California State Board of Pharmacy
400 R Street, Suite 4070, Sacramento, CA 95814
Phone (916) 445-5014
Fax (916) 327-6308
www.pharmacy.ca.gov

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

Contact Person: Patricia Harris
(916) 445-5014 x 4004

ENFORCEMENT COMMITTEE MEETING

December 7, 2005
9:00 a.m. – 1:00 p.m.

Holiday Inn Capitol Plaza
300 J Street
Sacramento, CA 95814
(916) 446-0100

This committee meeting is open to the public and is held in a barrier-free facility in accordance with the Americans with Disabilities Act. Any person with a disability who requires a disability-related modification or accommodation in order to participate in the public meeting may make a request for such modification or accommodation by contacting Candy Place at telephone number (916) 445-5014, at least 5 working days prior to the meeting.

Opportunities are provided to the public to address the committee on each agenda item. Members of the board who are not on the committee may attend and comment during the meeting.

AGENDA

CALL TO ORDER **9:00 a.m.**

A. Implementation of the Electronic Pedigree Requirement for Prescription Drugs Effective January 1, 2007

   Questions and Answers Regarding Implementation
   Status Update on Technology and Standards

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

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

D. Review of Citation and Fine Program

E. Discussion Regarding the Importation of Prescription Drugs

F. GAO Report on the Purchase of Anabolic Steroids without a Prescription

G. Proposed Meeting Dates for 2006
   March 14th or 16th (Sacramento)
   June, September and December

H. Adjournment 1:00 p.m.

Committee materials will be available on the board's website by December 1, 2005

ATTACHMENT A

California State Board of Pharmacy
400 R Street, Suite 4070, Sacramento, CA 95814
Phone (916) 445-5014
Fax (916) 327-6308

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

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

State of California | Department of Consumer Affairs

Memorandum

To: Enforcement Committee

Date: November 29, 2005

From: Patricia F. Harris
Executive Officer

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

Attached is a proposed amendment to 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.

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 C

State of California | Department of Consumer Affairs

Memorandum

To: Enforcement Committee

Date: November 29, 2005

From: Patricia F. Harris
Executive Officer

Subject: **Proposal to Amend B&P § 4073(b)**
Prohibition of Generic Substitution

Attached is 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 not additional need for the handwritten initial.

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

RECEIVED BY CALIF
BOARD OF PHARMACY

2005 NOV -3 AM 10: 43

Sunnyvale Main Clinic
Administrative Offices
301 Old San Francisco Rd.
Sunnyvale, CA 94086
408-739-6000

Dermatology
250 Sobrante Way
Sunnyvale, CA 94086
408-730-4370

Mathilda Office
323-325 N. Mathilda Ave.
Sunnyvale, CA 94085
408-733-4380

Pediatrics at Fremont Center
877 W. Fremont Ave., Bldg. N
Sunnyvale, CA 94087
650-934-7956

Vision Care Center
413 E. El Camino Real
Sunnyvale, CA 94087
408-524-5900

Los Altos Clinic
4906 El Camino Real
Los Altos, CA 94022
650-404-8370

Mountain View Offices
Internal Medicine
125 South Drive
Mountain View, CA 94040
650-934-7956

Internal Medicine
1174 Castro St., Suite 200
Mountain View, CA 94040
650-934-7808

Obstetrics & Gynecology
515 South Drive, Suite 21
Mountain View, CA 94040
650-934-7956

Santa Clara Clinic
2734 El Camino Real
Santa Clara, CA 95051
408-241-3801

West Valley/Cupertino Clinic
7225 Rainbow Drive
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 D

State of California | Department of Consumer Affairs

Memorandum

To: Enforcement Committee | Date: September 6, 2005

From: Patricia F. Harris
Executive Officer

Subject: **Citation and Fine Program**

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 placed on this agenda. Subsequently, CRA requested that the agenda item be deferred until the December 7th meeting. Committee Chair Bill Powers agreed to place the Citation and Fine Program on the December agenda for discussion. However, since the topic was already noticed for this meeting, opportunity to discuss the program will also be provided at this meeting.

Background Material

Attachment 1
Overview of the investigation process that includes recommended actions that the board may take including the issuance of a citation and fine

Attachment 2
Citation and fine data since the program's inception

ATTACHMENT 1

California State Board of Pharmacy
400 R Street, Suite 4070, Sacramento, CA 95814-6237
Phone (916) 445-5014
Fax (916) 327-6308
www.pharmacy.ca.gov

STATE AND CONSUMER SERVICES AGENCY
DEPARTMENT OF CONSUMER AFFAIRS
GRAY DAVIS, GOVERNOR

INVESTIGATION PROCESS

Complaint Investigation

When the Board of Pharmacy ("Board") receives a complaint or uncovers potential violations of the law through its own efforts, the matter may be assigned for investigation to either an enforcement analyst or to an inspector.

During the course of the investigation, evidence is obtained in order to determine if the alleged violation of the law occurred. As part of the investigation, the licensee may be asked for documents (e.g., business records, patient records, and/or policies and procedures) and/or for statements regarding the events that transpired. Licensees are encouraged to respond in a timely and accurate manner, as the information is used as part of the investigative record. A licensee's responsiveness or non-responsiveness may be considered as a factor in mitigation or aggravation.

If it is believed that a violation of pharmacy law took place, the licensee may be advised of the alleged violation on the inspection report. This notification will simply notify the licensee the violations of pharmacy law that the inspector or enforcement analyst believes occurred. This notification is not the Board's final or formal determination regarding the matter. It is also neither a citation nor is it a disciplinary action.

At this time, the licensee will be provided with another opportunity to respond in writing to the alleged violation. In the written response, the licensee may address the specifics of the violation, as well provide any mitigatory information that the licensee wishes to have included in the investigation report.

After the investigation is completed and there is a determination by the inspector or enforcement analyst that the law was violated, the case is referred to a supervising inspector for review. If the supervising inspector determines that there was no violation or that the violation was so minor as to not merit any action, then the case may be closed and the matter goes no further.

Recommended Actions

If after review by a supervising inspector, it is determined that action may be warranted, the case is then referred to the executive officer. The executive officer, with the assistance of the supervising inspectors, reviews the matter and determines what is the appropriate course of action to pursue. The types of action that may be undertaken include:

- **Case Closure – No Further Action**
  The executive officer may decide that no action is now warranted. That may occur when the executive officer determines that there was no violation, that the violation

was so minor as to not merit an action, or that the mitigating circumstances were such that it would be best not to pursue an action. The matter then ends.

- **Order of Correction**

If an Order of Correction has been issued, the licensee can contest the order by requesting an office conference with the executive officer. However, if no office conference is requested, compliance with the order is not an admission of the noted violation. The order of correction is not considered a public record for purposes of disclosure.

- **Further Investigation**

The executive officer may decide that there is insufficient evidence to determine if a violation occurred or if any action is warranted. The executive officer may then send the matter back for further investigation.

- **Letter of Admonishment**

After review, the executive officer may issue a Letter of Admonishment to the licensee for failure to comply with Pharmacy Law. The letter will include a reference to the statute or regulation violated, a description of the nature and facts of the violation, and a notice to the licensee of available appeal rights.

- **Citation and Fine**

After review, the executive officer may issue a citation, with or without a fine. The citation will be issued to the licensee and will include a reference to the statute or regulation violated. It will also include a description of the nature and facts of the violation, as well as a notice to the licensee of the appeal rights.

The following factors are considered when issuing a citation with or without a fine:

- Gravity of the violation.
- Good or bad faith of the cited person or entity.
- History of previous violations.
- Evidence that the violations were or were not willful.
- Recognition by the licensee of his/her wrongdoing and demonstration of corrective action to prevent recurrence, e.g., new policies and procedures, protocol, hiring of additional staff, etc.
- Extent to which the cited person or entity has cooperated with the Board's investigation and other law enforcement or regulatory agencies.
- Extent to which the cited person or entity has mitigated or attempted to mitigate any damage or injury caused by the violation.
- If the violation involved multiple licensees, the relative degree of culpability of each licensee should be considered. In the case where the staff pharmacist failed to consult, the pharmacist-in-charge and the pharmacy may also be issued a citation and fine, if warranted by the circumstances.
- Any other relevant matters that may be appropriate to consider.

Fine Amount

The Board's regulation provides that a fine can be up to a maximum of $5,000 per licensee for each investigation

If an investigation involves multiple licensees (e.g., a staff pharmacist, the pharmacist-in-charge, a pharmacy technician, and the pharmacy), then each licensee may be cited and fined. The amount of each fine will depend on which of the above factors are present and applicable to each licensee. The Citation and Fine Committee will consider the amount of the fine on a case-by-case basis.

Request for an Office Conference

A licensee has 14 calendar days after service of the citation and fine to request an office conference with a board member and supervising inspector, pursuant to the California Code of Regulations, title16, section 1775.4, subdivision (b).

Appeal Process for Citation and Fines

Payment of a fine does not constitute an admission of the violation charged. A licensee has 30 days after service of the citation and fine to file a written appeal (request for a hearing). Appeals are referred to the Attorney General's Office for a hearing in accordance with the Administrative Procedure Act. For more complete description on the entire the appeal process please see California Code of Regulations, title 16, sections 1775, subdivision (c), and 1775.4.

Disciplinary Action

The executive officer may determine that the violation is substantial and warrants discipline of the license. The matter is then referred to the Attorney General's Office, where, if appropriate to do so, an accusation is prepared, which identifies the alleged violations of pharmacy law.

ATTACHMENT 2

Fines Assessed
Statistic Comparison

Statistic Category	02/03	03/04	04/05
Total number of citations issued	908	1410	689
Average days from case open to citation	228	142	177
Total amount of fines assessed	$407,775.00	$939,259.00	$365,525.00
Total amount of fines collected to date	$361,975.00	$852,707.00	$405,579.00
Number of office conferences requested	124	399	409
Total number of conferences held	20	21	20
Total number of appearances	97	197	350
Number of citations dismissed	20	82	100
Number of citations modified	17	72	68
Number of citations affirmed	60	43	173

A Comparison of the Top Ten Violations by License type by fiscal year

Pharmacists	%	Pharmacists	%	Pharmacists	%	Pharmacists	%
2002 – 2003		2003 – 2004		2004 – 2005		2005 - 2006	
1716 - Variation from prescription	27	1716 - Variation from prescription	42	1716 - Variation from prescription	48	1716 - Variation from prescription	52
1707.2 – Duty to consult	8	4051(a) - Conduct limited to a pharmacist; conduct authorized by pharmacist (unlicensed activity by a revoked pharmacist)	8	1716/1761 - Variation from Rx / Erroneous Rx	16	1716/1761 - Variation from Rx / Erroneous Rx	18
1714(d) – Operational standards and security	7	1716/1761 - Variation from Rx / Erroneous Rx	7	1714(d) - Operational standards and security; pharmacist responsible for pharmacy security	6	1764/56.10 et seq. - Unauthorized disclosure of prescription and medical information	5
1761- Erroneous or uncertain prescriptions	5	1761(a) - No pharmacist shall compound or dispense any prescription, which contains any significant error or omission...	5	1717(b)(4)/4076(a)(4) Preprinted multiple check off Rx blanks/ container requirements for labeling - Name of the prescriber	4	4081(a)- Records of dangerous drugs kept open for inspection	5
4076/4077- Rx container labeling requirements	5	4125/1711 - Quality assurance program	4	4059 – Furnishing dangerous drugs or devices prohibited without prescription	3	1714(b)- Operational standards and security; pharmacy responsible for pharmacy security	3
4081/4332/4333 – Records of dangerous drugs.	2	4301(q) - Engaging in any conduct that subverts or attempts to subvert an investigation of the board.	3	4125/1711 - Quality assurance program	2	4051(a)- Conduct limited to a pharmacist; conduct authorized by pharmacist	3
4115/1793.7 – Pharmacy technician/ Requirements for Pharmacies Employing Pharmacy Technicians	2	4063 – Refill of prescription for dangerous drug or device; Prescriber authorization.	3	1715 - Self-assessment of a pharmacy by the pharmacist in charge	2	4063- Refill of prescription for dangerous drug or device; prescriber authorization	3
1764/56.10– Unauthorized disclosure of Rx	2	4231/1732.5 - Requirements for renewal of pharmacist license/ Accreditation agencies	2	1716/4076(a)(4) - Variation from prescription/ container requirements for labeling - Name of the prescriber	2	1707.2(b)- In addition to the obligation to consult...a pharmacist shall provide oral consultation to his or her patients...whenever the prescription drug has not previously be dispensed	3
4059.5 - Who may order dangerous drugs	1	1707.2 – Duty to consult	2	1707.2 – Duty to consult	2	1761(a) - Variation from prescription/No pharmacist shall compound or dispense any prescription, which contains any significant error or omission...	3
1716.2 - Records requirements-compounding for future furnishing	1	1715 - Self-assessment of a pharmacy by the pharmacist in charge	2	4116/1714(d) - Security of Dangerous Drugs and Devices in Pharmacy: Pharmacist responsibility for individuals on premises; Regulations/Operational standards and security	2	4052(a)(5)- Furnishing to Prescriber; Permissible Procedures by Pharmacist in Health Care Facility or Clinic or for Other Health Care Provider	3

A Comparison of the Top Ten Violations by License type by fiscal year

Pharmacies	%	Pharmacies	%	Pharmacies	%	Pharmacies	%
2002 – 2003		2003 – 2004		2004 – 2005		2005 - 2006	
1716 - Variation from prescription	21	1716 - Variation from prescription	21	1716 - Variation from prescription	35	1716 - Variation from prescription	34
1714 (b) – Operational standards & security	9	1714(b) - Operational standards and security; pharmacy responsible for pharmacy security	9	1714(b) - Operational standards and security; pharmacy responsible for pharmacy security	26	1716/1761 - Variation from Rx / Erroneous Rx	15
1761- Erroneous or uncertain prescriptions	6	4125/1711 - Quality assurance program	7	1715.6 – Reporting drug loss	12	4125/1711 - Quality assurance program	6
4115/1793.7 – Tech activities permitted; Req. supervision/Req. for PHY with techs	5	1716/1761 - Variation from Rx / Erroneous Rx	4	1716/1761 - Variation from Rx / Erroneous Rx	12	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.	6
1707.2 – Duty to consult	4	1715 - Self-assessment of a pharmacy by PIC	3	4125/1711 - Quality assurance program	6	4059.5(a)– Dangerous drugs and devices may only be ordered by an entity licensed by the board	4
4081/4332/4333 – Records of dangerous drugs	3	4076 - Prescription container requirements for labeling	3	4115(e)-Pharmacy Technician license required	4	1715.6- Reporting drug loss	4
1764/56.10 – Unauthorized disclosure of Rx	2	4328 -Misdemeanor permitting compounding, dispensing, or furnishing by non-pharmacist	2	4127.1(a) - License to compound injectable sterile drug products required	2	4063- Refill of prescription for dangerous drug or device; prescriber authorization	4
4076/4077 - Rx container labeling requirements	2	4116/1716(b) -Security of dangerous drugs & devices/Operational standards and security; pharmacy responsible for pharmacy security	2	4116/1714(d) - Security of Dangerous Drugs and Devices in Pharmacy: Pharmacy responsibility for individuals on premises;	2	1714(b)- Operational standards and security; pharmacy responsible for pharmacy security	4
4067 - Internet: Dispensing Dangerous drugs or Devices without prescription	2	1716.2 - Record requirements - compounding for future furnishing	2	1708.2 – Discontinuance of business	2	4081(a)- Records of dangerous drugs kept open for inspection	4
4125/1711 – Quality Assurance	2	4113(a)(c)/1709.1 - Pharmacist in charge notification to board and responsibilities /Designation of a pharmacist in charge	2	1714(c) - Operational standards and security; the pharmacy must be maintained in a sanitary condition	1	1708.2- Discontinuance of business	2

A Comparison of the Top Ten Violations by License type by fiscal year

Pharmacists in charge 2002 – 2003	%	Pharmacists in charge 2003 – 2004	%	Pharmacists in charge 2004 – 2005	%	Pharmacists in charge 2005 - 2006	%
4115/1793.7 – Pharmacy technician license req. /Requirements for PHY with techs	13	1716 - Variation from prescription	11	1714(d) - Operational standards and security; pharmacist responsible for pharmacy security	28	1716 - Variation from prescription	15
1714(d) – Operational standards and security	12	4125/1711 - Quality assurance program	11	4125/1711 - Quality assurance program	12	4081/1718- Records of dangerous drugs kept open for inspection/Current inventory defined	14
1707.2 – Duty to consult	6	1714(b) - Operational standards and security; pharmacist responsible for pharmacy security	9	1716/1761 - Variation from prescription/Erroneous or uncertain prescriptions	7	1716/1761 - Variation from Rx / Erroneous Rx	10
1715 - Self-Assessment of a pharmacy by the Pharmacist-in-Charge	5	1715 - Self-assessment of a pharmacy by PIC	5	4127.1 – License to compound injectable sterile drug products required	6	4125/1711 - Quality assurance program	10
4081/4332/4333 – Records of dangerous drugs.	5	1716.2 - Record requirements - compounding for future furnishing	4	4051/11207/4036 - Conduct limited to a pharmacist; conduct authorized by pharmacist/Only pharmacist or Intern authorized to fill prescription/Pharmacist	6	1714(c)/4005- Operational Standards and security; Pharmacy shall be clean and orderly/ Board may Adopt Rules and Regulations	10
4125/1711 Quality Assurance	5	4342/USP 25th edition page 10 - Actions by board to prevent sales of preparations or drugs lacking quality or strength	3	4115(e) -4115(e)-Pharmacy Technician license required	6	4125/1711- Pharmacy quality assurance program required/Quality assurance program	10
1716 - Variation from prescription	5	4115(e) - Pharmacy technician license required	3	4059 – Furnishing dangerous drugs or devices prohibited without prescription	4	1717(f)- A pharmacist may transfer a prescription for Schedule III, IV, or V controlled substances to another pharmacy for refill purposes in accordance with Title 21, Code of Federal Regulations § 1306.25...	10
1761- Erroneous or uncertain prescriptions disclosure of Rx	3	1793.7(e) - Requirements for pharmacies employing pharmacy technician - Job description and written policies and procedures required	3	1715 - Self-assessment of a pharmacy by the pharmacist in charge	4	4059.5(a)- Dangerous drugs and devices may only be ordered by an entity licensed by the board	5
4076/4077 - Rx container labeling requirements	3	1716/1761 - Variation from Rx / Erroneous Rx	3	4114 – Intern pharmacist: activities permitted	2	1710(a)- A hospital pharmacy which predominantly furnishes drugs to inpatients of that hospital my furnish drugs to walk-in customers, provided that sales do not exceed 1% of all pharmacy's prescriptions.	5
1716.2 - Records requirements- compounding for future furnishing	3	4116/1716(d) -Security of dangerous drugs & devices/Operational standards and security; pharmacist responsible for pharmacy security	2	1305.11(a) - Unaccepted & defective order forms; No order form shall be filled if not complete, legible, or properly prepared, executed, or endorsed; or shows any alteration, erasure, or change of any description	2	4063- Refill of prescription for dangerous drug or device; prescriber authorization	5

Citation Appeals to Attorney General's Office

	FY 02/03	FY 03/04	FY 04/05
Citation Appeals	84	23	24
Citations Settled	75	12	10
Citations to Hearing	1	1	0

citation and fine upheld at hearing - 1
citation and fine upheld and reduced at hearing - 3

ATTACHMENT E

State of California | Department of Consumer Affairs

Memorandum

To: Enforcement Committee

Date: November 29, 2005

From: Patricia F. Harris
Executive Officer

Subject: **Importation of Prescription Drugs**

This is a standing agenda item for the meetings of the Board and the Enforcement Committee. Attached are various articles that have appeared since the last board meeting.

kaisernetwork.org

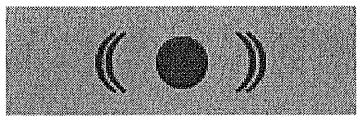
Daily Health Policy Report

Email this story to a friend.
Print this story.
View entire Policy Report.

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).

About Us Privacy Policy Help Site Map



Kaisernetwork.org is a free service of the Henry J. Kaiser Family Found

Welcome. Visitors wishing to view more than two items will be asked to login or register.

Past Issue

Across the Nation

forward
next article

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.

back

next article

forward

Today's News | Upcoming Events | Multimedia | Health Currents | Contact Us
Login | About CHL | Advanced Search | Sources | Help | Privacy Policy | Logout

California Healthline is published for the California HealthCare Foundation by the Advisory Board Company. © 2005 the Advisory Board Company. All Rights Reserved.

Daily Health Policy Report

Email this story to a friend.
Print this story.
View entire Policy Report.

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

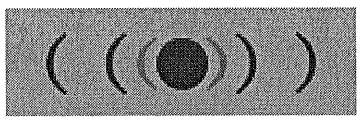
U.S. consumers import a "substantial and increasing" amount of illegal prescription drugs, but "very limited" information exists to help federal regulators intercept shipments of addictive medications or other treatments that could have safety risks, according to a report released on Thursday by the 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).

....
....
....

About Us Privacy Policy Help Site Map



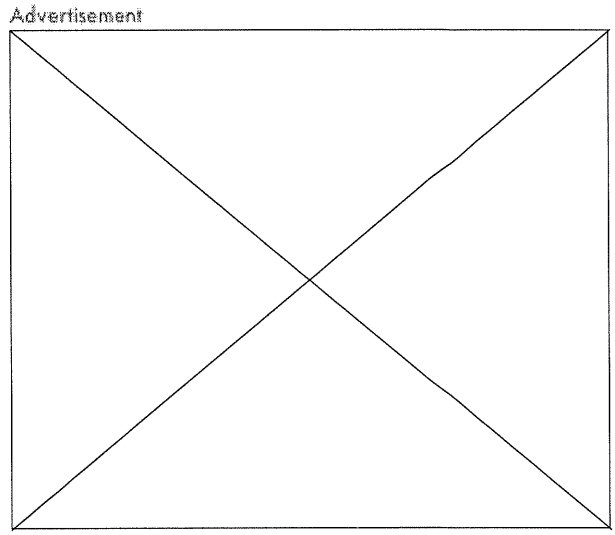
Kaisernetwork.org is a free service of the Henry J. Kaiser Family Found

washingtonpost.com

GAO Faults Efforts on Drug Sales

Illegal Importation Of Prescriptions Up

Advertisement



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."

© 2005 The Washington Post Company

ATTACHMENT F

GAO
Accountability * Integrity * Reliability

United States Government Accountability Office
Washington, DC 20548

November 3, 2005

The Honorable Tom Davis
Chairman
The Honorable Henry Waxman
Ranking Minority Member
Committee on Government Reform
House of Representatives

Subject: *Anabolic Steroids Are Easily Purchased Without a Prescription and Present Significant Challenges to Law Enforcement Officials*

This report responds to your request that we investigate whether anabolic steroids can be purchased without a prescription and test whether such purchases are easily made. You also asked us to identify common sources of illegal anabolic steroids, and significant challenges law enforcement officials encounter in investigating, prosecuting, and deterring criminal anabolic steroid traffickers.

To complete this work, we made purchases through the Internet of anabolic steroids commonly used by athletes and bodybuilders, and had tests performed on the products purchased by the National Medical Services, a commercial laboratory, and the Food and Drug Administration (FDA). To identify significant challenges law enforcement officials encounter in the investigation and prosecution of illegal anabolic steroid traffickers, we interviewed officials of federal agencies that have responsibility for enforcement of laws relating to anabolic steroids–FDA, the Drug Enforcement Administration (DEA), the Department of Justice (DOJ), and the U.S. Customs and Border Patrol Agency (CBP)—and we visited CBP international mail facilities at two airports that receive significant quantities of mail containing anabolic steroids, New York's Kennedy Airport and at the Miami International Airport. Additionally, to obtain the perspective of state and local officials on enforcement issues, we interviewed officials of New York's Office of the Special Narcotics Prosecutor, the only prosecutorial agency in the country that is exclusively dedicated to the investigation and prosecution of felony drug offenses. We also spoke with officials of the United States Sentencing Commission and researched current and proposed legislation relating to illegal anabolic steroid activity.

Summary

Our 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. The

investigators then used an e-mail account in a fictitious name to place 22 orders. From these orders, we received 10 shipments of anabolic steroids; all were shipped from foreign countries. We also received 4 shipments from within the United States but the substances they contained, though marketed as anabolic steroids or other "muscle building" products, were not anabolic steroids according to the FDA.[1] We are referring the evidence concerning our purchases to DEA and to FDA for appropriate action.

The officials we spoke with told us that most anabolic steroids sold illegally in the United States come from abroad, and that the Internet is the most widely used means of buying and selling anabolic steroids illegally. They also reported that, because of the foreign origin of the steroids and the widespread use of the Internet in steroid trafficking, extensive time and resources are usually required to investigate and prosecute steroid cases. Further, the sheer volume of all types of imports from abroad presents significant challenges in efforts to prevent anabolic steroids from illegally entering the United States. Additionally, some officials noted the relatively low sentences that result from application of the federal sentencing guidelines to persons convicted of illegal steroid trafficking.

Background

Anabolic steroids are synthetic forms of the male sex hormone testosterone that can be taken orally, injected, or rubbed on the skin. Under U.S. law they cannot be sold without a prescription, and are dispensed to treat conditions associated with low testosterone levels, such as delayed puberty or body wasting associated with AIDS. When used in combination with exercise, training, and a high protein diet, anabolic steroids can improve endurance and promote increased muscle size and strength. Because of these effects, they are illicitly used as performance-enhancing drugs by some athletes, bodybuilders, and others to improve competitiveness or appearance.

However, steroid abuse can cause devastating side effects, including liver, kidney, and heart disease; cancer, stroke, and behavioral changes such as increased aggression and severe depression. The availability and use of anabolic steroids in sports, particularly among adolescents, is a growing concern. According to a National Institute of Health study, use of steroids by American young people underwent a period of sharp rise in the late 1990s, and continues to be at an all time high among 12th graders. Moreover, in a recent study performed by the University of Michigan, more than 42 percent of 12th graders reported that anabolic steroids are easy or fairly easy to obtain without a prescription.

In 1990, Congress passed the Anabolic Steroids Control Act of 1990[2] adding anabolic steroids to the federal schedule of controlled substances.[3] The act placed anabolic steroids on Schedule III of the Controlled Substance Act and specifically identified

[1] Eight orders were never received.
[2] Anabolic Steroids Control Act of 1990, Pub. L. No. 101-647, 104 Stat. 4851 (1990) (*amending* the Controlled Substances Act, 21 U.S.C. § 812 (c)).
[3] Prior to 1990, anabolic steroids were not classified as a controlled substance under federal law, and their use was subject to regulation by the FDA.

27 anabolic steroids. The maximum term of imprisonment for a Schedule III controlled substance offense is 5 years, or 10 years if the person has a prior felony drug offense conviction.[4] The Anabolic Steroid Control Act of 2004 added additional anabolic steroids to Schedule III of the Controlled Substance Act.

Purchases of Anabolic Steroids without a Prescription

Our investigators tested whether it would be easy for anyone who has access to a computer to locate and make purchases from dealers who sell anabolic steroids illegally.

To do this, they replicated what any athlete or bodybuilder of any age can do on a home computer. First, they conducted Internet searches using the words "anabolic steroids," or the names of specific anabolic steroids that DEA identified for us as commonly used by athletes and bodybuilders. As a result, they found hundreds of Web sites offering anabolic steroids for sale.

The investigators placed a total of 22 orders for anabolic steroids through 22 of these Web sites that were selected randomly. Using an e-mail account that they established in a fictitious name, the investigators completed these orders and paid for them. As a result, we received 14 shipments. Of that number, 10 were anabolic steroids; the 4 additional shipments contained substances that were not anabolic steroids.[5]

Steroids Received

The 10 orders of anabolic steroids we received were obtained through Web sites that openly and boldly offer anabolic steroids for sale. Some of the Web sites offer a variety of pharmaceutical drugs, while others sell anabolic steroids exclusively. They typically offer "private and confidential" sales of "discretely shipped" anabolic steroids that will "shape your body the way . . . you want it to look." Many sites offer dozens of anabolic steroids for sale. They promote anabolic steroid use through claims that they have good affects on the body, touting, for example, that one product is a "growth-promoting agent."

Other Web sites, including some of those from which we made purchases, offer packages of different steroids for those who "cycle" or "stack" their use of anabolic steroids. A cycle is a period of from 6 and 14 weeks of steroid use, followed by a period of abstinence or gradual reduction in use; stacking is using multiple anabolic steroids concurrently. The packages offered by the Web sites are designed for a variety of different users, from "beginning" muscle builders to advanced "mass" builders, to customers interested in the "ladies lean stack."

---

[4] Anti-Drug Abuse Act of 1986, Pub. L. No. 99-570 , 100 Stat. 3207 (*codified at* 21 U.S.C. § 841(b)(1)(D); 21 U.S.C. § 960(b)(4) (5-year maximum term of imprisonment for import violations).

[5] The National Medical Services laboratory tested the 10 products that were anabolic steroids to confirm that they were in fact anabolic steroids and to determine the type of anabolic steroid received; the FDA tested the 4 other products we received to determine their contents.

The Web sites do not indicate the country from which the steroids are shipped, but we later learned from return addresses and postmarks on the shipments that the anabolic steroids all came from outside the United States. Although we placed these 10 orders at 10 different Web sites, the shipments came from just three different countries: five were from Trieste, Italy; four from Shanghai, China; and one from Athens, Greece. The shipment from Athens, Greece came in a plain 5- by 6- inch envelope bearing a return address label with an individual's name and address. It contained one bottle of the anabolic steroid Testosterone Propionate in liquid form. We paid $114.00 for the order using a credit card.

The five orders shipped from Trieste, Italy, came in plain 5 by 7 inch envelopes bearing one of three different return address labels with an individual's name and address. From one address we received two orders, each containing 100 tablets of the anabolic steroid Methandrostenolone. Using a credit card, we paid $109.20 for one of these orders and $107.90 for the other.

From a different return address in Trieste we received two other packages, each containing one bottle of the anabolic steroid Testosterone Cypionate in liquid form. Using a credit card, we paid $120.90 for one of these orders. For the other, we followed instructions sent through e-mail communications from the dealer to wire $144.00 through Western Union to an individual in Vienna, Austria. From the third address in Trieste we received a package containing 100 tablets of Methandrostenolone. We paid $117.00 for the order and wired the money through Western Union to an individual in Salzburg, Austria, as instructed.

Each of the four shipments from Shanghai came in a plain 6 by 9 inch envelope. Each envelope had a return address label bearing a different individual's name and address.

We paid for each of them by credit card. One package contained 150 yellow tablets of the anabolic steroid Stanozolol for which we paid $200.00. A second package containing 20 tablets of Stanozolol was also received, and we paid $97.00 for them. Additionally, we received a package containing crushed green tablets of the anabolic steroid Oxymetholone and paid $124.00 for them. The fourth package from Shanghai contained 40 green tablets of Oxymetholone and cost $323.00.

Other Products Received

We also received four shipments from dealers in the United States through Web sites that claimed to sell anabolic steroids or products that have the muscle-building effects of anabolic steroids. However, according to FDA, none of these shipments contained anabolic steroids. We have referred the results of our investigation concerning these products to the FDA.

Challenges Faced by Law Enforcement Officials When Investigating and Prosecuting Illegal Steroid Trafficking Cases

Law enforcement officials identified significant challenges in their efforts to investigate, prosecute, and deter criminal anabolic steroid traffickers. These challenges arise from the foreign origin of many illegally sold steroids, the widespread use of the Internet in steroid trafficking, the volume of mail CBP must screen in its efforts to prevent entry of anabolic steroids into the United States, and the relatively low sentences that result from application of the federal Sentencing Guidelines to illegal steroid offenders.

Most Illegally Sold Anabolic Steroids Come From Abroad

The law enforcement officials we spoke to reported that, in their experience, most anabolic steroids distributed illegally in the United States come from abroad. The results of our test purchases tend to confirm this. Larger illegal anabolic steroid dealers in the United States frequently have multiple overseas sources of steroids. Significant quantities of anabolic steroids come from Mexico, as well as other countries such as Russia, Romania, and Greece.

There is a readily available supply of steroids worldwide because, in most countries, anabolic steroids can be sold legally without a prescription. Thus, many foreign distributors do not violate the laws of their own country when they sell these substances to people in the United States. As a result, U.S. law enforcement agencies have difficulty in obtaining assistance from their foreign counterparts in investigations of such distributors.

Law enforcement officials also identified smuggling of anabolic steroids[6] across international borders into the United States as an important part of the illegal distribution network and described how smugglers typically operate. A smuggler in the United States takes orders from steroid customers in person, over the phone, or via e-mail. After obtaining advance payment from customers, the smuggler will travel to the source country, usually Mexico, to purchase the steroids. Some smugglers pay someone else to perform this function or have a foreign source that will ship the steroids. Smugglers who travel either carry the steroids back or ship them to the United States. In Mexico and European countries, smugglers usually buy anabolic steroids from pharmacies.

In some cases, the smuggler may ship the steroids to a partner in the United States, known as a remailer, and provide the remailer with addresses of specific U.S. customers. The remailer repackages the steroids and sends them to the customers. According to

[6] An emerging issue identified by officials we spoke with is the illegal importation of anabolic steroids in bulk powder form. Large quantities of steroids can be smuggled in bulk powder form into the United States where injectible forms of steroids can be reconstituted from them. These shipments are more difficult to detect than steroids in tablet or liquid form.

law enforcement officials, the remailer normally performs this task in exchange for money or free steroids. The customer may then use the steroids or resell them to others in places such as gyms and at bodybuilding contests.[7]

The Internet Facilitates Illegal Anabolic Steroid Trafficking

Law enforcement officials reported that the Internet is a primary vehicle for buying and selling anabolic steroids illegally. Internet Web sites, usually foreign based, advertise steroids for sale. Customers access these sites, inquire about purchases, and place orders. Sellers typically require advance payment through Western Union, PayPal, money orders, or credit cards. After receiving payment, sellers ship the steroids through international mail or an express carrier. A remailer may also be used to resend packages once they arrive in the United States.

The Internet also provides an easy means for sellers to market to young people. Moreover, according to some of the law enforcement officials we spoke to, sales of steroids and other synthetic drugs are used by some sellers as a "gateway" to sales of narcotics, such as cocaine. Typically, in such cases, the seller uses an initial series of steroid or designer drug transactions to gauge whether the buyer is a legitimate customer and is not an undercover law enforcement investigator. After the seller has gained assurances that the customer is legitimate through the initial steroid sales, narcotics are offered for sale.

To prosecute illegal steroid dealers, law enforcement officials must identify them and gather evidence of their trafficking activity. However, anabolic steroid dealers can capitalize on the anonymity afforded by the Internet to thwart efforts to identify them. Internet sites can be installed, moved, or removed easily and quickly, making it difficult for law enforcement agencies to identify, track, monitor, or shut them down. As a result, investigations of anabolic steroid dealers require substantial time and resources.

Further, dealers operating through the Internet typically communicate with individual customers through e-mail, and establish e-mail accounts using fictitious identifying information and mailing addresses with one of the free e-mail services.[8] Some officials reported to us that the use of free e-mail accounts with fictitious account holder identity information is found frequently in investigations, and is many dealers' preferred means of communication with customers. Such accounts add an additional layer of anonymity to the dealer and complexity to law enforcement efforts to track down and identify them.

Of particular concern to some officials are offshore providers of free e-mail services such as Hushmail,[9] based in Ireland, and Operamail, based in the Netherlands. Officials at one

---

[7] You also specifically asked about the extent to which steroids are illegally diverted from pharmacies and synthesized in clandestine laboratories. The officials we spoke with indicated that, in their experience, the number of pharmacy diversion and clandestine laboratory cases is relatively small; the Internet, smuggling, and foreign source anabolic steroids are the most significant anabolic steroid trafficking issues.

[8] Since there are no fees for these accounts, the service providers may have no reason to verify the account holder's name, address, or other identifying information.

agency told us that they believe it is too risky to approach these providers with requests for voluntary cooperation because they can ignore nondisclosure requests with impunity, and may intentionally or unintentionally tip off the subjects of investigations.

Internet drug crime investigations are further complicated by service providers who strip e-mail messages of information about their point of origin. E-mail generally contains "header" information identifying various Internet Protocol (IP) addresses, including "routing" and "originating" IP addresses. IP addresses may prove useful in determining the identity of the user of a particular e-mail account. However, in some cases, investigators find that some service providers automatically eliminate origination and routing IP addresses from e-mail sent through their services. Hushmail, for example, strips origination IP addresses and substitutes the IP Address of Hushmail's own computers on its customers' communications. The result, for example, is that when a steroids dealer in Florida sends an e-mail to a customer in Virginia, the e-mail that arrives in Virginia has Hushmail's originating IP Address in Ireland rather than the actual IP originating address of the dealer.

Challenges in Interdicting Entry of Steroids into the United States

All international mail entering the United States through the U.S. Postal Service and private carriers is subject to inspection by the CBP at the 14 international mail facilities and 29 express consignment carrier facilities located around the country. CBP inspects for illegally imported controlled substances, such as anabolic steroids, contraband, and other items that are inadmissible into the United States. Each year the international mail and carrier facilities process hundreds of millions of pieces of mail and packages. For example, the international mail facility at John F. Kennedy Airport in New York alone receives approximately 1.3 million pieces of mail each day. The volume of mail, together with the steps illegal steroid shippers use to disguise their product and the labor-intensive nature of the inspection process itself, present formidable challenges to the CBP in its efforts to interdict the entry of anabolic steroids into the United States.

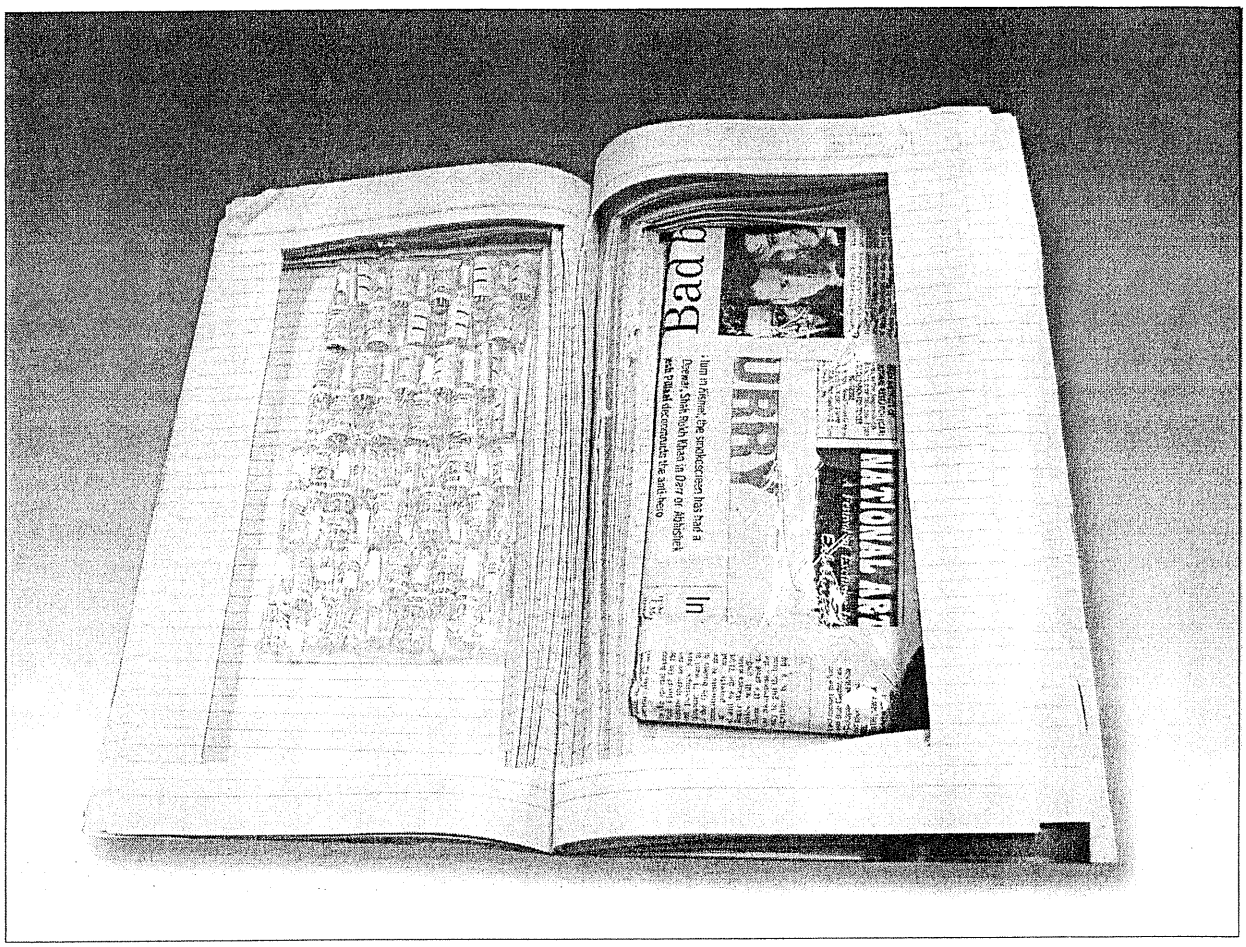
The inspection process is very labor and time intensive, and can include visual examination, x-ray, and opening mail to physically inspect the contents. At the international mail facilities we visited in New York and Miami, mail goes through a series of processes before being released or detained by the CBP. It passes through a portal monitor designed to screen for nuclear and radiological materials, and is placed on a conveyer belt where officers screen individual pieces of mail. CBP officers target packages for inspection based on factors such as their knowledge, intuition, and experience; whether the mail originated in suspect countries; and intelligence gained from prior interceptions of controlled substances. Suspicious mail is separated, x-rayed, opened by individual inspectors, and searched.

The difficulty of detecting anabolic steroids is further increased because dealers conceal them in items such as books or small electrical equipment to avoid detection by CBP. Anabolic steroids are commonly secreted in small electronic equipment, such as

[9] Hushmail also offers free automatic encryption services.

speakers, blenders, or alarm clocks, or hidden in compact disk cases or in hollowed sections of books. We observed examples of such shipments that had been intercepted by CBP during our visits to U.S. Postal Service International Mail facilities in Miami and in New York. Figure 1 is a photograph of a book in which CBP in New York found a shipment of the anabolic steroid Testosterone Enanthate from India.

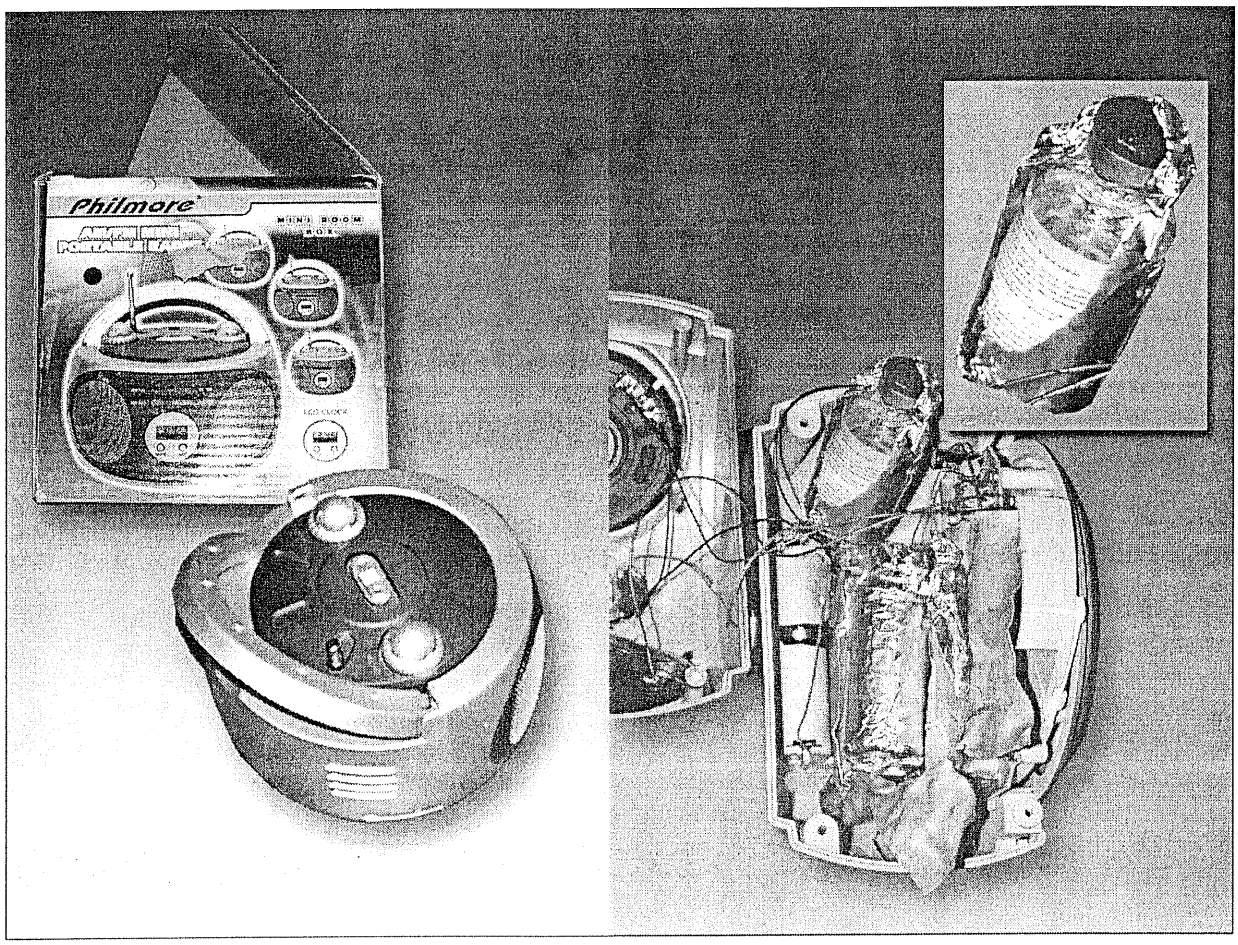
Figure 1: Book From India Containing Anabolic Steroids Interdicted By CBP



Source: GAO.

The left side of figure 2 is a photograph of a box and radio that were in a package shipped from Panama. CBP in Miami found that the radio had been used to hide a shipment of the anabolic steroid Testosterone Cypionate. The right side of figure 2 shows the opened radio with the steroid secreted inside.

Figure 2: Radio From Panama Interdicted By CBP (left); Radio Opened To Disclose Anabolic Steroids (right)



Source: GAO.

CBP officials noted that shippers and customers can also use an on-line tracking system made available by the Postal Service to track packages sent through express mail. This enables illegal traffickers in steroids to determine whether and where a shipment has been detained by the CBP. This is a disadvantage for law enforcement officials when they attempt to conduct an investigation through what is known as a controlled delivery. In a controlled delivery, a law enforcement employee poses as a Postal Service employee and delivers the package to the intended recipient. This may provide an opportunity to gather evidence or make an arrest. However, the value of a controlled delivery as an investigative tool may be compromised if the trafficker, through the tracking system, has notice that the shipment was detained by the CBP.

Federal Sentencing Guidelines for Steroids Offenses Do Not Provide a High Level of Deterrence

Law enforcement officials told us that although extensive time and resources are required to locate, charge, and convict criminal anabolic steroid dealers, the penalties under the Federal Sentencing Guidelines faced by persons convicted of such offenses do not reflect the seriousness of their crimes or provide adequate deterrence.[10] Drug quantity is a principal factor in determining offense level and sentence for drug offenses under the sentencing guidelines. Quantity of anabolic steroids and other Schedule III controlled substances under the sentencing guidelines is based on a "unit" system. A unit of a Schedule III controlled substance, other than anabolic steroids, is "one pill, capsule, or tablet" or, if in liquid form, 0.5 grams. However, the sentencing guidelines treat anabolic steroids differently from all other Schedule III substances. One unit of an anabolic steroid is 50 pills, capsules, or tablets or, if in liquid form, one unit equals a 10 cc vial of injectable steroid.[11]

As a result, an offender responsible for selling 40,000 pills of a Schedule III substance other than an anabolic steroid, such as ketamine, would face a sentence of 33 to 41 months under the drug quantity rules of the sentencing guidelines. On the other hand, an offender convicted of selling 40,000 pills of an anabolic steroid would face a sentence of 0 to 6 months under those rules. According to DOJ, DEA's laboratory seizure analysis from 2003 suggests that anabolic steroid seizures in major cases consist of quantities in the order of magnitude of 20,000 to 40,000 tablets and 2,000 to 6,000 milliliters. Thus, in the case of DEA's largest seizure in 2003, in which 44,000 tablets of the anabolic steroid Methandienone were seized, a defendant convicted of trafficking in those steroids would face a sentence of 0 to 6 months under the drug quantity rules of the current sentencing guidelines.

Section 3 of the Anabolic Steroid Control Act of 2004 directed the United States Sentencing Commission to review and consider amending the Federal Sentencing

[10] The state officials we spoke with informed us that penalties for illegal steroid trafficking under New York law similarly do not provide adequate deterrence.
[11] *U.S. Sentencing Guidelines Manual*, § 2D1.1, Notes to Drug Quantity Table (G).

Guidelines with respect to steroids offenses.[12] The Sentencing Commission began its review of anabolic steroids offenses during its 2004-2005 amendment cycle.[13] In February 2005, the Commission issued a notice for public comment in the *Federal Register* on whether the guidelines governing steroids offenses should be amended. The Sentencing Commission received public comment from various parties and in April, 2005, held a public hearing at which it received testimony from the Department of Justice, the Federal Public Defenders Service, the National Association of Criminal Defense Lawyers, and the Practitioners Advisory Group.[14] After reviewing the information obtained, the Sentencing Commission deferred promulgation of steroids-related amendments to the federal sentencing guidelines because it concluded that it did not have sufficient information on offenses involving anabolic steroids, particularly anabolic steroids trafficking.

Instead, the Sentencing Commission decided to conduct further research and outreach in order to determine the most appropriate course of action.[15] It also decided to seek "emergency amendment authority" from Congress that would give the Sentencing Commission the option of promulgating an amendment that would take effect immediately upon date of promulgation. The Sentencing Commission submitted its request to Congress on April 20, 2005.[16] On September 29, 2005, the President signed a bill[17] which provides that, if the Sentencing Commission determines that amending the federal sentencing guidelines for anabolic steroids offenses is appropriate, such amendments will take effect by March 29, 2006.

- - - - -

This report will be available on GAO's web page at http://www.gao.gov. If you have questions, please contact me at (202) 512-7227 or cramerr@gao.gov. Barry Shillito,

---

[12] Anabolic Steroid Control Act of 2004, Pub. L. No. 108-358, 118 Stat. 1661 (*codified at* 28 U.S.C.A. § 994 Note (2004)).

[13] The Sentencing Commission operates under "amendment cycles" that culminate in the submission of proposed amendments to the federal sentencing guidelines to Congress on or before May 1 of each calendar year. The Sentencing Commission typically announces its list of final priorities for consideration in the summer; works on policy issues related to that list in the fall; publishes proposed amendments in the *Federal Register* for public comment in the late winter; holds public hearings on proposed amendments in the early spring; and votes to promulgate amendments in April of every calendar year. Amendments are submitted to Congress by May 1 and Congress has 180 days to take affirmative action with regard to the proposed amendments. If Congress does not act, the amendments become effective no later than November 1. *See* 28 U.S.C. § 994(p)(2004).

[14] The Practitioners Advisory Group is a standing advisory group to the Sentencing Commission.

[15] The Sentencing Commission prepared an extensive report on the use of steroids in 1991 and will update that report as part of its review of steroids penalties.

[16] The Sentencing Commission also placed consideration of steroids offenses on its *Federal Register* list of proposed priorities on which public comment was requested. Public comment was received in August 2005 from the Food and Drug Administration, the Federal Public Defenders Service, the DOJ, and the Practitioners Advisory Group.

[17] United States Parole Commission Extension and Sentencing Commission Authority Act of 2005, Pub. L. No. 109-76, 199 Stat. 2935 (2005).

Daniel Kaneshiro, Ramon Rodriguez, and Richard Egan made major contributions to this report.

Robert J. Cramer
Associate General Counsel

(601322)

This is a work of the U.S. government and is not subject to copyright protection in the United States. It may be reproduced and distributed in its entirety without further permission from GAO. However, because this work may contain copyrighted images or other material, permission from the copyright holder may be necessary if you wish to reproduce this material separately.

GAO's Mission

The Government Accountability Office, the audit, evaluation and investigative arm of Congress, exists to support Congress in meeting its constitutional responsibilities and to help improve the performance and accountability of the federal government for the American people. GAO examines the use of public funds; evaluates federal programs and policies; and provides analyses, recommendations, and other assistance to help Congress make informed oversight, policy, and funding decisions. GAO's commitment to good government is reflected in its core values of accountability, integrity, and reliability.

Obtaining Copies of GAO Reports and Testimony

The fastest and easiest way to obtain copies of GAO documents at no cost is through GAO's Web site (www.gao.gov). Each weekday, GAO posts newly released reports, testimony, and correspondence on its Web site. To have GAO e-mail you a list of newly posted products every afternoon, go to www.gao.gov and select "Subscribe to Updates."

Order by Mail or Phone

The first copy of each printed report is free. Additional copies are $2 each. A check or money order should be made out to the Superintendent of Documents. GAO also accepts VISA and Mastercard. Orders for 100 or more copies mailed to a single address are discounted 25 percent. Orders should be sent to:

U.S. Government Accountability Office
441 G Street NW, Room LM
Washington, D.C. 20548

To order by Phone: Voice: (202) 512-6000
TDD: (202) 512-2537
Fax: (202) 512-6061

To Report Fraud, Waste, and Abuse in Federal Programs

Contact:

Web site: www.gao.gov/fraudnet/fraudnet.htm
E-mail: fraudnet@gao.gov
Automated answering system: (800) 424-5454 or (202) 512-7470

Congressional Relations

Gloria Jarmon, Managing Director, JarmonG@gao.gov (202) 512-4400
U.S. Government Accountability Office, 441 G Street NW, Room 7125
Washington, D.C. 20548

Public Affairs

Paul Anderson, Managing Director, AndersonP1@gao.gov (202) 512-4800
U.S. Government Accountability Office, 441 G Street NW, Room 7149
Washington, D.C. 20548

PRINTED ON RECYCLED PAPER

ATTACHMENT G

State of California | Department of Consumer Affairs

Memorandum

To: Enforcement Committee | Date: November 29, 2005

From: Patricia F. Harris
Executive Officer

Subject: **Proposed Meeting Dates for 2006**

The Enforcement Committee needs to set its meeting dates for 2006. I am requesting that the March meeting be scheduled for either March 14th or the 16th in Sacramento because a staff meeting is planned for the 15th to perform strategic planning. Since the inspectors will be in Sacramento for strategic planning, the goal is to have them attend the Enforcement Committee as well.

The other meeting months are June, September and December. June and December meetings will also be held in Sacramento.