussion, requests were made to the committee that the Board of Pharmacy form an ad hoc committee that included all representatives of the industry to address the intricacies of the new law and its application. It was suggested that the board review the new Arizona law as a model for the distribution of prescriptions drugs from a chain wholesale distribution center to its chain pharmacy stores. It was questioned in this an example where a chain pharmacy had its own wholesale distribution center for distribution to its own pharmacies whether the pedigree would be required since a "change of ownership" of the prescription drug would not take place. It was explained that the way the law is written it requires that the pedigree information be recorded when there is a change of ownership. The board cannot advise whether or not a change has taken place in the example that was provided for chain pharmacy stores.

There was also a comment regarding the licensure of out-of-state wholesalers who ship into California. It was requested that the board consider amending the law to only require licensure of those wholesalers that ship over a specified amount of prescription drugs into California.

Another suggestion recommended that the board consider requiring an electronic pedigree for only a subset of prescription drugs such as controlled substances for the initial implementation in 2007. Concern was expressed that California law is different from the Florida pedigree law in that California requires the pedigree to be initiated by the manufacturer. Because the technology is evolving in this area, there is apprehension that each manufacturer will have its own and varied pedigree system that the wholesaler and eventually the pharmacy will have to work with. While the industry anticipates the use of RFID technology, California law only requires an electronic pedigree. There is concern about the compatibility of systems. In addition, California pedigree requirements although specific only to California may require manufacturers to initiate an electronic pedigree on all its prescription drugs because the manufacturer will not be able to differentiate which prescription drugs are going to be distributed in California.

Others commented such as the Healthcare Distribution Management Association (HDMA) that it has many questions that would be more appropriate for discussion if a workgroup were formed. Committee Chair Powers encouraged that additional questions be submitted to staff in advance of any future meetings. HDMA further stated that it is working on an initiative for the federal licensure of prescription drug distributors. Because many states are trying to address this complex issue, it has become a burden for wholesalers to comply with many different state requirements. The intent of federal licensure would set one standard nationwide. Unfortunately,

as the states have witnessed, the absence of any federal initiative requires the states to step in to assure the safety of its citizens.

It was noted that at the National Association of Chain Drugs Stores (NACDS)/HDMA RFID Healthcare Adoption Summit in November 2005, Randall Lutter, Associate Commissioner for the FDA announced that the FDA Counterfeit Drug Task Force is going to hold a public workshop in January or February 2006. The purpose of the meeting is to facilitate RFID standard-setting and coordination of issues, discuss the implementation of the pedigree requirements of the Prescription Drug Marketing Act (PDMA) and reaffirm FDA's commitment to facilitate and drive the adoption of electronic track/trace technology.

Committee Chair Powers stated that the next step is to bring forward the request that the Board of Pharmacy form an ad hoc committee to discuss and facilitate the implementation of the electronic pedigree requirement. The board will consider this request at its meeting on February 1, 2006.

Proposal to Amend B&P §4040(c) to Allow a Pharmacy to Accept a Fax Prescription from a Patient

Executive Officer Patricia Harris provided the committee with a proposal to amend B&P § 4040(c) to allow a pharmacy to accept a fax prescription from a patient provided that the pharmacy has the original prescription before dispensing the prescription medication to the patient. She stated that the proposal came from a consumer as a result of a complaint. Current law only authorizes a pharmacy to accept a fax prescription from a prescriber. In the specific complaint, the pharmacy was accepting a fax from the patient; however, the pharmacy stopped the practice because of the law. The consumer was not happy that he could no longer fax his prescription to the pharmacy.

The proposal is an option for pharmacies to implement. Concern was expressed that patients would fax their prescriptions (especially a controlled substance prescription) to various pharmacies to have it filled. There was also concern that accepting a fax from a patient would disrupt a pharmacy's workflow. It was discussed that this proposal is an option for pharmacies to implement as a service to patients if it chose to do so. Also, it would be incumbent on the pharmacy to obtain the original prescription prior to dispensing the medication to the patient to prevent the patient from having the same prescription filled at several different pharmacies. There was also discussion that the patient would more than likely forget to bring in the original prescription when picking up the dispensed medication. It was stated that the patient would have to return with the original prescription. The decision to allow for a patient to fax a prescription would be a customer service decision that each pharmacy would need to make.

Committee Chair Powers stated that this proposal would be discussed at the February board meeting.

Proposal to Amend B & P §4073(b) to Indicate the Prohibition of Generic Substitution by a Prescriber on an "Electronic Data Prescription"

The committee was provided with a proposed amendment to B&P § 4073(b) to update pharmacy law regarding the prohibition of generic substitution by a prescriber on an electronic data transmission prescription. Current law requires the physician to personally indicate either orally or on the prescription "Do Not Substitute" or words of similar meaning. If a prescriber checks a box indicating no substitution, then he/she must initial the box or checkmark.

The purpose of the amendment is to clarify that a physician is not required to manually initial an electronic data transmission prescription in order to prohibit generic substitution. It is presumed that prescriber is already electronically verified for the data transmission prescription and there is no additional need for the handwritten initial. Concern was expressed that software programs would automatically default to "Do Not Substitute."

Moreover, it was noted that the Centers for Medicare and Medicaid Services (CMS) issued its final rule on November 7, 2005, that covers transactions involving the electronic transmission of prescriptions and certain other information for covered Part D drugs prescribed for Part D eligible individuals. Essentially CMS has interpreted the federal law to preempt all contrary State laws that are applicable to a prescription that is transmitted electronically not only for those individuals who are enrolled in Part D, but for all Part D eligible individuals. Categories that are anticipated by CMS include state laws prohibiting e-prescribing, state laws prohibiting transmissions through intermediaries, state laws requiring certain language if not consistent with the federal Act and state laws requiring handwritten signatures. Therefore, this proposal is consistent with the final rule issued by CMS.

Review of Citation and Fine Program

Chair William Powers stated that at the June Enforcement Committee meeting, the California Retailers Association (CRA) requested that the review of the board's Citation and Fine Program be placed on the agenda for discussion the next Enforcement Committee meeting.

As requested, the matter was on the agendas for both the September and December Enforcement Committee meetings. The committee was provided an overview of the investigation process, historical data that gave a three-year summary of the citation and fine program since its inception, which included, the number of citations issued, the type of citations issued and the violations, the number of appeals and the result of those appeals.

No comments were provided.

Importation of Prescription Drugs

Chair Powers reported that the importation of prescription drugs is an ongoing issue that continues to be on the agenda for the meetings of the Enforcement Committee and Board of Pharmacy. Articles that have appeared since the last board meeting were provided.

Government Accountability Office (GAO) Report on the Purchase of Anabolic Steroids without a Prescription

Committee Chair Powers explained that the GAO report was issued in November 2005 at the request of Representative Henry Waxman. Representative Waxman requested the GAO investigate whether anabolic steroids can be purchased without a prescription and test whether such purchases are easily made. He also asked that the GAO identify common sources of illegal anabolic steroids, and significant challenges law enforcement officials encounter in investigating, prosecuting, and deterring criminal anabolic steroid traffickers.

A summary of the report concluded that the GAO investigators easily obtained anabolic steroids without a prescription through the Internet. After conducting Internet searches, they found hundreds of Web sites offering anabolic steroids commonly used by athletes and bodybuilders for sale. Then the investigators used an e-mail account in a fictitious name to place 22 orders. From these orders, the GAO received 10 shipments of anabolic steroids; all were shipped from foreign countries. They also received 4 shipments from within the United States but the substances contained, though marketed as anabolic steroids or other "muscle building" products, were not anabolic steroids according to the FDA. The GAO referred the evidence concerning the purchases to the DEA and to the FDA for appropriate action.

Proposed Meeting Dates

The subcommittee selected March 16, 2006, for the next meeting date. The meeting will be held in Sacramento.

Adjournment

Chair Powers adjourned the subcommittee meeting at 11:15 p.m.

ATTACHMENT G

California State Board of Pharmacy
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Phone (916) 445-5014
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STATE AND CONSUMER SERVICES AGENCY
DEPARTMENT OF CONSUMER AFFAIRS
Arnold Schwarzenegger, Governor

Enforcement Team Meeting
December 7, 2005

11:30 a.m. – 12:30 p.m.

Present: Committee Chair William Powers
President and Member Stan Goldenberg
Executive Staff
Supervising Inspectors
Inspectors

Announcements/Introductions
The meeting began at 11:30 a.m.

Quality Improvement Efforts
Supervising Inspector Robert Ratcliff announced that after lunch the supervising inspectors will present an overview of the new pharmacy laws and regulations.

Enforcement Committee Discussions
The Enforcement Team discussed the agenda items from the subcommittee meeting.

Adjournment
The meeting was adjourned the meeting at 12:30 p.m.

ATTACHMENT H

Board of Pharmacy Enforcement Statistics
Fiscal Year 2005/2006

Workload Statistics	July-Sept	Oct-Dec	Jan-Mar	Apr-June	Total 05/06
Complaints/Investigations					
Initiated	407	254			661
Closed	548	408			956
Pending (at the end of quarter)	637	587			587
Cases Assigned & Pending (by Team)					
Compliance Team	68	62			62
Drug Diversion/Fraud	85	70			70
Mediation Team	99	103			103
Probation/PRP	28	50			50
Enforcement	15	8			8
Application Investigations					
Initiated	37	10			47
Closed					
Approved	21	10			31
Denied	5	0			5
Total*	34	12			46
Pending (at the end of quarter)	46	53			52
Citation & Fine					
Issued	189	151			340
Citations Closed	153	137			290
Total Fines Collected	$46,236.00	$49,086.00			$95,322.00

* This figure includes withdrawn applications.

** Fines collected and reports in previous fiscal year.

Board of Pharmacy Enforcement Statistics
Fiscal Year 2005/2006

Workload Statistics	July-Sept	Oct-Dec	Jan-Mar	Apr-June	Total 05/06
Administrative Cases (by effective date of decision)					
Referred to AG's Office*	49	34			373
Pleadings Filed	38	17			55
Pending					
Pre-accusation	64	76			76
Post Accusation	75	73			73
Total	160	161			161
Closed**					
Revocation					
Pharmacist	4	1			5
Pharmacy	1	1			2
Other	11	8			19
Revocation,stayed; suspension/probation					
Pharmacist	9	4			13
Pharmacy	1				1
Other					
Revocation,stayed; probation					
Pharmacist	5	2			7
Pharmacy	2				2
Other	1				1
Suspension, stayed; probation					
Pharmacist					
Pharmacy					
Other					
Surrender/Voluntary Surrender					
Pharmacist	1	1			2
Pharmacy					
Other	3	3			6
Public Reproval/Reprimand					
Pharmacist					
Pharmacy	1				1
Other					
Cost Recovery Requested	$120,408.25	$68,542.75			$188,951.00
Cost Recovery Collected	$46,386.35	$64,815.08			$111,201.43

* This figure includes Citation Appeals

** This figure includes cases withdrawn

Board of Pharmacy Enforcement Statistics
Fiscal Year 2005/2006

Workload Statistics	July-Sept	Oct-Dec	Jan-Mar	Apr-June	Total 05/06
Probation Statistics					
Licenses on Probation					
Pharmacist	108	103			103
Pharmacy	16	14			14
Other	19	19			19
Probation Office Conferences	20	8			28
Probation Site Inspections	54	48			102
Probationers Referred to AG for non-compliance	3	3			6

As part of probation monitoring, the board requires licensees to appear before the supervising 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 12/31/05)

Program Statistics					
In lieu of discipline	1	1			2
In addition to probation	5	4			9
Closed, successful	0	0			0
Closed, non-compliant	4	0			4
Closed, other	0	0			0
Total Board mandated Participants	47	51			51
Total Self-Referred Participants*	16	16			16
Treatment Contracts Reviewed	40	40			80

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 supervising 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.

As of December 31, 2005.

Citation and Fine Statistics
July 1, 2005 – January 23, 2006

386 citations have been issued this fiscal year

Total dollar amount of fines issued
$ 165,250.00

Total dollar amount of fines collected
$ 81,125.00*

*This amount only reflects payment of the citations issued this fiscal year.
Citations issued prior to this fiscal year have also been paid during this quarter.

The average number of days from date case is opened until a citation is issued is 147

Average number of days from date citation is issued to date citation is closed is 44

Citation Breakdown by license type

Total issued	RPH with fine	RPH no fine	PHY with fine	PHY no fine	PIC with fine	PIC no fine	TCH with fine	TCH no fine
389	72	7	64	82	36	24	8	1

Miscellaneous Citation Breakdown by license type

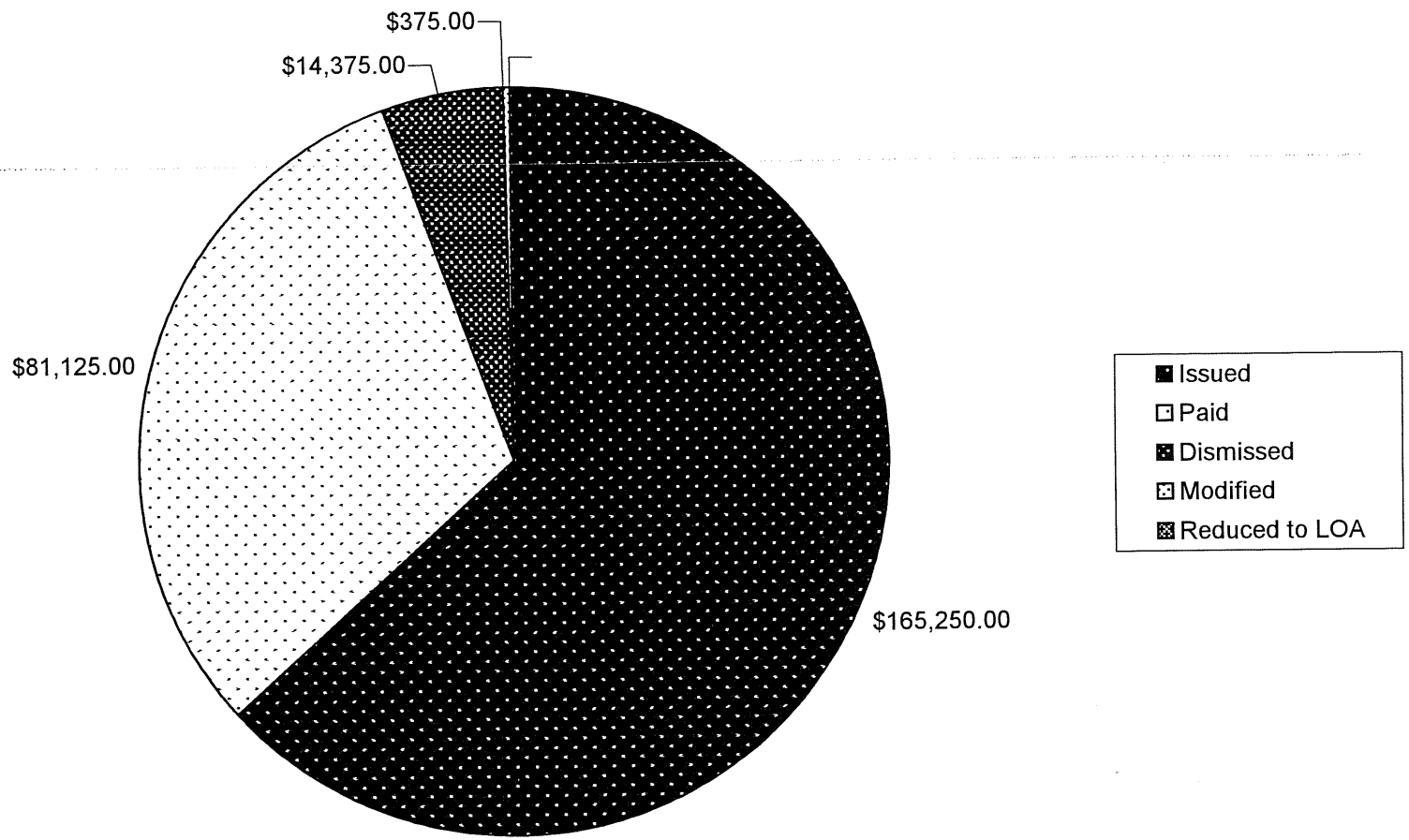
Wholesalers	Exemptee's	Clinics	Drug room	Exempt Hosp.	Hosp. pharmacy	Misc.	Unlicensed Premises	Unlicensed person
40	27	3	1	4	9	6*	1	1

*Licensed Correctional Facilities, Exempt Pharmacies, and Vet Retailer

Top Ten Violations for the first quarter of 2005/2006 by license type

Pharmacists	%	Pharmacies	%	Pharmacists in charge	%
1716 - Variation from prescription	28%	1716 - Variation from prescription	34%	1716 - Variation from prescription	12%
1716/1761 - Variation from Rx / Erroneous Rx	13%	1714(b)- Operational standards and security; pharmacy responsible for pharmacy security	12%	4125/1711 - Quality assurance program	12%
4342 - Actions by board to prevent sales of preparations or drugs lacking quality or strength; Penalties for knowing or willful violation of regulations governing those sales	5%	1716/1761 - Variation from Rx / Erroneous Rx	10%	4081/1711 - Records of dangerous drugs kept open for inspection/Current inventory defined	10%
1716/1761(a) - Variation from prescription/No pharmacist shall compound or dispense any prescription, which contains any significant error or omission...	5%	1715.6- Reporting drug loss	10%	1714(d)- Operational standards and security; pharmacist responsible for pharmacy security	9%
4115(e) - Pharmacy technician license required	5%	4125/1711 - Quality assurance program	5%	1716/1761 - Variation from Rx / Erroneous Rx	7%
1793.7 -Requirements for Pharmacies employing pharmacy technicians	3%	4115(e) - Pharmacy technician license required	5%	1717(e) No licensee shall participate in any arrangement.., whereby medications may be left at, picked up from..., any place not licensed as a retail pharmacy.	5%
4071 - Prescriber may authorize agent to transmit prescription; Schedule II excluded	3%	4342 - Actions by board to prevent sales of preparations or drugs lacking quality or strength; Penalties for knowing or willful violation of regulations governing those sales	5%	4342 - Actions by board to prevent sales of preparations or drugs lacking quality or strength; Penalties for knowing or willful violation of regulations governing those sales	5%
4081 - Records of dangerous drugs kept open for inspection; maintenance of records, current inventory	3%	4081(a)- Records of dangerous drugs kept open for inspection	4%	1751.7(a)(4) - Written justification of the chosen expiration date for compounded sterile injectable products	5%
1311.11(a) - Persons Required to Register; Agents for Controlled Substances shall obtain DEA registration	3%	1764/56.10 et seq - Unauthorized disclosure of prescription and medical information	4%	4115(e) - Pharmacy technician license required	5%
1764/56.10 et seq - Unauthorized disclosure of prescription and medical information	3%	1717(e) No licensee shall participate in any arrangement.., whereby medications may be left at, picked up from..., any place not licensed as a retail pharmacy.	4%	4051 - Conduct limited to a pharmacist; conduct authorized by pharmacist	4%

Citation totals for the first half of 2005 - 2006



Contested Citations Office Conference

(These statistics also include contested Letters of Abatement)

There were four office conferences held

Number of requests	122

Number scheduled	122

Number appeared	66

Number Postponed	40*

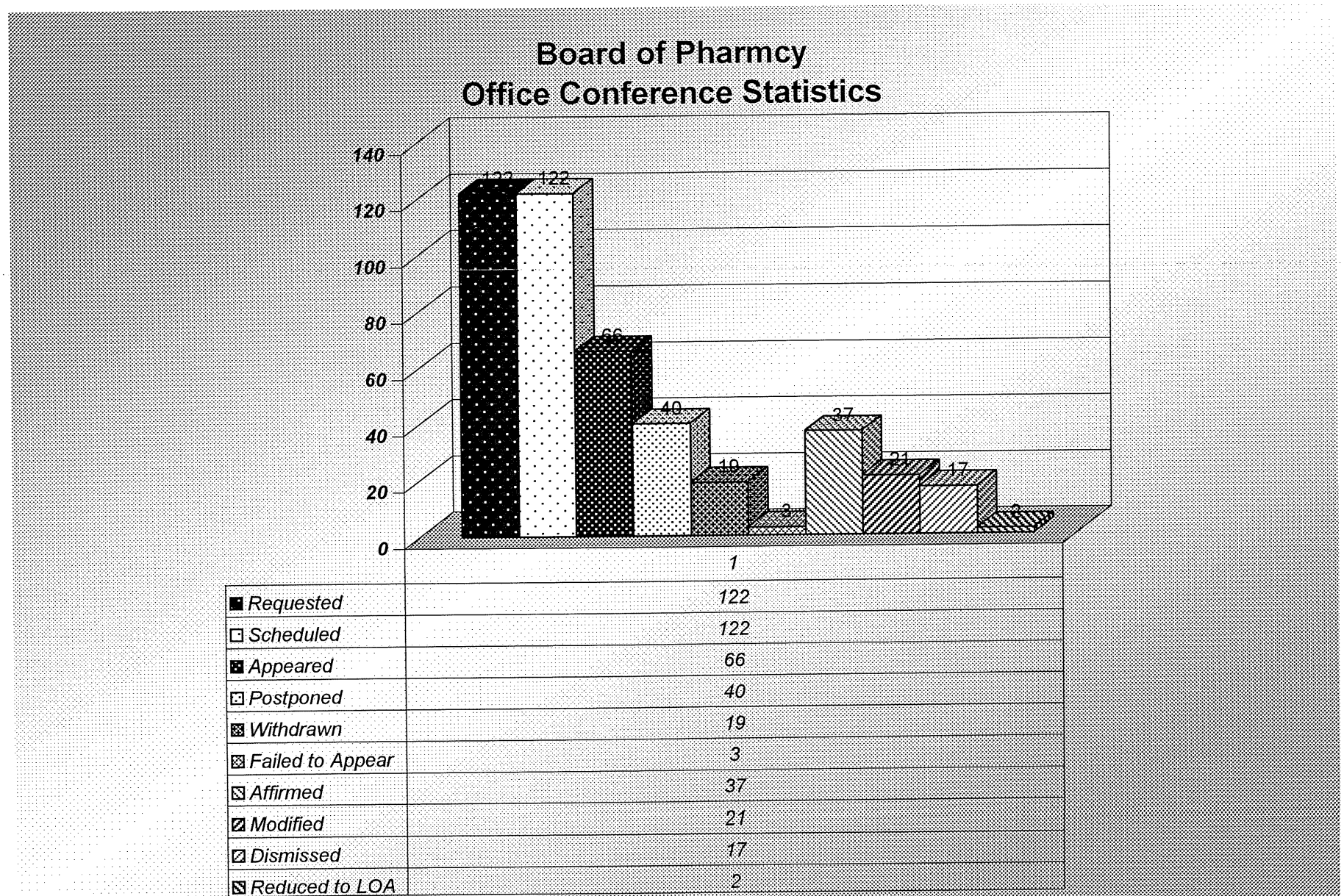
*Please note these are added back into the number of requests and scheduled case totals above.

Total number of requests withdrawn	19
Failed to appear	3

Office Conference results

Total number of citations affirmed	37

Decision	Total citations	Total dollar amount reduced
Modified	21	$14,375.00
Dismissed	17	$375.00
Reduced to letter of admonishment	2	$0.00


Board of Pharmcy
Office Conference Statistics
140
120
100
80
60
40
20
0
122
122
66
40
19
3
37
21
17
2
1
Requested 122
Scheduled 122
Appeared 66
Postponed 40
Withdrawn 19
Failed to Appear 3
Affirmed 37
Modified 21
Dismissed 17
Reduced to LOA 2

ATTACHMENT I

Strategic Plan Status Report
Second Quarter 2005/2006
October 1, 2005 thru December 31, 2005

Enforcement Committee

Goal 1: **Exercise oversight on all pharmacy activities**

Outcome: **Improve consumer protection**

Objective 1.1: **To achieve 100 percent closure on all cases within 6 months by June 30, 2006.**

Measure: Percentage of cases closed or referred within 6 months.

Task: **1. Mediate all consumer complaints within 90 days.**

Quarter 1: Based on **211** mediations/investigations sent to Supervising Inspectors for review.
Quarter 2: Based on **239** mediations/investigations sent to Supervising Inspectors for review.

Time Frame	Number/Percentage Per Quarter							
Number of Days	Q1		Q2		Q3		Q4	
0 to 90	24	11%	35	15%				
91 to 180	11	5%	30	12%				
181 to 365	1	0%	5	2%				
366 and over	1	0%	0	0%				

Task: **2. Investigate all other cases within 120 days.**

Review total stats same as above

Time Frame	Number/Percentage Per Quarter							
Number of Days	Q1		Q2		Q3		Q4	
0 to 120	106	50%	77	32%				
121 to 365	63	30%	89	37%				
366 and over	5	2%	3	1%				

Task: **3. Close (e.g. issue citation and fine, refer to the AG's Office) all board investigations and mediations within 180 days.**

Quarter 1: Based on **550** closed mediations/investigations.
Quarter 2: Based on **421** closed mediations/investigations.

Time Frame	Number/Percentage Per Quarter							
Number of Days	Q1		Q2		Q3		Q4	
0 to 180	405	74%	303	72%				
181 to 365	123	22%	106	25%				
366 to 730	18	3%	11	3%				
731 and over	4	1%	0	0				

Task:	**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.** First and Second Quarters: Nothing to report.
Task:	**5. Integrate data obtained from computerized reports into drug diversion prevention programs and investigations (CURES, 1782 reports, DEA 106 loss reports).** **CURES** **Number of pharmacies reporting to CURES and number of prescription records reported.** Pharmacies / Records Quarter 1: 5,044 / 2,799,811 Quarter 2: **5,680** / **3,440,267** **CURES reports provided to supervising inspectors and/or inspectors to aid in an investigation or inspection:** ▪ Quarter 1: **15** ▪ Quarter 2: **23** **CURES data used in complaint investigations:** Quarter 1: **20** Quarter 2: **8** **CURES compliance issues found in inspections:** Quarter 1: **10** Quarter 2: **25** **1782 Wholesaler Data Base:** No changes. Board has not been using 1782 reports for the last 3 to 4 years. **DEA 106 Theft/Loss :** Quarter 1: Approximately **42** investigations opened from DEA 106 loss reports. Quarter 2: Approximately **37** investigations opened from DEA 106 loss reports.
Task:	**6. Re-establish the CURES workgroup that includes other regulatory and law enforcement agencies to identify potential controlled substance violations and coordinate investigations.** ▪ The CURES Users Group is scheduled to meet the 2nd Wednesday of every month to work on pharmacy noncompliance and data issues, share case information, as well as to improve database functionality. Additionally, the boards and DOJ have used these meetings to discuss issues and share information related to the implementation of SB 151 and more recently, SB734. Meetings were held November 13 and January 18. BNE canceled the October meetings due to database issues. We do not meet in December.

	First Quarter: During a recent driver upgrade to the new CURES web-based database, the BNE encountered a corruption to the front end portion of the database. The front end is the part of the database that allows users the ability to run standard and ad hoc queries and reports. None of the data was lost, only lost query and report functionality. While BNE is fixing the web-based system, they have temporarily reinstated the previous Impromptu CURES database to allow users access to the data and the ability to run queries and reports. **Second Quarter:** The BNE completed repairs to the Web-based CURES system in December 2005. Board staff can now access CURES data through both the old and the new applications. BNE information technology staff are working with board staff to develop several automated standard reports using the new Web-based system's report-scheduling functionality, which will save staff time and provide monthly or weekly statistical and trend data via email automatically. Board staff is learning to use the new Web-based ad hoc reporting capabilities and will begin rebuilding CURES reports used regularly by the board for investigations and non-compliance. Reports that board staff developed in the old CURES database cannot be used on the new Web-based system. In the interim, the BNE is allowing access to CURES data through the old software to access the board's reports. BNE has applied for federal grant money to fund additional improvements to CURES and allow BNE to meet new federal regulations (NASPER), such as capturing method of payment, and the legal identification of the patient or person picking up the controlled substance in CURES, the addition of Schedule IV controlled substance reporting, etc. The DOJ is also studying ways to automate the process for physicians and pharmacists to request a patient activity report (PAR) from CURES. This will be especially useful for emergency room physicians and pharmacists. DOJ is also working on an automated reporting tool for direct dispensing physicians. **Each Quarter:** An inspector and a supervising inspector continue to participate on 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.

Task:	**7. Secure sufficient staffing for a complaint mediation team and to support an 800 number for the public.** First and Second Quarters: Nothing to report.
Task:	**8. Improve public service of the Consumer Inquiry and Complaint Unit.** First Quarter: ▪ Three new informational flyers were developed through UCSF addressing the issues of recalled medication, generic medication, and cutting drug costs. ▪ "What You Should Know Before Buying Drugs from Foreign Countries or the Internet" and "Tips to Save You Money When Buying Prescription Drugs", are now available in Chinese, Vietnamese, Spanish, and English languages. ▪ The board now has 24 consumer brochures and publications, including Health Notes. ▪ Board staff provided consumer information at the City of Sacramento Public Safety Center's Community Celebration on September 24, 2005. ▪ Board staff provided consumer information at the UCD Healthy Aging Summit on October 15, 2005. Second Quarter: ▪ Nothing to report this quarter. However, several events are scheduled for next quarter.
	9. Automate processes to ensure better operations and integrate technology into the board's investigative and inspection activities. Investigative Activities: First Quarter: ▪ With the addition of Schedule III prescriptions added to the CURES database, the volume of data has grown too large to transmit to the inspectors via email. Staff developed a program to put on CD for each inspector that will automatically install an updated CURES data file to their laptops with the click of a button. CD's with updated CURES data files are mailed monthly to each inspector. ▪ To improve case management efforts, a monthly report is prepared and submitted to management. This report reflects the age of the case, who the case is assigned to, which cases are under review with the Supervising Inspector, cases that are referred to citation and fine and/or the Attorney General. The report identifies those cases not currently assigned. The report is also used as a tool to identify and locate those cases that have not had any recent activity. ▪ The department is currently evaluating tools to implement ad hoc reporting. Through the Enforcement Users Group meetings the latest information is that they are in the selection process and hope to be able to test the product soon. All vendor demonstrations are complete. The selection has not been announced. OIS has met with the Chief Information Officer and Project Executive Sponsor to discuss findings. The CIO and PES will determine what further action will be taken. ▪ Staff performed various updates to improve functionality of the various enforcement databases. Second Quarter: Nothing to report

	Inspection Activities – Automated inspection assignment status reports are sent to supervising inspectors weekly. Revisions and additions made to the automated inspection database include: First Quarter: ▪ Color coding queries showing licensees that have already been scheduled for inspection, need to be scheduled for inspection, and those inspections completed had to be updated with new criteria now that the new 4 year inspection cycle has started. ▪ Revised wholesale and LSC automated reports to include assignment information. ▪ 75 security printers are currently approved to produce controlled substance prescription forms. 10 of the approved printers utilize the services of several hundred distributors that market their prescription products to prescribers. Second Quarter: ▪ Staff developed a tool to print case action summaries. ▪ Staff developed a Probation / PRP database for staff and field inspectors. The system has been in the test mode for 3 months. Data entry of all participants and scanning of relevant documents is in the process. ▪ Staff set up and trained new inspectors on computers, cell phones, and GPS. ▪ CURES data is extracted monthly and integrated into the Inspector Data program allowing the Inspectors to view the total number of prescriptions by drug for a specific pharmacy during a three-month rolling cycle. Each month staff prepares a CD that contains a list of over 13, 000 inspection reports that can be viewed and printed; all active board-licensed California sites and licensees; DEA 106 list of scanned DEA 106 forms; and the CURES data file. The CD also provides other updates, when applicable, such as new issues of The Script and the new Pharmacy Law Book. ▪ Ongoing improvements to the Inspector Data and Inspector Activity installed in November 2005 and December 2006. ▪ Report functionality improvements to the Evidence database. ▪ Ongoing functionality and report capability improvements to the inspection assignment program. ▪ Staff copied inspector laptop data files and compared laptop Access data tables to the data tables on the server and made adjustments. Staff also generated missing inspection reports from inspector laptop files in electronic format and added to the server. ▪ SB734 transfers the application process for security printer approval to the Department of Justice January 1, 2006. Staff made changes to the database to provide greater functionality and ease in data entry before sending it to the DOJ. The board had approved 79 security printers as of January 1, 2006.
Objective 1.2	**To achieve 100 percent closure on all administrative cases within one year by June 30, 2006.** **Measure:** Percentage closure on administrative cases within one year.
Task:	1. **Pursue permanent funding to increase Attorney General expenditures for the prosecution of board administrative cases.** ▪ First Quarter: DAG costs increase to $139 per hour. Board receives supplemental funding of $216 thousand to purchase the same level of AG services at a higher hourly rate. ▪ Second Quarter: Nothing to report.

Task:

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.

	Q1	Q2	Q3	Q4
Status memos sent to AG	35	**24**		
0-365 days	21	**11**		
366 + days	21	**11**		
Accusations reviewed	39	**25**		
Accusations needing revision	7	**3**		
Accusations filed	38	**17**		
Stips/proposed decisions reviewed	15	**19**		
Cases reviewed for costs	10	**8**		

Task:

3. **Establish a disciplinary cause of action for fraud convictions similar to current cash compromise provisions related to controlled substances.**

   First and Second Quarters: Nothing to report.

Task:

4. **Automate processes to ensure better operations and integrate technology into the board's investigative and inspection activities.**

   - Administrative Case Management Database Program:

   First and Second Quarters: No changes.

Objective 1.3: **Inspect 100 percent of all licensed facilities once every 3 years by September 30, 2005.**

Measure: Percentage of licensed facilities inspected once every 3 years.

Task:

1. **Automate processes to ensure better operations and integrate technology into the board's investigative and inspection activities.**

   - For all quarters, see response to Objective 1.1, Task #9

Task:

2. **Inspect licensed premises to educate licensees proactively about legal requirements and practice standards to prevent serious violations that could harm the public.**

Inspection Statistics Background:

First Quarter:
On July 1, 2005, the board began its second 3 to 4-year cycle of inspections towards the goal of inspecting all sites once every 3 to 4 years (by June 30, 2009):

- Total number of locations identified to inspect from those licensed as of July 1, 2005 (does not include sites licensed after 7/1/05) to meet the board's goal of inspecting all sites once every 3 to 4 years was approximately **7,735**;
  - Total number of inspections completed **611**,
  - Total number of inspections to be completed by June 30, 2009 are **7,119 or 7.9%**.

- Total number of locations identified to inspect (including sites licensed before and after 7/1/2005) was approximately **7,915**;
  - Total number of inspections completed **618** or **7.8%.**
  - Total number of inspections to be completed by June 30, 2009 are **7,292**

*inspection data as of 10/1/05

Second Quarter:

- Total number of locations identified to inspect from those licensed as of July 1, 2005 (does not include sites licensed after 7/1/05) to meet the board's goal of inspecting all sites once every 3 to 4 years was approximately **7,670**;
  - Total number of inspections completed **1.202 or 15.67%;**
  - Total number of inspections to be completed by June 30, 2009 are **6,464.**

- Total number of locations identified to inspect (including sites licensed before and after 7/1/2005) was approximately **7,947**;
  - Total number of inspections completed **1,227** or **15.44%;**
  - Total number of inspections to be completed by June 30, 2009 are **6,716.**

*inspection data as of 1/1/06

Total Number	**Q1**	**Q2**	**Q3**	**Q4**
Inspections Completed	710	**568**		
Routines/ Wholesaler-Vet-Retailer/ Probation/PRP	584	**463**		
Sterile Compounding *(included in routines)*	79	36		
Investigation Inspections	126	**105**		
Status 3 (included in routines)	4	9		
Routine resulting in complaint investigation. (included above)	34	14		

Wholesaler/Vet Retailer Inspection Program – The board implemented the Wholesaler Inspection Program beginning March 1, 2005. Data are included in the previous table and shown separately here for reference only.

A total of **506** sites identified for inspection.

- As of September 30, 2005, the Diversion Team has completed a total of 239 inspections since program inception.
- As of January 1, 2006, the Diversion Team has completed a total of **285** inspections since program inception.

	Q1	**Q2**	**Q3**	**Q4**
Wholesaler/Vet Retailer Inspections Completed	95	**52**		

Task:	**3. Seek legislation to mandate that periodic inspections be done on all board-licensed facilities** First and Second Quarters: Nothing to report.
Objective 1.4	**Develop 4 communications in addition to the inspections program to educate board licensees by June 30, 2006.** **Measure:** Number of communication venues (excluding inspection program)
Task:	**1. Develop the board's website as the primary board-to-licensee source of information.** ▪ Public disclosure of disciplinary history on licensees is online. First Quarter Web Additions/Revisions ▪ Posted board meeting dates for 2006 ▪ Posted board and committee information - agenda, materials & minutes ▪ Regulation updates ▪ Updated several application packets ▪ Added new version of self-assessment forms ▪ Created a page on Hurricane Katrina Information and Resources ▪ Added newly approved Security Printers (total 77) ▪ Updated the Script Newsletter Index ▪ Sent out subscriber alert notifications to the board's e-mail notification list Second Quarter Web Additions/Revisions: ▪ Updated all Web pages with the board's new address and phone numbers. ▪ Added bond information to applications. ▪ Sent subscriber alerts. ▪ Update the regulation and legislation Web pages. ▪ Posted board and committee meeting agendas and materials. ▪ Updated the strategic plan. ▪ Revised the security printer Web page to link to the DOJ. ▪ Added the revised community, hospital, and sterile compounding self-assessment forms.
Task:	**2. Prepare two annual *The Scripts* to advise licensee of pharmacy law and interpretations.** ▪ January 2005 Script Newsletter published. ▪ October 2005 Script Newsletter published. ▪ January 2006 Script Newsletter is currently at the publisher.
Task:	**3. Update pharmacy self-assessment annually.** First Quarter: Revised form so that fields can be filled in online. New version posted of the web ▪ Regulation requiring 2005 version took effect 10/7/05.] Second Quarter: Board approved the wholesale self-assessment October 2005 and recommends moving ahead with regulations to require wholesalers to complete a self-assessment every 2 years.

Task:	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.** First Quarter CE Presentations ▪ Supervising Inspector Nurse presented information about the board and how it investigates cases to a group of United States Attorneys on July 20. ▪ Supervising Inspector Nurse participated in a training module for federal investigators who will be monitoring fraud in the Medicare Prescription Drug Plan programs in San Diego on September 20. ▪ The board staffed a public information booth the City of Sacramento Public Safety Public Fair on September 24. ▪ The board will staff a public information booth on October 15 at the UCD Healthy Aging Fair. ▪ Supervising Inspector Ratcliff will present information on pharmacy law changes at a UFCW-Orange County Pharmacist Association continuing education conference on October 16. ▪ The board will staff an information booth at CSHP Seminar on October 21 and 22. ▪ Several board members will present information at this association meeting. ▪ Supervising Inspector Ming will present information about pharmacy law to a group of UCSD pharmacy students in mid-November ▪ Assistant Executive Officer Herold will present information about the board to a group of UCSD pharmacy students on November 28. ▪ Supervising Inspector Ming will present information about sterile compounding to a group of pharmacy technician students at Santa Ana College on November 30. ▪ Board Member Jones will present information about pharmacy technology at the NABP Fall Conference in December. Second Quarter CE Presentations: ▪ Supervising Inspector Nurse participated as the board's representative to the Northern California Pain Initiative on January 9. ▪ Board President Goldenberg participated on an NABP Task Force on Telepharmacy and the Implementation of the Medicare Drug Benefit Medication Therapy Management Provisions conference call on October 27. ▪ Board President Goldenberg was keynote speaker at a conference of long-term care executives on Medicare Part D in Los Angeles on November 4. ▪ Supervising Inspector Ming presented information about pharmacy law and board pharmacy inspections to a group of UCSD pharmacy students on November 14. ▪ Assistant Executive Officer Herold presented information about the board to a group of UCSD pharmacy students on November 28. ▪ Supervising Inspector Ming presented information about sterile compounding to a group of pharmacy technician students at Santa Ana College on November 30. ▪ Board Member Jones presented information about pharmacy technology at the NABP Fall Conference in Florida on December 4. ▪ Board Member Fong presented information about new pharmacy laws to pharmacists at the Diablo Valley Pharmacists Association Meeting on December 28. ▪ Supervising Inspector Ratcliff presented information to the California State University Pharmacists on current law topics on January 12. ▪ Board President Goldenberg and Supervising Inspector Ratcliff presented information about the board and new pharmacy law on January 19 to USC students.

Task:	**5. Hold quarterly Enforcement Committee Meetings** First Quarter: ▪ Meeting held June 2005. Discussed importation, use of automated devices in clinics. Interpretation of pharmacy law related to Interns, waiver requests for self-use automated delivery systems, and petitions for consideration. ▪ Meeting held September 2005. Discussed importation, disciplinary guidelines, self assessment for wholesalers, legibility of prescriptions, DEA requirements for prescribing Schedule II drugs, new labeling requirements, and electronic pedigree requirements. Second Quarter: ▪ Meeting held in December 2005. Discussed implementation of pedigree requirement, faxed prescription form patients, generic substitution by prescriber on electronic data transmission prescriptions, citation and fine program, GAO report on anabolic steroid without prescription, and importation of prescription drugs.
Objective 1.5	**To monitor alternative enforcement programs for 100 percent compliance with program requirements by June 30, 2006.** **Measure:** Percentage compliance with program requirements
Task:	**1. Administer effective alternative enforcement programs to ensure public protection (Pharmacists Recovery Program, probation monitoring program, citation and fine program).**

Pharmacists Recovery Program	**Q1**	**Q2**	**Q3**	**Q4**
Total # of PRP Participants	63	**67**		
Number Referred to PRP	6	**5**		
Number Closed from PRP	4	**0**		
Probation Monitoring Program - Number on Probation	**Q1**	**Q2**	**Q3**	**Q4**
Pharmacists	108	**103**		
Pharmacies	16	**14**		
Other	19	**19**		
Citation and Fine	**Q1**	**Q2**	**Q3**	**Q4**
Citations Issued	189	**151**		
Fines Collected	$46,236	**$49,086**		

Task:	**2. Automate processes to ensure better operations and integrate technology into the board's investigative and inspection activities.** First Quarter: Currently in the process of establishing a database for the Citation and Fine unit. The database will automate the processes of creating letters, memos and statistics, which are currently completed by staff manually. ▪ Working with staff in linking databases ▪ Working with OIS to automatically receive monthly licensure information ▪ Working with Citation and Fine unit to verify needs for letters and memos ▪ Testing for integrity of statistical data Second Quarter: No changes
Objective 1.6	**Respond to 95 percent of all public information requests within 10 days by June 30, 2006.** **Measure:** Percentage response to public information requests within 10 days.
Task:	**1. Activate public inquiry screens to expand public information. Establish web look-up for disciplinary and administrative (citation) actions.** ▪ Web Enforcement Look-Up – In production May 2004. Completed disciplinary actions are entered into the database on an on-going basis. ▪ Staff has begun scanning public disciplinary documents for availability as a PDF document on the Web Enforcement Look Up.

Task:	**2. Establish on-line address of record information on all board licensees-**
	
	▪ Licensee address of record information became available on-line to public in December 2003.
	  ▪ Regulation to ban posting on Website the address of record of intern pharmacists goes to the board for adoption. If approved, the rulemaking files will be submitted to the Administration for approval in November 2005.
	  ▪ Regulations are anticipated to go into effect late spring 2006.

Task:	**3. Respond to specialized information requests from other agencies about board programs, licensees (e.g. subpoenas) and Public Record Act requests.**

Total by Type of Requests Received				
Request Type	**Q1**	**Q2**	**Q3**	**Q4**
Public	30	**17**		
Licensees	24	**7**		
Other agencies	29	**34**		
License Verifications	223	**200**		

Time Frame Records Requests Responded To	**Q1**		**Q2**		**Q3**		**Q4**	
	Number and Percentage Per Quarter							
Within 10 days	67	81%	**38**	**66%**				
Over 10 days	16	19%	**20**	**34%**				

	Time Frame License Verifications Responded To	Q1		Q2		Q3		Q4	
		Number and Percentage Per Quarter							
	Within 10 days	210	94%	**176**	**88%**				
	Over 10 days	13	6%	**24**	**12%**				

Objective 1.7	**Initiate policy review of 25 emerging enforcement issues by June 30, 2006.** **Measure**: The number of issues.
Tasks (Issues)	1. Reimportation of drugs from Canada. ▪ Importation of Drugs - 2004: discussed at every Enforcement Committee meeting and board meeting. ▪ January 2005: Discussed at Board Meeting. ▪ March 2005: Discussed at Enforcement Committee Meeting. ▪ April 2005: Discussed at Board Meeting. ▪ May 2005: Discussed at Enforcement Committee Meeting. ▪ July 2005: Discussed at Board Meeting. ▪ September 2005: Discussed at Enforcement Committee Meeting. ▪ October 2005: Discussed at Board Meeting ▪ December 2005: Discussed at Enforcement Committee Meeting 2. Modification to the Quality Assurance Regulation regarding patient notification. (completed) 3. Proposals regarding wholesale transactions. ▪ Sponsored legislation (SB 1307). ▪ January 2005 – SB 1307 became effective. ▪ January 2005– Participated in NABP Task Force to develop e-pedigree elements. ▪ January 2005 – Participated in NABP Wholesaler's Distributors Regulatory meeting and participated in NABP Task Force to develop e-pedigree elements. ▪ February 2005 –Implementation of SB 1307. ▪ April 2005– Presentation to board on pedigree software ▪ June 2005 – two presentations to Enforcement Committee on pedigree software. ▪ September 2005– discussed at the Enforcement Committee Meeting regarding the difficulty of implementation. ▪ November 2005: Recommend legislation clean-up language for 2006. ▪ December 2005: Developed Q & A for implementation discussion at the Enforcement Committee Meeting. 4. Clarification regarding prescription records by authorized officers of the law. ▪ October 2005: updated article in the board's newsletter. 5. Review of Pharmacy Law regarding the delivery of medications after the pharmacy is closed and a pharmacist is not present. ▪ Sponsored legislation SB 1913 ▪ January 2005– bill passed, SB 1913 effective 6. Off-site order entry of hospital medication orders (Bus. & Prof. Code Section 4071.1). ▪ DOJ and board approved for controlled substances. 7. Prescriber dispensing. ▪ May 2003 - Workgroup with Medical Board on proposal on prescriber dispensing by physician groups. 8. Implementation of federal HIPAA requirements. 9. Prohibition of pharmacy-related signage. 10. Implementation of enforcement provisions from SB 361. 11. Implementation of SB 151 (elimination of the Triplicate). ▪ January 2005 – new changes to controlled substance law took effect. Continued CE presentations.

- February 2005 – continued CE presentations
- March 2005 – discussed Q & A at Enforcement Committee meeting.
- April 2005 – discussed at board meeting.
- June 2005 – discussed at Enforcement Committee meeting.

12. Dispensing non-dangerous drugs/devices pursuant to a prescriber's order for Medi-Cal reimbursement
13. Authorized activities in a pharmacy.
14. Review of Quality Assurance Program.
15. Limited distribution and shortage of medications.
16. Conversion of paper invoices to electronic billing.
17. Automated dispensing by pharmacies.
18. Public disclosure and record retention of substantiated complaints.
19. Evaluation of QA regulation
20. Biometric technology
    - Statutory change (SB 1913), regulation proposal to implement.
    - October 2005 - Regulation became effective.
21. Update of pharmacy laws related to PRP.
    - October 2004–board approved statutory changes.
    - February 2005 – Legislation introduced – SB 1111.
    - January 2006: Statutory change (SB111) became effective.
22. Update of pharmacy law related to pharmacy technicians.
    - October 2004–board approved statutory changes.
    - February 2005 – Legislation introduced – SB 1111.
    - January 2006: Statutory change (SB111) became effective.
23. Clean-up of "Letter of Admonishment" provision.
    - October 2004–board approved statutory changes.
    - February 2005 – Legislation introduced – SB 1111.
    - January 2006: Statutory change (SB111) became effective.
24. Use of "kiosks: for drop-off of prescriptions.
    - October 2005– board approved waiver for kiosks and regulation change
    - October 2005: Board held regulation hearing – regulation tabled.
    - December 2005: Proposed regulation withdrawn
    - January 2006: Revised language to be considered by Legislation and Regulation Committee.
25. Use of self-services dispensing units for pick-up of refill prescriptions.
    - October 2004– board approved statutory changes
    - January 2005– board approved second waiver
    - April 2005 – board approved third waiver in conjunction with a study.
    - June 2005– request to require "Pharmacy Service Plans" for approved waiver.
    - July 2005Board approved two more waivers.
    - Overview of study by UCSD presented.
    - September 2005 - Regulation change noticed.
    - October 2005: Board held regulation hearing – regulation tabled.
    - December 2005: Proposed regulation withdrawn
    - January 2006: Revised language to be considered by Legislation and Regulation Committee.
26. Mandatory reporting of impaired licensees.
    - January 2005–board approved statutory change
    - March 2005 - SB 1111 introduced
    - January 2006: Statutory change (SB111) became effective.
27. Electronic Prescribing Standards for the implementation of the Medicare Drug Improvement and Modernization Act (MMA) of 2003.
    - March 2005 – Discussed at Enforcement Committee meeting – no action necessary.
28. Prescribing Authority for Naturopathic Doctors
    - February 2005 – Met with Bureau of Naturopathic Doctors and other interested parties

	regarding proposed legislative changes to address inconsistencies in pharmacy law. ▪ February 2005 – Requested legal opinion from DCA. ▪ April 2005 -Opinion provided to Board. ▪ June 2005 -Clean-up statutory provisions introduced in bill. 29. Pharmacy law clarification regarding pharmacist interns, orally and electronically transmitted prescriptions, and filling on non-security Rx form for controlled substances. (June 2005) 30. Use of automated drug delivery systems in clinics. (June 2005) ▪ July 2005: Board clarified use of systems 31. Request to repeal CCR 1717.2. ▪ July 2005 Board approved – Referred to Legislation and Regulation Committee. 32. Legal requirements and process for Petitions for Reconsideration. (June 2005) ▪ July 2005: Board reaffirms the process for petition for reconsideration. 33. Proposed self-assessment for wholesalers. (September 2005) ▪ October 2005: Board approved proposed regulation to implement self-assessment form for wholesalers – Referred to Legislation and Regulation Committee. 34. Legibility of prescription – Refer to SCR49 Medication Error Panel for review. (Sep 2005) 35. Revised self-assessment for pharmacies. ▪ October 2005 - Regulation became effective. 36. Update regulation 1745 regarding the partial fill of Schedule II prescriptions. ▪ October 2005 - Regulation change became effective. 37. Proposal to amend B & P Code section 4040© to allow a pharmacy to accept a fax prescription from a patient. ▪ December 2005: Discussed at Enforcement Committee Meeting and will be referred to the board. 38. Proposal to amend B & P 4073(b) to indicate the prohibition on generic substitution by a prescriber on an "electronic data transmission" prescription. ▪ December 2005: Discussed at Enforcement Committee Meeting and will be referred to the board. 39. Reviewed citation and fine program at the request of California Retailers Association ▪ September 2005: Noticed on agenda and provided 3-yar data on program – no comments were received. ▪ December 2005: Noticed on agenda and provided 3-yar data on program – no comments were received. 40. Revised Disciplinary Guidelines ▪ September 2005: Discussed at Enforcement Committee Meeting ▪ October 2005: Board approved the changes for a proposed amendments to the regulation – referred to the Legislation and Regulation Committee.