California State Board of Pharmacy
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STATE AND CONSUMER SERVICES AGENCY
DEPARTMENT OF CONSUMER AFFAIRS
Arnold Schwarzenegger, GOVERNOR

Enforcement Committee Report

William Powers, Public Member, Chair
Stan Goldenberg, RP.h.
David Fong, Pharm.D.

Report of March 9, 2005

Due to the cancellation of flights to the Burbank airport, Committee Chair Bill Powers was unable to attend the meeting. Because the Enforcement Committee did not have a quorum, staff counsel advised that an official meeting of the Enforcement Committee could not be held. President Goldenberg as a committee member discussed the agenda items. The following are not recommendations from the Enforcement Committee but are actions items for board consideration. A motion will be required for each action item.

FOR ACTION

ACTION ITEM 1

That the Board of Pharmacy consider the request from University of San Diego (UCSD) Medical Center for a waiver of 1717(e) to install and use a self-service dispensing unit for refill prescriptions at its hospital outpatient pharmacy.

Discussion
The Board of Pharmacy has received a request from UCSD for waiver of California Code of Regulations section 1717(e) to install and utilize a self-service dispensing unit at its hospital outpatient pharmacy. **(Attachment A)**

At its October meeting, the Board of Pharmacy granted to Longs Drug Stores its request for a waiver of 1717(e) to install and utilize a self-service dispensing unit, such as the Asters ScriptCenter, at various Long Drug Stores in California. At its January meeting, the board granted a similar waiver to Safeway Inc. to install and utilize these same units at its Safeway and Vons pharmacies.

At previous meetings, John Cronin, Senior Vice-President for the California Pharmacists Association (CPhA) raised concerns about the effect that granting these waivers will have on the interactions between pharmacists and consumers. He discussed the philosophical question of technology in pharmacies and the impact that these devices will have on consumers and the role

pharmacists play in monitoring ongoing drug therapies. In his letter dated April 12, 2005, Dr. Cronin is recommending that as part of the waiver process, the board require the pharmacy to submit a "pharmacy services plan" that would include a clear description of how the requested waiver would facilitate the provision of pharmacist care and improve patient care in the pharmacy. CPhA is suggesting that it should also include a description of how the requesting pharmacy will monitor and measure attainment of the plan goals. It may also include a description of the anticipated impact on business operations, hours of operation and staffing. Compliance with the plan would be monitored by periodic inspections and failure to comply with the proposed pharmacy services plan would be basis for withdrawal of the waivers, or other action by the board. **(Attachment AA)**

The board granted the waivers to permit the use of an automated dispensing device that allows a patient to access his/her filled prescriptions under the following specified conditions:

- The automated dispensing device is used for refill prescriptions only.
- It is the patient's choice to use the automated dispensing device.
- The device is located in reasonable proximity to the licensed pharmacy premises.
- The device is secure from access and removal by unauthorized individuals.
- The pharmacy provides a means for the patient to obtain a consultation with a pharmacist if requested by the patient.
- The pharmacy is responsible for the prescriptions stored in the device.
- A pharmacist is not to use the device to dispense refilled prescriptions if the pharmacist determines that the patient requires counseling pursuant to CCR, title 16, sec. 1707.2(a)(2).

In conjunction with this waiver, the UCSD Skaggs School of Pharmacy and Pharmaceutical Sciences (SSPPS) is developing a formal study on the impact of this technology to pharmacy and patients. SSPPS plans to provide the information regarding the study at this meeting. **(Attachment B)**

The Asters ScriptCenter is an automated, self-contained instrument that allows patients to access their filled prescriptions. The intent is to install the units in close proximity to the pharmacy area. To improve patient convenience and therapeutic compliance, a patient may access the units during pharmacy hours or during those times when the main store is open, but the pharmacy is closed.

At the request of the patient and through the use of a secure method designed to guard against inappropriate access, a patient may retrieve his/her filled prescription from the unit at their convenience. New prescriptions, or those prescriptions requiring consultation, would not be available through these units.

Prescriptions would be filled by a pharmacist and placed into the units either by a pharmacist or pharmacy personnel, under the supervision of a pharmacist. As medications are placed into the units, security measures are used to ensure accurate dispensing.

ACTION ITEM 2

That the Board of Pharmacy consider the request from White Cross Drug Store for a waiver of 1717(e) to install and use a self-service dispensing unit for refill prescriptions.

Discussion
White Cross Drug Store is requesting a waiver of waiver of California Code of Regulations section 1717(e) to install and utilize a self-service dispensing unit in its pharmacy. White Cross Drug Store plans to install and utilize a self-service prescription-dispensing unit, such as the ddn, APM (Automated Product machine). **(Attachment C)**

NO ACTION

Importation of Prescription Drugs

The importation of prescription drugs has been an ongoing agenda item for the Enforcement Committee and Board of Pharmacy meetings for over the last three years. This has been a sensitive and controversial issue. The board has been tasked with balancing consumer access to affordable prescriptions against the safety and effectiveness of drugs obtained from foreign sources. The board has heard from many interested parties on this issue during its committee meetings and at its quarterly board meetings. The board's mandate is to protect the public, which includes patient access to "safe and affordable" prescription medications.

Attached are articles regarding recent developments on the issue of drug importation nationally and in various states. Also, articles from the National Association of Boards of Pharmacy (NABP) monthly newsletter are provided. **(Attachment D)** A copy of a report by consulting firm Giuliani Partners for the Pharmaceutical Research and Manufacturers of American on prescription importation that was released on April 12, 2005 is also included. **(Attachment E)**

This year, Governor Schwarzenegger is sponsoring SB 19 "California Rx", which is in response to his last year's veto of SB 1149 (Ortiz 2004). In his veto message, the Governor stated, "A top priority of my Administration is to provide access to affordable prescription drugs. However, importing drugs from Canada or assisting residents in their efforts to do so would violate federal law and could expose the State to civil, criminal and tort liability. In an effort to bring significant price reductions to California's most at-risk consumers, my Administration put forward California Rx that seeks to provide real assistance to these Californians. California Rx represents an approach that harnesses the purchasing power of low-income seniors and uninsured Californians up to 300% of the federal poverty level ($28,710 for an individual and $58,050 for a family of four) to secure meaningful discounts in prescription drug costs. My Administration has begun negotiations with pharmaceutical companies regarding their participation in California Rx." A copy of SB 19 and analysis is in the Legislation/Regulation Committee report.

Letter from Jeffrey Moss, Attorney for the Pharmacy Defense Fund Related to the Waiver of CCR, title 16, section 1717(e) Use of an Automated Dispensing Device

Attached is a letter from Attorney Moss representing the Pharmacy Defense Fund (PDF). The PDF has requested that Mr. Moss investigate the issues related to the board's approval of the temporary waiver that it issued to Longs Drug Stores for use of an automated dispensing device. In his letter, Mr. Moss provides a list of comments regarding the PDF's concerns with the waiver and the use of these machines. The letter is being provided as requested. **(Attachment F)**

For the Enforcement Committee meeting, Supervising Inspector Dennis Ming inspected Longs Drug Store #247. This pharmacy has installed the Scriptcenter automated refill device as authorized by the board. Dr. Ming's report is being provided. **(Attachment G)**

Update from Longs Drug Stores

Long Drug Stores will be providing an update on the installation and use of the automated dispensing device (patient delivery unit) in its Oceanside pharmacy. This is the pharmacy that Supervising Inspector Dennis Ming inspected. **(Attachment H)**

Information Regarding the Prescribing Authority for Naturopathic Doctors

The board has requested a legal opinion from staff counsel Dana Winterrowd regarding the prescribing authority for naturopathic doctors. An article appeared in the board's January 2005 newsletter regarding the authority of Naturopathic Doctors to prescribe; however, since the article appeared, the board has been working with the Bureau of Naturopathic Medicine to further clarify this authority. **(Attachment I)**

Implementation of SB 151 (Chapter 406, Statutes of 2003) – Requirements for Controlled Substance Prescriptions to Become Effective January 1, 2005

As of January 1, 2005, written prescriptions for all controlled substances must be on tamper-resistant security prescription forms that have been printed by a board-approved printer and must contain specific elements. There is no specific format, size or color for the security prescription forms, so pharmacists need to be aware of the required elements.

If a pharmacist has questions concerning the validity of the prescription, the board is advising that the prescription should be treated like any other questionable prescription – call the prescriber to verify the prescription. If the form does not contain the proper features, it may indicate that a board-approved printer did not print it. Such prescriptions should be reported to the BNE at (916) 319-9062.

In summary the changes that take effect January 1, 2005 are:

- Triplicate prescription forms are no longer valid.

- All written controlled substance prescriptions must be on the new controlled substance prescription forms printed by an "approved" printer (oral and fax orders for Schedules III-V are still permitted).
- Pharmacies must report Schedule III controlled substance prescription information to the CURES system.
- Prescribers dispensing Schedule III controlled substances must report those prescriptions to the CURES system.
- The exemption for Schedule II prescriptions for the terminally ill remains in effect (H&S Code 11159.2). (This exemption doesn't apply to Schedule III prescriptions.)

To further aid in the implementation of the new controlled substance laws, a series of articles appeared in the board's January newsletter and on the board's Web site. **(Attachment J)**

A question that is not on this recent updated series of questions but was asked at a recent SB 151 presentation is regarding prescriptions for Schedule III-V medications that are not on the new security forms. The board's direction to pharmacies is to treat these prescriptions as "oral" prescriptions and for the pharmacist to initial and date under Health and Safety Code 11164(b)(1). The pharmacist should always use his or her professional judgment when filling the prescription, contact the prescriber to verify if necessary and to advise the prescriber that for future written prescriptions, security forms are required.

Clarification also has been recently provided regarding the filling of prescriptions by California pharmacies for prescriptions that are written by prescribers from another state. Health and Safety Code section 11164.1 provides that a California pharmacy may fill a prescription for a controlled substance issued by a prescriber in another state for delivery to a patient in another state if the prescription conforms with the requirements for controlled substances in the state in which the controlled substance was prescribed, and the prescriptions for Schedule II and Schedule III controlled substances dispensed must be reported to CURES.

Pharmacies may dispense prescriptions for Schedule III, Schedule IV and Schedule V for out-of-state prescribers pursuant to Business and Professions Code section 4005 and CCR, title 16, section 1717. This means that the prescriber must be authorized to prescribe Schedules III-V in that state and the prescription must be either faxed or an oral order. Otherwise, the prescription must be on California's security prescription form.

The direction that board inspectors are giving to pharmacists is to take care of the patient. It is not the board's position that pharmacists be the "forms police." It is the responsibility of the prescriber to have the correct legal forms. Board members and supervising inspectors continue to provide extensive outreach presentations on this new law change.

Implementation of SB 1159 (Chapter 608, Statutes of 2004)

With the recent signing and enactment of Senate Bill 1159 (SB 1159, Vasconcellos), local cities and counties can now legally authorize the establishment of the Disease Prevention Demonstration Project (DPDP), allowing pharmacies to sell syringes without requiring a doctor's

prescription. The new legislation stipulates that the California Department of Health Services (DHS) must convene an uncompensated Evaluation Advisory Panel and, in coordination with this panel, design and implement a comprehensive evaluation that will assess the impact that SB 1159 has on HIV and HCV risk behaviors as well as the health and well-being of surrounding communities and stakeholders.

SB 1159 requires that the panel include the following:

- Infectious disease control specialists
- California State Board of Pharmacy representative(s)
- Representative(s) of independent pharmacies
- Representative(s) of chain pharmacies
- Law enforcement representatives
    - Executives, such as police chiefs and sheriffs
    - Rank and file officers
- Specialist(s) in hazardous waste management from DHS
- Waste management industry representative(s)
- Local health officers

SB 1159 requires that DHS evaluate the effects of allowing licensed pharmacists to furnish or sell a limited number of hypodermic needles or syringes without prescription, and provide a report to the Governor and the Legislature on or before January 15, 2010.

The report shall include, but need not be limited to, the effect of nonprescription hypodermic needle or syringe sale on all of the following: 1) hypodermic needle or syringe sharing practices among those who inject illegal drugs; 2) rates of disease infection caused by hypodermic needle or syringe sharing; 3) needle stick injuries to law enforcement officers and waste management employees; 4) drug crime or other crime in the vicinity of pharmacies; 5) safe or unsafe discard of used hypodermic needles or syringes; and 6) rates of injection of illegal drugs.

President Goldenberg and Vice-President Powers are the Board of Pharmacy representatives and the first meeting was held March 29th and the second meeting is scheduled for June 7th. **(Attachment K)**

It appears from panel's first meeting that implementation of this legislation involves many factors such as: pharmacy participation, local city or county approval of the project, the disposal of hypodermic needles, and local enforcement of the law. Board participation on this advisory committee will provide the opportunity to be knowledgeable about the implementation and provide outreach to licensees and to the public. To date, nine counties and/or cities have approved participation in the demonstration project. **(Attachment L)**

Implementation of SB 1307 (Chapter 857, Statutes of 2004) Relating to Regulation of Wholesalers

Last year, the Board of Pharmacy sponsored SB 1307 (Figueroa). Governor Schwarzenegger signed the bill, which became effective January 1, 2005. The bill made various changes to the wholesaler requirements and distribution of dangerous drugs.

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

The pedigree must contain 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, 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.

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

EPCglobal, a non-profit organization, has developed broad industry standards for the use of electronic product codes (EPC) in global commerce. An EPC is a simple "license plate" that uniquely identifies objects (items, cases, pallets) in the supply chain. Multiple committees within EPCglobal are currently working to develop standards and fully examine both the feasibility and the ramifications of implementing EPCs to support the use of RFID with pharmaceutical products. EPCs can securely store information about a specific product in a tag that is affixed by the manufacturer. With the development of global standards and the utilization of RFID technology, EPCs will provide for immediate, automatic, and accurate identification of any pharmaceutical item in the supply chain and will enable the industry to track a product's distribution history, which constitutes an e-pedigree. The industry goal is to develop EPC standards by the summer of 2005, with the expectation of meeting the FDA's requirements for recommended time frame for implementation of electronic track and track technology by late 2007.

Meanwhile, the National Association of Boards of Pharmacy (NABP) announced in November that it is exploring the creation of a clearinghouse of pedigree data. To facilitate the collection and maintenance of electronic pedigree information, NABP stated that it would establish a task force of state regulators, manufacturers, wholesalers, pharmacies, government regulators, and information technology experts to explore the feasibility of creating a clearinghouse for relevant information to establish an electronic pedigree. The task force will work with EPCglobal to create the necessary standards for the development of e-pedigree software. It is the intent of NABP to act as an honest broker to facilitate the creation of policies and business rules for the exchange of information among trading partners.

In January, Executive Officer Patricia Harris participated on the National Association of Boards of Pharmacy (NABP) Task Force to Develop Recommendations for Electronic Pedigree Requirements that were convened via teleconference call. The task force recommended the electronic pedigree data elements. **(Attachment M)** Staff has also participated in two other NABP wholesale distributor regulatory meetings in January and February. In addition, staff has been involved in two telephone conference calls with Accenture. This company has been serving as the project manager for a group of trading partners in the pharmaceutical industry to explore the use of RFID/EPC technologies. They are currently working with several companies over the next 4 months to create company specific plans to enable RFID capabilities while facilitating collaboration among the trading partners.

At the December 2004 Enforcement Committee meeting, T3Ci, an application software company that provides drug counterfeit, diversion detection and electronic drug pedigree for the pharmaceutical market demonstrated their technology solution for the electronic pedigree. This presentation was for informational purposes only. Currently, they are pilot testing their system with various manufacturers. It is not the intent of the Board of Pharmacy to support or endorse any specific technological solution for the electronic pedigree requirement.

At this meeting, Acerity Corporation will present its security software program, which is an electronic authentication process. The system employs a cryptography techniques in conjunction with RFID forming a multiplayer secure process, which provides numerous advantages and allows versatile applications. **(Attachment N)**

Enforcement Committee Meeting Summary of March 9, 2005 (Attachment O)

Enforcement Team Meeting Summary of March 9, 2005 (Attachment P)

Report on Enforcement Actions (Attachment Q)

Quarterly Status Report on Committee Strategic Objectives for 2004/2005 (Attachment R)

ATTACHMENT A

UCSD Medical Center
HILLCREST

RECEIVED BY CALIF
BOARD OF PHARMACY
2005 FEB 25 PM 2:52

February 23, 2005

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

RE: REQUEST FOR WAIVER- CCR 1717(e)

Dear Ms. Harris:

University of California San Diego (UCSD) Medical Center, in an effort to improve patients' access to pharmacy services and therefore improve their compliance with their prescribed drug regime, respectfully requests a waiver to allow the installation and implementation of ScriptCenter, a self service prescription delivery unit manufactured by Asteres.

A waiver of 1717(e) was granted at the January board meeting for use of this machine in another California retail chain. UCSD is seeking the same waiver as we'd like to use ScriptCenter in our outpatient pharmacy locations. As you may recall, this unit is an automated, self contained unit that, at the request of a patient and through the use of a secure method designed to guard against inappropriate access, allows patients to access their refilled prescriptions for which no consultation is required.

The unit would be installed adjacent or in close proximity to the pharmacy area and may be accessed by patients during and after pharmacy hours. Prescriptions would be filled then checked by a pharmacist using the same safeguards we currently observe. The filled prescriptions would be placed into the unit under the supervision of a pharmacist. As medications are placed into the unit, security measures will be used to ensure accurate dispensing.

Other privacy and security features and additional information regarding ScriptCenter have been previously provided the Board by Asteres. However, I would be more than happy to provide further information at your request.

In conjunction with this waiver, the UCSD Skaggs School of Pharmacy and Pharmaceutical Sciences (SSPPS) is developing a formal study on the impact of this technology to pharmacy and patients and would be happy to share these results with the Board as they become available.

Please place this request in the agenda of the Board's next Enforcement meeting and also in the agenda for the next full Board meeting. Please contact me at the above address or directly by phone (619) 543-3283 with any questions or comments.

Sincerely,

Charles E. Daniels, R.Ph, Ph.D.
Pharmacist-In-Chief

Department of Pharmacy *UCSD Healthcare, University of California, San Diego*
200 WEST ARBOR DRIVE, ROOM 1-317 SAN DIEGO, CALIFORNIA 92103-8765 TEL: (619) 543-6194 FAX: (619) 543-5829

ATTACHMENT AA

California Pharmacists Association

RECEIVED BY CALIF. BOARD OF PHARMACY
2005 APR 18 AM 11:32

April 12, 2005

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

Re: Requests to the Board for waivers to allow the use of drug delivery machines

Dear Ms. Harris:

As you are aware, the Board of Pharmacy has received several requests for waivers of the Pharmacy Law to allow the use of drug delivery machines, such at the Asteres ScriptCenter. In the past, such waivers have been granted to Longs Drugs and Safeway Stores and at the upcoming Board meeting in Sacramento, the Board will consider another such request, this time from the UCSD Medical Center.

On behalf of the California Pharmacists Association, I have raised concerns about the effect that granting these waivers will have on the interactions between pharmacists and consumers. The Board has been very generous in allowing CPhA to present these concerns and should be applauded for their willingness to discuss what I termed the "philosophical question" of moving toward the increased use of this type of technology in pharmacies. CPhA recognizes that use of technological advances of the type involved here is inevitable; yet, we also believe that the Board would be well advised to move cautiously and consider the full impact of these devices on consumers as well as on the role pharmacists play in monitoring ongoing drug therapies.

The arguments in favor of increased utilization of these devices are strong – the economic and competitive pressures on pharmacies today require that operational efficiencies be utilized where ever appropriate. At the same time, however, the Board needs to maintain the strides it has made over the last 10 years in improving the interaction and communication between pharmacists and consumers. I need go no further than the logo currently used by the California Board of Pharmacy – the dual image of a mortar and pestle combined with two people talking to each other. I note as well the Board's efforts in recent years to reach out and educate consumers about the realities of medication use and the value pharmacists can bring to improve their understanding of their medicines. This effort is reflected in the Board's "motto": "Be Aware, Take Care – Talk to your Pharmacist!" The excellence of the Board's efforts has been twice recognized by the National Associations of Boards of Pharmacy, an achievement for which the Board should rightly be proud.

Because of these consumer outreach efforts, it struck CPhA as out of character for the Board to so readily embrace a technology that, in our view, is likely to dramatically decrease the interaction between pharmacists and consumers. It is clear that the use of machines such as the Asteres ScriptCenter make the greatest economic sense only if used when the pharmacy itself is closed – that is, by extending the time during which consumers can access their refill medications with minimal cost in overhead and labor. We cannot deny the benefits that this brings to the retailer, nor can we question the fact that it will be somewhat more convenient for the consumer, or that consumers are exposed to the same minimal level

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of pharmacist interaction when their prescriptions are filled by mail service pharmacies. Regardless, we believe there must be a better way to promote the use of this technology while simultaneously providing a level of pharmacist care that is more in keeping with the consumer protection goals of the Board. We note as well that at least some of the Board members have expressed a desire for some means of measuring the impacts on consumers that occur as a result of using these machines. With this in mind, CPhA has a proposal for the Board to consider.

Some years ago, in new CPhA policy on pharmacy technicians, the Association incorporated the concept of a Board approved "pharmacy services plan" as a necessary component of any request to deviate from "standard" ratios or practices. A similar requirement currently exists in the pharmacy law in other states, including Washington[1]. CPhA believes requiring such a plan fits well as part of the consideration of waivers for automated delivery machines.

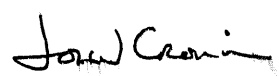
As envisioned here, a pharmacy services plan would be prepared by the pharmacy requesting the waiver and would include a clear description of how the requested waiver would facilitate the provision of pharmacist care and improve patient care in the pharmacy. It should also include a description of how the requesting pharmacy will monitor and measure attainment of the plan goals. The plan could also include a description of the anticipated impact on business operations, hours of operation and staffing. Compliance with the plan would be monitored by periodic visits by Board Inspectors. Failure to comply with the proposed pharmacy services plan would be a basis for withdrawal of the waivers, or other action by the Board.

Including a requirement for an approved pharmacy services plan provides the Board with clear objectives that can be evaluated over time. It also provides the Board members with a written record of how the pharmacy requesting the waiver proposes to maintain high levels of patient care when utilizing the automated drug delivery device. CPhA believes this type of review and ongoing evaluation is needed to ensure that waivers to use new technologies are not being sought purely for economic reasons at the cost of opportunities for pharmacist-patient interactions.

Incorporating a requirement for a pharmacy services plan at this point will provide the Board with valuable experience in dealing with such a system without significant administrative burden. The experience will be useful in developing the regulation language the Board has proposed to deal with the use of this and similar technologies in the future without having to go through the waiver process.

CPhA believes incorporating a pharmacy services plan into the requirements for a waiver request is a reasonable requirement for any entity seeking a waiver from the Board to use an automated drug delivery machine. We believe our proposal will result in the desired results of promoting the use of more efficient technology, responding to consumer and market needs and promoting the Board's ongoing efforts of improving pharmacist-patient communication. We are prepared to work with the Board and others involved in these waiver requests to make this idea work. We look forward to discussing this further with the Board at its next meeting.

Sincerely,



John A. Cronin, Pharm.D., J.D.
Senior Vice-President

[1] RCW 18.64A.040

ATTACHMENT B

March 22, 2005

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

RE: UCSD REQUEST FOR WAIVER- CCR 1717(e)

Dear Ms. Harris:

As you know, University of California San Diego (UCSD) is requesting a wavier to allow the installation and implementation of ScriptCenter®. The waiver request is scheduled to be reviewed at the April 27th Board Meeting. Asteres is excited to be working with UCSD and has been collaborating with them over the past few months to bring this project to fruition.

In addition to installing ScriptCenter, UCSD has also agreed to conduct a study to evaluate the impact of the technology on both patients and pharmacy personnel. Discussion of a study has come up in previous Board meetings so Asteres has worked hard with UCSD and we are very excited to help make this happen. With that being said, it has come to our attention that there may be some attendees at the next Board meeting that may ask for future waiver requests to be put on hold until the study is complete. The technology continues to perform very well in the field and although we are excited about the study, we feel strongly it should not be used as a prerequisite to future waivers.

Asteres will work hard to collaborate with customers to continue to provide the Board with information on the technology's performance but respectfully requests the Board's consideration in not penalizing those efforts by delaying future waivers.

Thank you very much and please feel free to contact me with any questions at (916) 580-7789.

Sincerely,

Bob Hansen, Pharm.D
VP of Pharmacy Services
Asteres Inc.

ATTACHMENT C

White Cross Drug Store
4074 Fairmount Avenue, San Diego CA 92105

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

March 24, 2005

Re: REQUEST FOR WAVIER CCR-1717(e)

Dear Ms. Harris,

White Cross Drug Store, is requesting a waiver to install and utilize self service prescription dispensing units, such as the ddn, APM™ (Automated Product machine) at various pharmacies located within the state of California.

The ddn APM™, that would be featured as the unit for our test, is an automated, self contained unit that allows patients to access their refilled prescriptions for which no consultation is required. To facilitate a test environment the units would be installed adjacent or in close proximity to the pharmacy area. In addition, a few units may be placed away from the pharmacy towards to the front of the store to evaluate patient acceptance and usage especially for those patients that are ambulatory impaired. A patient may use these self-contained units during pharmacy hours or during those times when the main store is open but the pharmacy is closed, to improve therapeutic compliance.

The refill prescription would be filled, then verified by a pharmacist using the same safeguards currently in place. The refilled prescription would be placed into the APM™ unit under the supervision of a pharmacist. As medications are placed into the unit, security measures are used to ensure accurate dispensing, including dual barcode scanning at loading and prior to being retrieved by the patient. ddn, Corp, the manufacturer of the unit is available to present the board with additional information, specifically illustrating the unit's numerous privacy and security features.

California Code of Regulations, Section 1717(e) places limitations as to how patient may receive his/her prescription, but also allows the Board to waive this section for good cause. Accordingly, White Cross Drug Store is requesting a waiver for California Code of Regulations, Section 1717(e) to install and utilize self-service dispensing units at its pharmacies within the state. Please place this request in the agenda of the Board's May Enforcement and Full Board meetings for consideration.

Please contact me at the address listed or directly by phone (619) 284-1141 with any questions or comments.

Sincerely,

Bassam Massaad, R.Ph
Pharmacy Manager,
White Cross Drug Store

Cc: Mr. Max Atiya, President/CEO
Mr. William Holmes, ddn, Corp

ATTACHMENT D

Daily Health Policy Report

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

Prescription Drugs | *Associated Press* Examines Effects of Increased Prescription Drug Use in United States
[Apr 18, 2005]

The *AP/St. Paul Pioneer Press* on Sunday examined the amount of prescription drugs used by U.S. residents, with many researchers and public health experts saying people are "buying and taking far too much medicine, too readily and carelessly, for their own health." According to CDC data, about 130 million U.S. citizens use prescription drugs every month. A recent IMS Health report stated that the number of prescriptions issued annually in the United States has increased about 67% in the last 10 years to 3.5 billion. U.S. prescription drug sales in 2004 totaled $250 billion, or $850 per U.S. resident. Meanwhile, according to an *Associated Press* analysis of projections from 1990s studies, more than 125,000 U.S citizens die from "drug reactions and mistakes" annually, the *AP/Pioneer Press* reports. According to the *AP/Pioneer Press* , that would make prescription drugs the fourth-leading national cause of death, following heart disease, cancer and stroke. While some prescriptions, including some antibiotics and HIV/AIDS medicines, "yank many people away from almost certain death," the benefit and risk analysis of prescriptions that treat "common, persistent, daily life conditions" is "harder to strike," according to the *AP/Pioneer Press*. Former *New England Journal of Medicine* Editor in Chief Marcia Angell, author of the book, "The Truth About Drug Companies," said, "What the drug companies are doing now is promoting drugs for long-term use to essentially healthy people. Why? Because it's the biggest market." However, Pharmaceutical Research and Manufacturers of America spokesperson Jeff Trewhitt said, "We now have more medicines and better medicines for more diseases" (Donn, *AP/St. Paul Pioneer Press*, 4/17).

Daily Health Policy Report

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Prescription Drugs | *Kaiser Daily Health Policy Report* Examines News Coverage of Prescription Drug Reimportation Developments in Three States
[Apr 06, 2005]

- Kansas: State Attorney General Phill Kline (R) last week issued a nonbinding legal opinion that states I-Save RX -- a multistate program that Kansas joined to allow state residents to purchase lower-cost prescription drugs from other nations -- does not violate state law, the *AP/Topeka Capital-Journal* reports (Hanna, *AP/Topeka Capital-Journal*, 4/5). Illinois officials established I-Save RX in October 2004, and Wisconsin, Missouri and Kansas later joined the program. The states contract with CanaRx, a Canadian pharmacy benefit manager that operates a network of online pharmacies, to allow residents to connect with a clearinghouse of 45 pharmacies and prescription drug wholesalers in Canada, the United Kingdom and Ireland. Residents can purchase only prescription refills, and most generic medications, narcotics and treatments that require refrigeration or other special care are excluded (*Kaiser Daily Health Policy Report*, 3/10). In his opinion, Kline said that neither the state nor physicians likely would face liability for damages in lawsuits related to problems with medications purchased through the program. Kline also said that he would defend the administration of Gov. Kathleen Sebelius (D) in the event FDA files a lawsuit. Kline said, "We believe that, at best, Kansas' involvement comes perilously close to causing violations of (federal law) and at worst does cause such violations" (*AP/Topeka Capital-Journal*, 4/5).

- Maryland: Six Canadian pharmacies have submitted business

proposals in response to a request from Montgomery County, Md., officials to provide less-expensive prescription drugs for county employees, the Washington *Examiner* reports. The deadline for the proposals was April 1. County officials plan to interview the pharmacies in the next few weeks and select a partner by the end of the month, according to Montgomery County Council spokesperson Patrick Lacefield. Council President Tom Perez said that county employees could begin to receive prescription drugs through the partnership on July 1. The council will consider health and regulatory issues in the selection process to ensure the safety of county employees, according to Perez. He said, "I'm not at all concerned with the safety and legality" of prescription drugs purchased from Canada, adding, "I don't want it to become a political process, but, if it's so illegal, why (hasn't the FDA) sued anybody?" (Marino, Washington *Examiner*, 4/5).

- Minnesota: Shareholders of Pfizer, Merck and Eli Lilly at annual meetings later this month likely will hold "largely symbolic votes" on a resolution sponsored by the state that asks "each company to examine the legal and financial risks" of restrictions on supplies of prescription drugs to Canada, the AP/Minneapolis *Star Tribune* reports (AP/Minneapolis *Star Tribune*, 4/4). The resolution -- sponsored by the Minnesota Board of Investment and supported by board Chair and Minnesota Gov. Tim Pawlenty (R) -- asks the companies to establish business practices that do not rely on "exorbitant revenue" from U.S. sales; end restrictions on supplies to Canadian wholesalers and pharmacies that sell prescription drugs to U.S. residents; and disclose expenditures on attorneys, lobbyists and marketers as part of efforts to maintain the current price structure for the prescription drug market (*Kaiser Daily Health Policy Report*, 3/4/04). According to the resolution, "The company's actions to limit supply of medicines in Canada may violate local, national and international law and could result in large settlements, large awards of damages and potential punitive damages." Minnesota Attorney General Mike Hatch (D), a member of the board, said that he supports the resolution but called the expected shareholder votes "political theater," adding, "I don't expect anything to come of those. Those pharmaceutical boards have not listened to any of these resolutions." Howard Bicker, executive director of the board, said that shareholder resolutions, which are not binding, in most cases fail when company officials oppose them. In response to the resolution, officials for Pfizer, Merck and Eli Lilly have cited safety concerns about prescription drugs purchased from Canada. In a statement to shareholders, Pfizer said, "Counterfeiting poses a very real ... threat to patients in both Canada and the U.S. Buying drugs over the Internet involves significant safety risks." Eli Lilly shareholders will vote on the resolution on April 18, followed by Merck shareholders on April 26 and Pfizer shareholders on April 28. Pawlenty does not plan to attend the shareholder meetings (AP/Minneapolis *Star Tribune*, 4/4).

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Opinion | Rep. Gutknecht Responds to Criticism About Prescription Drug Reimportation Legislation
[Apr 06, 2005]

Rep. Gil Gutknecht (R-Minn.), in a letter to the editor of *The Hill*, disputes criticism from some lawmakers that a bill he has introduced in the House (HR 328) would allow the reimportation of prescription drugs from Latvia and Slovenia. Gutknecht writes that such criticism is based on "misinformation" from the Pharmaceutical Research and Manufacturers of America (Gutknecht, *The Hill*, 4/5). The bill, sponsored by Rep. David Vitter (R-La.), is a revised version of legislation sponsored by Gutknecht that the House passed in July 2003. The original bill would have allowed U.S. pharmacists to import prescription drugs manufactured in 25 industrialized nations, provided that the medications are manufactured by companies that use counterfeit-resistant technologies and that the companies have registered their production operations with FDA. The new bill has 77 co-sponsors. Gutknecht has said that he hopes to attract 220 co-sponsors (*Kaiser Daily Health Policy Report*, 3/30). In the letter, Gutknecht writes that Seniors Coalition has purchased advertisements in *The Hill* and other publications "implying our bill will allow importation from Latvia, Estonia and Slovakia." According to Gutknecht, the ads cite a Luntz Research poll that "can't be applied to our bill." Gutknecht writes that the bill "allows for market access to FDA-approved medicines manufactured in FDA-inspected facilities" in Belgium, Germany, France, Italy, Luxembourg, the Netherlands, Denmark, Ireland, the United Kingdom, Greece, Spain, Portugal, Austria, Finland and Sweden, Australia, Canada, Iceland, Israel, Japan, Liechtenstein, New Zealand, Norway, Switzerland and South Africa. He adds, "As anyone can see, neither Latvia nor Slovenia is on this list. Incidentally, this list of countries that employ safety standards similar to the United States came from the FDA!" Gutknecht concludes, "It's not surprising that PhRMA would mislead

Rhode Island Moves Forward in Licensing Canadian Pharmacies

Rhode Island became the first state in the nation to legalize the licensure of Canadian pharmacies after the passage of Senate Bill 2160A on July 6, 2004, which amends the state's General Laws to allow licensing of Canadian-based pharmacies and Internet pharmacies. With this legislation comes many difficult issues, not only regarding patient safety – a point that NABP has consistently voiced to state and federal officials and the news media – but also the strain on the Rhode Island Board of Pharmacy's resources.

Effective January 15, 2005, Rhode Island's new law, entitled "An Act Relating to Businesses and Professions – Pharmacies," calls for the state's Department of Health (DOH) to establish "standards to protect the health and safety of the public and governing the operation and licensing of Canadian pharmacies." According to Rhode Island State Representative Fausto C. Anguilla (D), the principal representative who introduced the House version of the bill, "The bill was introduced because some Rhode Island senior citizens are in dire straits – some have to make the choice between buying food or medications and for many of our citizens both are of equal life-sustaining value. This is a horrible situation and the pharmaceuticals are exorbitantly priced."

But according to Anguilla, all of the state's consumers benefit – not just its senior citizens – from the availability of reduced prescription drug prices that is intended to occur under this new law.

Although the state of Rhode Island believes that it is addressing safety issues by requiring the Rhode Island Board of Pharmacy to set rules and regulations for the licensure of Canadian pharmacies, Food and Drug Administration (FDA) is still concerned over the importation of drugs from foreign countries. In a January 28, 2005 letter to Rhode Island Attorney General Patrick C. Lynch, William K. Hubbard, FDA associate commissioner for policy and planning, stated, "FDA is very concerned about the safety risks associated with the importation of prescription drugs from foreign countries. In our experience, many drugs obtained from foreign sources that purport and appear to be the same as [United States] approved prescription drugs have been of unknown origin and quality."

Lynch has also voiced his concerns to the governor of Rhode Island, Donald L. Carcieri, by stating in a February 1, 2005 letter addressed to the governor, "The health and safety of the citizens of Rhode Island should be paramount in the regulatory scheme to import lower-priced prescription drugs."

Due to the lack of assurance of the origin and quality of drugs obtained from foreign sources, the importation of Canadian drugs would violate the federal Food, Drug, and Cosmetic Act (FD&C Act), which strictly limits the types of drugs that may be imported into the US and the entities that may import them. This Act was developed to create a "closed" drug distribution system, which helps ensure that the domestic drug supply is safe and effective.

FDA's letter elaborates on this subject: "... [I]f an entity or person within the State of Rhode Island were to import

prescription drugs into the State of Rhode Island from Canada, it would violate the [FD&C Act] in virtually every instance."

Anguilla refutes FDA's worries. "There should not be concern over the safety of the medications bought in Canada because when developing the licensing provisions, safety was our main concern – we limited the purchasing of the medications solely to Canada because it [Canada] has a rigorous drug inspection program [Health Canada] similar to FDA and through this licensing provision we are channeling consumers toward legitimate pharmacies," he explains.

According to FDA's letter, the Rhode Island law violates the FD&C Act in the following ways:

- Most of the drugs that are imported into the US from Canada are not approved, are labeled incorrectly, or are dispensed without a valid prescription.
- Drugs sold outside the US are not manufactured by a firm that has FDA approval for a particular drug. Even if the manufacturer has obtained FDA approval for a drug, the version produced for the foreign market usually does not meet all of the requirements for US approval, and thus is unapproved.
- It is illegal for any person other than the original drug manufacturer to import into the US a prescription drug that was originally manufactured in the US and then sent abroad.

The Board's Response

In his letter to Governor Carcieri, Lynch explains, "Safety is the essential element for the importation of low-priced prescription drugs; the Rhode Island General Assembly recognized and addressed this by requiring the DOH '. . . to promulgate rules . . . establishing standards and procedures to protect the health and safety of the public and governing the operation and licensing of Canadian pharmacies. . . .' . . . [I]t is crucial that the Department of Health address these safety issues before, or simultaneous with, the issuance of any Canadian licenses."

Rhode Island Board of Pharmacy Executive Director Catherine A. Cordy explains that the state has mandated that, to ensure public safety, the DOH (the jurisdiction under which the Board falls) enlist the help of pharmacists, the attorney general, drug manufacturers, and state pharmacy associations when writing these regulations, even though the Board is not in favor of this new law.

According to Cordy, these regulations will tentatively be in place by late spring, but this deadline hinges on finding the time and resources to write these regulations. "Since the law has been passed it has affected the Board's workload immensely," Cordy says. "We [the Board] are unable to focus on state licensure applications, nor has it had the time to update its own regulations in regard to other issues like wholesale distributors. In addition, the Board would like to start working on reviewing NABP's Model Rules for the Licensure of Wholesale Distributors but cannot because its workload is concentrated on the licensure of Canadian pharmacies."

Cordy believes that this law will affect Rhode Island pharmacies in that the pharmacies may need to hire consultants to review Canadian regulations versus the US regulations. As far as the inspection of Canadian pharmacies is concerned, it is likely that none will be performed soon because the state does not have any jurisdiction over Canadian pharmacies or pharmacists.

The Board has developed a Pharmacy – Non-resident License application for Canadian pharmacies, which is to be used to license a pharmacy that ships, mails,

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Rhode Island

(continued from page 73)

or delivers prescription drugs and/or devices to a patient in Rhode Island, or to apply for a new license due to a change in ownership or location.

The application also states, "Prescription drugs or devices cannot be shipped, mailed, or delivered to a patient in this state without being licensed by the BOARD [the Board's emphasis]. The nonresident pharmacy must maintain, at all times a valid unexpired license, permit or registration to operate in compliance with the laws of the province in which it is located."

At press time, Rhode Island has received three licensure applications from Canadian pharmacies. It is unknown if Rhode Island consumers are purchasing medications from Canadian pharmacies; the Board has received some inquiries regarding Rhode Island-licensed Canadian pharmacies, to which the Board responds that, at present, there are none licensed.

Other States and Canadian Pharmacies

Rhode Island may be the first state in the nation to authorize the licensure of Canadian pharmacies, but other states, especially border states, have legislation, current or pending, regarding Canadian pharmacies.

North Dakota's Article 61-08, Out-of-State Pharmacies, requires "Any pharmacy operating outside the state which ships, mails, or delivers in any manner a dispensed prescription drug or legend drug into North Dakota shall obtain and hold a pharmacy permit issued by the North Dakota [S]tate [B]oard of [P]harmacy and that part of the pharmacy operation dispensing the prescription for a North Dakota resident shall abide by state law and rules of the [B]oard."

Article 61-08 goes on to explain that the pharmacist-in-charge and pharmacy owner, or partners, or corporate officers and owners where applicable will be responsible for complete compliance with North Dakota's laws and rules regarding the practice for the "pharmacy operation pertaining to the provisions of receiving[,] dispensing, and delivering prescription drugs to North Dakota."

As far as inspections are concerned, Article 61-08 allows for the evaluation of registered out-of-state pharmacies to conduct business in North Dakota. Also, the North Dakota State Board of Pharmacy "may contract with the respective out-of-state regulatory authorities to conduct and perform periodic routine inspections."

Currently in the state of Washington there are three bills being proposed in various committees in the state legislature related to importation, says Washington State Board of Pharmacy Executive Director Steven M. Saxe.

House Bill 1168: Reimportation of Prescription Drugs

- Adds a new section to the Revised Code of Washington (RCW) 18.64.350 identifying the issue of high prescription drug cost and allows the Board to regulate nonresident pharmacies.
- Makes RCW 18.64.350 and 18.64.360 applicable

Legal Briefs

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general fitness requisite for an attorney. . . ."

The court continued and assessed the applicant's additional disclosures against the character and fitness requirements of the Hawaii Bar admission. Regarding the bankruptcy filings, the court held that while the filings alone cannot justify denial of a licensure application, there is a distinction between considering an applicant's financial reputation and considering a bankruptcy filing alone. The bankruptcy statutes do not prohibit an examination of the circumstances surrounding the bankruptcies as they illustrate the applicant's judgment in handling serious financial obligations.

Based upon the totality of the circumstances and the fact that the court is able to consider factors surrounding arrests and bankruptcies, the Hawaii Supreme Court upheld the denial of the licensure application. Importantly for regulatory boards and associations of boards that prepare the licensure examinations, the court not only refused to license the applicant, but also refused to allow him to sit for the Hawaii Bar exam.

Boards may wish to consider the order in which licensure applications are assessed to determine moral character issues before unnecessarily exposing the examination to an individual who may not become licensed no matter what exam score is received.

The case presents an excellent analysis of the obligations and duties of a board to assess the background and character of applicants for licensure. As noted, exoneration or dismissal at the criminal level may not preclude board assessment of the underlying facts surrounding the accusations.

In the Matter of the Application of W.D.P., 91 P. 3d 1078 (HI 2004)

to Canadian provinces by adding "or Canadian province" throughout the text of these RCWs.

- Asks the Board to develop licensing agreements with Canadian pharmacies either through Canadian regulatory agencies or Washington State on-site inspections and certifications.

House Bill 1194: Reimporting of Prescription Drugs – Using Canadian Wholesaler/Facilitate Personal Importation

- Allows each agency administering a state-purchased health care program to control the cost of prescription drugs by purchasing drugs in bulk from approved Canadian wholesalers and pharmacies or by facilitating the personal importation of FDA-approved drugs by patients.
- Certain drugs not conducive to international transport, that are prone to counterfeiting, or that do not result in cost savings are excluded from importation.
- Canadian pharmacies must meet Washington State Board of Pharmacy retail pharmacy standards (does not specify licensing).
- The Health Care Authority (HCA) shall develop a Web site to communicate information to individuals regarding opportunities to purchase drugs in Canada and steps to ensure drug safety.
- Any parts of the bill in conflict with federal requirements as a condition for allocation of federal funds those sections are inoperative. The rules developed must also meet federal requirements necessary to obtain federal funds.

House Bill 1316: Importation of Drugs from Canadian Wholesalers.

This bill was developed as a request by Governor Christine Gregoire.

- By September 1, 2005, the Board must work with the HCA to submit a waiver to FDA to allow the Board to license Canadian drug wholesalers.
- Canadian wholesalers must meet the requirements of RCW 18.64.046 and any rules adopted by the Board.
- Drugs purchased from Canadian wholesalers must be from an approved manufacturer.
- The Board must routinely test drugs purchased from Canadian wholesalers.
- The Board must establish safe labeling, tracking, and shipping procedures for drugs purchased from Canadian wholesalers.
- The bill limits the drugs purchased from Canadian wholesalers to those for which a potential savings to the patient can be demonstrated; this savings must be passed on to the consumer.
- The Board, in consultation with the HCA, must submit an implementation plan, on each component of the waiver, to Governor Gregoire and the legislative committees by December 1, 2005.
- The bill amends RCW 18.64.046 Drug Wholesale Law to include wholesalers in Canadian provinces.
- Requires the on-site inspection and certification of Canadian wholesalers if a reciprocal agreement is not reached with Health Canada.
- Any parts of the bill in conflict with federal requirements as a condition for allocation of federal funds those sections are inoperative. The rules developed must also meet federal requirements necessary to obtain federal funds.

In Montana, although there is no proposed legislation that would specifically allow or mandate Canadian pharmacy licensure, many bills addressing prescription drug importation (from Canada and elsewhere) have been considered during Montana's current legislative session. "It is important to note that nothing in Montana law at present would prohibit licensure of Canadian pharmacies," explains Montana Board of Pharmacy Executive Director Rebecca H. Deschamps. "Montana statute requires licensure with our board of pharmacy and registration with the Montana Secretary of State as an out-of-state business before an out-of-state pharmacy can legally ship medications to Montana citizens. Our Board has taken the position that as long as the FDA maintains its present position, we are not in a position to override the FDA."

Rhode Island's legislation sets a precedent for other states' legislators who have been attempting to pass importation legislation; however, it is a model that concerns NABP. The US Department of Health and Human Services' recent Task Force on Drug Importation found that there is a significant risk associated with importing prescription drugs, no matter how safe the host country's drug distribution system (see the February 2005 *NABP Newsletter*). In addition, the Task Force's report noted that the additional resources needed to make an importation program safe and effective would be substantial; NABP agrees with this assessment and believes that it transcends the state boards of pharmacy, which are often already stressed for time and resources.

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DRUG TOPICS THE ONLINE NEWSMAGAZINE FOR PHARMACISTS

Canadian mail-order pharmacy in turmoil

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Feb 7, 2005
By: Carol Ukens
Drug Topics

Already hurt by a drug company clampdown on supplies and a falling U.S. dollar that have raised prices to American consumers, Canadian mail-order pharmacies are bracing for a federal regulatory crackdown that they claim will force them to set up shop on friendlier shores.

Canada Health Minister Ujjal Dosanjh has proposed three regulatory changes to protect the country's domestic drug supply and pricing structure. He has proposed making it illegal for Canadian doctors to co-sign foreign scripts, prohibiting noncitizens from acquiring drugs unless they come to Canada and are physically examined by a Canadian doctor, and prohibiting certain drugs in short supply from being dispensed to foreigners.

Dosanjh was expected to deliver his final recommendations to the cabinet late last month. By using the order-in-council process, the government does not have to consult with the House of Commons and members of the opposition. And a requirement for a 75-day stakeholder consultation period could be waived.

All of the health minister's proposed regulations "would be lethal for the mail-order pharmacy sector in Canada and mean the loss of 4,000 jobs," said David MacKay, executive director, Canadian International Pharmacy Association (CIPA). "If they are implemented, hundreds of thousands of Americans could be thrown into therapeutic crisis."

Most Canadian mail-order pharmacies have drafted contingency plans to move their operations if the federal government follows through with its regulatory plans. "We have already begun to diversify our operations as a result of the drug supply restriction schemes of seven manufacturers," MacKay told *Drug Topics*.

"All of the CIPA pharmacies have contingency plans for foreign fulfillment—primarily in the European Union," MacKay continued. "Fulfillment would occur overseas with some aspects of the operations such as call centers remaining in Canada. Some will be partnerships; some will be operations owned by the original Canadian pharmacy. Distance-based healthcare delivery is a global trend that cannot be stifled. Instead of regulating a small pipeline from Canada, this will become a worldwide distribution model that involves more than 20 countries without sacrificing safety."

It's not clear where the Canadian regulations will leave the states that have set up drug importation plans. Also up in the air is Rhode Island's new law authorizing the state pharmacy board to license Canadian mail-order pharmacies. The new law, which expires on Dec. 31, 2007, was enacted last summer without the signature of the governor, who was leery of openly flouting U.S. drug laws.

A legal challenge to the new licensure law has been ruled out by the Rhode Island Pharmacists Association, said executive director Jack Hutson. He added that communications with the Food & Drug Administration indicated the agency would send a letter to the state attorney general saying importation is illegal.

"Everyone already knows it's illegal," Hutson said. "The reality is that proponents of drug importation wear its illegality like a badge of honor. The pharmacy board rejected the licensure regulations that were proposed. The department of health did very little work on promulgating the regulations because it fully expected to be enjoined in a lawsuit. That's not happening. This thing is going through."

The state pharmacy board did not respond to requests for comment on the new law or how it plans to implement it. However, there have been inquiries about the licensure regulations that appear to require only that pharmacies hold a valid Canadian license, said Carmen Catizone, executive director, National Association of Boards of Pharmacy.

The Rhode Island situation is worrisome because if it is not legally knocked down, other states will opt for licensure of Canadian pharmacies, said Catizone. "Our concern is that legislators and governors are bypassing the pharmacy board and, second, where does it end?" he said. "I don't put much credence in the Canadian pharmacies' threats to move to Great Britain because they're already operating there anyway. It almost seems as if it won't end unless the FDA takes legal action against a state or municipality or we simply create global pharmacies."

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Drug firms squeeze Canadian imports

They seek to bar resales to U.S.

By Judith Graham
Tribune staff reporter
Published January 30, 2005

As state and federal lawmakers debate proposals to help Americans buy cheap drugs from Canada, the supply of drugs available to Americans from their northern neighbor is rapidly drying up.

Seven major drug companies are now declining to sell their products to Canadian pharmacies that send medications south.

The prohibition affects almost one-third of the drugs previously available through Canada's online pharmacies, according to David MacKay, executive director of the Canadian International Pharmacy Association.

Americans haven't felt the shortages yet because Canadian Internet pharmacies have stocked up on products and cobbled together arrangements to purchase medications from colleagues. But those undercover arrangements are fragile at best, and no one expects them to last much longer.

"I think consumers will really start feeling the impact in the next two to three weeks," said Lee Graczyk, legislative director of the Minnesota Senior Federation, which runs a Canada drug-buying program for 30,000 members.

American consumers probably won't be able to get brand-name drugs from their usual Canada sources, he said, and will be forced instead to purchase generics from Canada, buy medications from overseas, pay more for the drugs in the U.S., or simply go without.

Entire classes of medications are being affected. For instance, two leading anti-cholesterol therapies, Lipitor and Zocor (made by Pfizer Inc. and Merck & Co., respectively) are now on drug companies' "don't sell" list for Canadian online pharmacies, along with a third cholesterol-buster, Mevacor (another Merck product).

About 2 million Americans seeking relief from soaring drug prices buy more than $700 millic discounted prescription medications from Canada each year. The medications cost up to 50 north of the border because Canada's government negotiates price breaks with pharmaceut companies. Most countries impose price controls on drugs, but the U.S. doesn't.

Two weeks ago, Merck & Co. became the latest pharmaceutical company to close its drug p Canada's online pharmacies. Among Merck's top-selling drugs are Fosamax, a treatment fo osteoporosis that is thought to be the best-selling imported medication from Canada.

"We ask that you confirm to us that you are not selling, and will not in the future sell, directly to ... parties who are selling Merck drug products into the U.S.," the company's Canadian su wrote in a Jan. 14 letter to an undisclosed number of pharmacies. Those who don't sign the won't receive Merck's medications, according to Tony Plohorous, a company spokesman.

Other firms that have cracked down on Canada's online pharmacies include GlaxoSmithKlir Eli Lilly and Co., Aventis, Astra Zeneca, and Wyeth Pharmaceutical.

Five Republican and three Democratic lawmakers--including Illinois Democrat Rahm Emanu importation issue on Congress' agenda again last week with a new bill that would allow Ame drugs from Canada and other countries. A similar proposal, bitterly opposed by the drug ind last year. Initiatives aimed at facilitating imports also are being considered in several states, Washington and Connecticut.

Illinois launched a program, I-SaveRx, that allowed residents to buy drugs from Canada, Ire United Kingdom last year.

Meanwhile, the squeeze on medication is contributing to a major shift in the online drug bus bid to keep operations going, Canadian Internet pharmacies are hatching plans to move to t Kingdom, forging partnerships or buying interests in European druggists, and developing ne can supply medications across the world, officials say.

"We have pharmacies now in almost 30 countries ready to ship to U.S. consumers," said Da Jorgenson, owner of Canadameds.com, one of Canada's largest Internet pharmacies.

A new generation of online pharmacies is being developed in the United Kingdom to step in if Canadian pharmacies become unable to serve U.S. customers, experts say. Although an between that country and the U.S., there are no language barriers, and quick delivery woulc problem.

Pharmacies' polls indicate that customers are ready to consider alternatives.

"About 99 percent of our customers tell us they'd accept product from the U.K.; 97 percent f way about Australia and New Zealand," said Andy Troszok, president of Extended Care Pha Internet drug outlet in Calgary, Alberta. The firm has plans to establish European operations summer, he said.

Drug companies' actions aren't the only threat to Canada's online drug outlets. The federal g in Ottawa has indicated it likely will impose strict new regulations. Options under considerati requiring Canadian physicians to examine American customers, mandating that customers t Canada to buy medications or putting drugs on a do-not-sell list if shortages seem imminent

While reports this month suggested government action was imminent, Ken Polk, a spokesm Canada's Health Ministry, says: "the department is still working up recommendations. There frame on this."

Seven U.S. governors, including Illinois' Rod Blagojevich, have asked Canadian Prime Mini Martin for a meeting and requested that he allow Canadian drug exports to the U.S. to conti Canada's government is reviewing the request, Polk said, and is "happy to sit down with the but a resolution to the issue of high drug prices needs to be found in the U.S., not in Canada

Meanwhile, Illinois is beginning to take action against drug companies shutting off supplies t pharmacies. The state has reduced business with the companies by $1 million so far and pl

remove many of their drugs from state-approved formularies in the year ahead, said Abby O spokeswoman for Blagojevich.

In Minnesota, Atty. Gen. Mike Hatch is investigating industry practices and plans to widen a against drug companies in the coming year.

Hatch sued the first drug company to cut off supplies to Canada's Internet pharmacies, Gla› last summer. In a telephone interview, he said he planned to extend that lawsuit this year to Lilly, Merck, Aventis, Astra Zeneca, and Wyeth, which have followed GlaxoSmithKline.

"A company on its own may decide who they want to sell to and who they want to boycott," "But if a company collaborates with other companies [in making these decisions], that's a vi antitrust laws."

Hatch says he has documents from GlaxoSmithKline substantiating a "conspiracy" among c companies to stop selling drugs to Canadian pharmacies serving U.S. customers. The docu sealed, and Hatch is petitioning the Minnesota Supreme Court to lift a court order that preve contents from being disclosed.

Nancy Pekarek, a Glaxo-SmithKline spokesman, said the firm acted independently and insi antitrust allegations have no merit.

In any event, U.S. drug companies now face an unprecedented challenge: a growing global discounted drugs, being pushed by some Canadian pharmacies, that will allow Americans t medications via the Internet.

A look at Canadameds.com's Web site shows what the future holds. Its home page announ "Worldwide supplier of discount medications. ... Not just from Canada anymore. You choose and you choose the savings."

Search for price information on a popular drug such as Prozac, an antidepressant made by entries pop up showing the cost of drug orders from the U.K. ($145.87 for 90 capsules), Aus ($208.94 for 84 capsules), Israel ($69.72 for 56 capsules), Chile ($172.65 for 84 capsules) a ($206.11 for 90 capsules).

But how comparable are these drugs' doses to those available in the U.S.? How safe are pr pharmacies that dispense them? How reliable is government oversight in these nations?

These are issues raised by Jeff Trewhitt, a spokesman for Pharmaceutical Research and M of America, the industry's major trade group, who said, "Taking imported medicines can be Russian roulette."

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Prescription Drug Importation Update: Oregon Proposes Novel Program

Importing prescription drugs from Canada and other countries has been a hot-button issue throughout 2004 and shows no signs of ceasing in 2005. Even though the United States Department of Health and Human Services (HHS) and Food and Drug Administration (FDA) had, as of press time, not changed their prohibition on reimportation due to public safety concerns, an increasing number of state and local officials across the country are establishing avenues through which their citizens may purchase prescription medications from outside the US. This proliferation of government-sponsored plans for providing access to drugs from outside the US raises important public safety issues for state boards of pharmacy.

In the August 2004 *NABP Newsletter*, the Association noted that 13 states and several cities were in the planning stages of or had already established programs facilitating their citizens' access to imported drugs. Since that time, more municipalities have entered the arena. The governors, mayors, and other politicians involved in these programs cite a sense of urgency in providing citizens with access to affordable medications, and frustration with lawmakers and regulators for not legalizing the process.

In response to these actions, regulatory officials continue to raise concerns over patient safety. "[HHS] Secretary [Tommy G.] Thompson has not yet been able to certify that importation would (1) pose no additional risk to the public health and safety and (2) result in a significant reduction in the cost of drugs to the American consumer," FDA noted in an August 2004 press release. HHS, meanwhile, through its Task Force on Drug Importation, is attempting to determine whether or not, and under what circumstances, drug importation might be conducted safely. As of press time, publication of the Task Force's findings is still scheduled to be released in December 2004. (See "HHS Task Force Studies Illegal Drug Importation" in the July 2004 *NABP Newsletter*.)

The HHS Task Force report will also address the likely consequences that legalizing prescription drug importation would have for US consumers' health, medical costs, and development of new medicines. The Congressional Budget Office (CBO) has already issued a brief analysis of the cost-reduction issue in April 2004; it concluded that permitting nationwide drug importation from Canada would produce "a negligible reduction in drug spending," largely because "unique aspects of the prescription drug market would limit the additional volume of prescription drugs reaching the United States." The report noted, "[W]hile an individual can fill a prescription in another country and realize savings reflecting the full difference in price, the same would not be true for the health care system overall." The CBO assumed that drug manufacturers would take measures to restrict supplies to Canada in the case that

importation to the US were legalized; it did not address the possible results if Congress outlawed such activities by manufacturers.

While those in charge of safeguarding the public health and safety examine and debate the importation issue, many individual states continue to forge ahead with their plans to help US consumers import prescription drugs. Most of these plans, like Illinois', have been established despite federal regulations in the matter. However, a few plans continue to attempt to work within the system: Vermont filing a lawsuit against FDA to force the creation of importation guidelines, for example, and Oregon working closely with its board of pharmacy to develop a unique pilot program proposal.

Typical State Activities

Some typical state and city actions in terms of prescription drug importation were outlined in the August 2004 *NABP Newsletter* article on the topic. Several of these localities including Illinois, New Hampshire, North Dakota, and Wisconsin operate official Web sites that contain links to Canadian pharmacies. Others, like Springfield, MA, have contracted with a Canadian company to provide a particular group (such as city employees) with prescription medications via mail order. Wisconsin now offers its citizens two options: the Web site links to the Canadian pharmacies discussed earlier, or enrollment in the Illinois-originated I-SaveRx program, discussed later.

Many states including those that have started importation programs have sought waivers from FDA that would make drug importation legal. Lawmakers and politicians in these states have expressed frustration that, thus far, FDA has not granted approval for any pilot projects or waiver requests, or developed a list of criteria that would describe "safe" importation. In May 2004, the attorneys general of 18 states and one US territory sent a letter to Secretary Thompson calling for limited, legalized importation and suggesting measures to ensure drug safety.

Oregon's Pioneer Prescription Drug Project

One of the most striking aspects of Oregon's Pioneer Prescription Drug Project is the initial approach taken by the state's Governor, Ted Kulongoski: He involved the Oregon State Board of Pharmacy.

His insistence on doing so, in fact, gained the respect and the assistance of the Board, according to Gary A. Schnabel, RPh, RN, the Board's executive director. "[Kulongoski] asked the Board for direction, and at first the Board was hesitant to work on an importation scheme," says Schnabel. "But the governor was not discouraged." The governor had been watching other states and their programs, says Schnabel, but did not want to follow in their footsteps. He wanted the Board's help "to do it right." And while the Board at first was skeptical, says Schnabel, "As time went on, the governor, working with the Board, started looking at the safety factors, and the Board started to think, 'Maybe this could work.' . . . The Board said straight up that we can't endorse a program that violates federal law."

Through collaboration that involved addressing the Board's concerns for the safety and integrity of the nation's prescription drug supply came the proposed project's other unique aspect: It puts the Board in a regulatory position to perform inspections and monitor the program.

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The project would accomplish this by using Oregon pharmacies to dispense the prescription drugs received from Board-registered Canadian wholesalers. Pharmacies that register with the Board to import and sell the drugs would be able to carry medications from a formulary (also selected by the Board) of 50 to 100 drugs available in Canada at a demonstrated savings, and charge dispensing fees predetermined by the Board. These imported medications would be available only for purchase using cash, removing insurance complications.

Canadian wholesalers involved in the program, already under the auspices of Health Canada, which is the Canadian equivalent to FDA, would have to pay a registration fee and meet the same standards required of US wholesalers. (Those standards may soon become more stringent than they are at present, says Schnabel. The Board has been evaluating NABP's new Model Rules for the Licensure of Wholesale Distributors, he says, and is likely to change its wholesaler licensing requirements in the not-too-distant future.) The Board would be in the position to perform inspections and monitor adherence with licensing requirements using its compliance staff.

Oregon submitted its plan to then HHS Secretary Thompson for approval on August 12, 2004, and a letter from Oregon's congressional delegation to the secretary requesting prompt approval followed on September 9. While no official response has been forthcoming as yet – and secretary Thompson's response to other states' proposals has not been positive – telephone conversations have taken place between HHS and the governor's staff, says Schnabel. With national elections over and the HHS Task Force report scheduled for impending release, however, a response may come soon. While Schnabel was impressed by the governor's interest in truly addressing safety concerns, he notes that the political atmosphere is "very hot." "We are still wondering what will happen if [HHS] says, 'No,' to the governor's request," he says. "At least everyone's still willing to sit around the table and talk."

I-SaveRx Program

At the beginning of October 2004, Illinois and Wisconsin (later joined by Missouri) launched one of the largest initiatives to date. The "I-SaveRx" program has another distinction: It is the first state-sponsored program that helps residents purchase prescription drugs not only from Canada, but also from Ireland and the United Kingdom.

In announcing the program's expansion to include Missouri, Illinois Governor Rod R. Blagojevich's 2003 proposal to launch an importation program did not receive a positive response from FDA. His response to this – in conjunction with Wisconsin Governor Jim Doyle – was to launch the I-SaveRx program. The program works through a Canadian clearinghouse, which residents of three participating states contact through a Web site or a toll-free phone number. The clearinghouse provides residents with enrollment forms as well as information on medications available through the program and prices in each of the three provider countries.

> Irish officials expressed surprise at their inclusion in the Illinois program and the three main firms that distribute drugs in Ireland also said they knew nothing of the plan.

According to Blagojevich, the program includes various safeguards to ensure patient safety. These include a requirement for new enrollees to provide a health profile form and signed prescription to the clearinghouse; a computer scan for "appropriateness" using the same drug interaction software used in Illinois pharmacies; a restriction on available medications to refills of those types used long-term and that cannot spoil during shipping; and a requirement for participating pharmacies "to agree to comply with Illinois pharmaceutical standards, and to only dispense drugs that are intended as domestic product in Canada, Ireland, or the UK," according to the governor's office.

Several organizations, however, find the safeguards to I-SaveRx suspect. Tom Engels, vice president of Public Affairs for the Pharmacy Society of Wisconsin (PSW), notes that the network of 45 international wholesalers and pharmacies are not publicly identified. In an August 19, 2004 *Chicago Tribune* article, Irish officials expressed surprise at their inclusion in the Illinois program and the three main firms that distribute drugs in Ireland also said they knew nothing of the plan. Anne Nolan, chief of the Irish Pharmaceutical Healthcare Association, told the *Tribune* that her organization would not be happy with the arrangement. "It would cause enormous problems for us to meet our local obligations here," she said.

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NABP Headquarters Moves to New Location

After more than 10 years of calling Park Ridge, IL, its Headquarters, NABP moved to 1600 Feehanville Drive, Mount Prospect, IL 60056, over the Thanksgiving holiday weekend. After a brief office closure to accommodate the move, NABP's operations resumed at the new Headquarters on November 30, 2004. The new phone number is 847/391-4406 and the new fax number is 847/391-4502. All printed communications can be sent to the Feehanville Drive address.

The new 57,000-square-foot building will enable NABP to enhance its program and service offerings to the boards of pharmacy, candidates, and applicants and provide ample space for future growth.

For more information about NABP's new Headquarters, please see "NABP Purchases New Building for Association Headquarters" in the February 2004 *NABP Newsletter*.

If you have any questions concerning the Association's new headquarters, please contact Customer Service at custserv@nabp.net or call 847/391-4406.

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Wisconsin Importation Program

In addition to the I-SaveRX program, Wisconsin has its own importation site, www.drugsavings.wi.gov, which promises consumers savings of 50% or more by purchasing drugs from Canadian pharmacies. During a continuing education session at NABP's Fall Educational Conference, held November 11-14, 2004, Engels related some disturbing violations by three of the participating Canadian pharmacies that PSW found when reviewing data reports submitted over the first six months that the program was in operation.

- Prescriptions dispensed – 2,299
- PSW-identified violations – 526
- Wisconsin-identified violations – 9 (often the state did not specify a number in its reports)

PSW broke these violations into three main categories:

- Drugs sold but not listed on the Drugsavings.wi.gov Web site (346)
- Non-FDA approved drugs (174)
- Drugs sold that require refrigeration (6)

In response to PSW's criticisms, the state of Wisconsin said that the organization was the only one that "has a problem," PSW is "making up violations," the drug listing on the Web site is simply informational, and that the Web sites have ceased dispensing non-FDA approved drugs and refrigerated items. The state of Wisconsin noted that it has sent warnings to those pharmacies in violation; however, PSW still has concerns about the public health.

PSW stated its concerns in a letter sent to Wisconsin's Department of Health and Family Services, "We suspect that instead of directing patrons through the front door of their pharmacies, the Canadian pharmacies are telling their patrons to use the side door: an Internet site with even less threat of regulation.... Just one of these many violations [those discussed earlier] would be sufficient to close a licensed Wisconsin pharmacy, yet the state of Wisconsin did not end its relationship with the Canadian pharmacies."

In a July 22, 2004 letter to Wisconsin Governor Jim Doyle, FDA's Associate Commission for Policy and Planning wrote, "It is increasingly clear that the participating pharmacies continue to sell drugs to Wisconsin citizens that are in violation of the standards you have established in an attempt to assure the quality and safety of such medications and despite your Warning Letters of April 27, 2004, to these pharmacies."

In his concluding remarks, Engels stressed the importance of a federally regulated importation system that is carried out through licensed pharmacies.

Vermont Sues FDA

At about the same time that Illinois' Blagojevich announced the I-SavRx program launch and a week after FDA denied Vermont's request for a waiver of the drug importation ban, the state of Vermont filed suit against HHS and FDA. The goal: to force the government to establish rules and guidelines under which legal importation may take place.

The lawsuit claims that the 2003 Medicare Prescription Drug, Improvement, and Modernization Act (MMA) granted waiver authority to HHS and FDA and also required them "to publish

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Deadlines Set for Advance Distribution of Proposed Resolutions

NABP will distribute proposed resolutions to allow boards of pharmacy to review the resolutions prior to NABP's 101st Annual Meeting, May 21-24, 2005, at the Sheraton New Orleans Hotel in New Orleans, LA.

Proposed resolutions received at NABP Headquarters by April 8, 2005, to be presented and voted upon during the 101st Annual Meeting, will be distributed to the boards of pharmacy on April 22, 2005, for review prior to the meeting. This mailing will constitute **only** the pre-conference distribution of proposed resolutions. All resolutions – those distributed for early review as well as those received after April 8 – will be presented to the delegates during the Annual Meeting on Monday, May 23, by the chair of the Committee on Resolutions.

To be considered during the Annual Meeting, resolutions must adhere to the requirements of Article IV, Section 6, Part (d) of the NABP Constitution, which states:

> Any active member board, district, or committee of the Association may submit resolutions to the Association. . . . [A]ll resolutions submitted in writing to the Association at least twenty (20) days prior to the date of the Annual Meeting shall be presented at the Annual Meeting for consideration. Resolutions not presented within such time limitations may be presented during the Annual Meeting, and will be considered for adoption by the Association upon the affirmative vote of three-fourths (¾) of those Association members present and constituting a quorum.

Questions regarding resolution procedures should be directed to NABP Executive Director/Secretary Carmen A. Catizone at NABP Headquarters by calling 847/391-4406 or e-mailing custserv@nabp.net.

Importation Update

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guidance describing the circumstances under which [HHS and FDA] will consistently grant waivers to allow importation of prescription drugs for personal use. . . . Despite explicit direction from Congress in the MMA to promulgate regulations permitting importation of prescription drugs from Canada and guidance regarding waivers that would also allow importation," the lawsuit states, "HHS and FDA denied Vermont's petition and have taken no action to promulgate regulations or issue any guidance regarding waivers."

FDA, while stating its appreciation that Vermont is working within the US legal system to address its disagreement with federal authorities, reminded the public in an official statement that the HHS Task Force was still in progress: "Completion of this required study is critical to making an informed decision as to whether the drug importation or not program in MMA can be implemented safely."

The Vermont Board of Pharmacy, which was not involved in the waiver-seeking process, has not made a public statement regarding the matter. Its position on the reimportation of prescription drugs was published, however, in the Board's June 2003 *Vermont Board of Pharmacy Newsletter*. "The Board finds itself in a difficult, and potentially unpopular, position **to protect the public safety**," the *Newsletter* states. "The practice of importing drugs from foreign jurisdictions is illegal and has been made so to support the overriding purpose of the law, namely the protection of the **health, safety, and welfare** of the public."

NABP's Position

While NABP sympathizes with the economic concerns of those patients who face difficulties affording their prescribed medications, the Association's position is clear. "NABP does not oppose importation within the safe and secure regulatory framework of the [FDA] and state boards of pharmacy," NABP Executive Director/Secretary Carmen A. Catizone told the HHS Task Force when he testified before it in May 2004. "NABP does oppose the illegal importation of medications which is presently occurring and compromising the integrity of our medication system and state regulation of the practice of pharmacy."

Catizone also reiterated regulators' concerns about patient safety. "NABP cannot accept the premise that people must die from the illegal importation of drugs before the existing laws ensuring the safety of patients are complied with and enforced," he said. "The 'show us the bodies' strategy proposed by some legislators, governors, mayors, and other public officials is irresponsible."

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville MD 20857

January 28, 2005

Patrick C. Lynch
Attorney General of Rhode Island
150 South Main Street
Providence, Rhode Island 02903

Dear Mr. Lynch:

I write in response to the recently enacted law authorizing the Rhode Island Department of Health to license Canadian pharmacies to import prescription medications into the state of Rhode Island. It is my understanding that regulations will soon go into effect and the Rhode Island Board of Pharmacy may soon get applications from Canadian pharmacies for licenses.

FDA is very concerned about the safety risks associated with the importation of prescription drugs from foreign countries. In our experience, many drugs obtained from foreign sources that purport and appear to be the same as U.S. approved prescription drugs have been of unknown origin and quality. We cannot provide adequate assurance to the American public that the drug products delivered to consumers in the United States from foreign countries are the same products approved by FDA. For example, an American consumer recently ordered an FDA-approved anti-seizure medication called Neurontin from a website that purported to operate in Canada and to ship FDA-approved drugs from Canada into the United States. Nevertheless, the drug the consumer actually received had been manufactured in India, shipped from India, and was not approved by FDA for any use in the United States. In another instance, a website that purported to operate in Canada mailed insulin into the United States for use by an American with diabetes. Although the drug originally had been manufactured in the United States, it was shipped back into the country in a manner that did not satisfy the refrigeration storage conditions specified in FDA-approved labeling and, therefore, that could potentially compromise the safety and effectiveness of the insulin. Because the failure to refrigerate the product may not change its appearance, American consumers may have had no way of knowing if their insulin had been mishandled abroad.

These safety concerns are reflected in the import provisions of the Federal Food, Drug, and Cosmetic Act (FFDCA), which strictly limit the types of drugs that may be imported into the United States who may import them. Congress enacted these provisions to create a relatively "closed" drug distribution system, which helps ensure that the domestic drug supply is safe and effective. Accordingly, if an entity or person within the State of Rhode

Island were to import prescription drugs into the State of Rhode Island from Canada, it would violate the FFDCA in virtually every instance. Furthermore, the drug importation scheme set forth by Congress preempts conflicting state or local legislation that would legalize the importation of certain drugs from Canada in contravention of the FFDCA.

General Legal Framework

The starting point for our analysis is the legal framework applicable to imports of prescription drugs from Canada.[1]

First, virtually all drugs imported for personal use into the United States from Canada violate the FFDCA because they are unapproved (21 U.S.C. § 355), labeled incorrectly (21 U.S.C. §§ 352, 353), or dispensed without a valid prescription (21 U.S.C. § 353(b)(1)). Importing a drug into the United States that is unapproved and/or does not comply with the labeling requirements in the FFDCA is prohibited under 21 U.S.C. §§ 331(a), and/or (d).

FDA approvals are manufacturer-specific, product-specific, and include many requirements relating to the product, such as manufacturing location, formulation, source and specifications of active ingredients, processing methods, manufacturing controls, container/closure system, and appearance. 21 C.F.R. § 314.50. Generally, drugs sold outside of the United States are not manufactured by a firm that has FDA approval for that drug. Moreover, even if the manufacturer has FDA approval for a drug, the version produced for foreign markets usually does not meet all of the requirements of the United States approval, and thus is unapproved. 21 U.S.C. § 355. The version also may be misbranded because it may lack certain information that is required under 21 U.S.C. §§ 352 or 353(b)(2) but is not required in the foreign country, or it may be labeled in a language other than English (see 21 C.F.R. § 201.15(c)).

Second, with respect to "American goods returned," it is illegal for any person other than the original manufacturer of a drug to import into the United States a prescription drug that was originally manufactured in the United States and sent abroad (21 U.S.C. § 381(d)(1)). This is true even if the drug at issue were to comply in all other respects with the FFDCA. Importing a drug into the United States in violation of section 381(d)(1) is prohibited under 21 U.S.C. § 331(t).

Thus, to ensure compliance with the FFDCA, any state or private entity that intends to import prescription drugs into the United States must ensure, among other things, that it only imports FDA-approved drugs that comply with their FDA approvals in all respects, including manufacturing location, formulation, source and specifications of active ingredients, processing methods, manufacturing controls, container/closure system, and appearance. 21 C.F.R. § 314.50. The importer must also ensure that each drug meets all U.S. labeling requirements, and that such drugs are not imported in violation of the "American goods returned" provision in 21 U.S.C. § 381(d)(1).

Practically speaking, it is extremely unlikely that all of the applicable legal requirements will be met if Canadian pharmacies ship drugs into Rhode Island. Consequently, virtually every shipment would violate the FFDCA. Moreover, individuals or programs that cause illegal shipments also violate the FFDCA. 21 U.S.C. § 331 ("The following acts and the causing thereof are hereby prohibited...").

Potential Liability

There are many sources of civil and criminal liability for parties who violate the FFDCA. A court can enjoin violations of the FFDCA under 21 U.S.C. § 332. A person who violates the FFDCA can also be held criminally liable under 21 U.S.C. § 333. A violation of 21 U.S.C. §§ 331(a), (d), or (t) may be prosecuted as a strict liability misdemeanor offense. *See United States v. Dotterweich,* 320 U.S. 277, 284 (1943); 21 U.S.C. § 333(a)(1). Any such violation that is committed with intent to defraud or mislead or after a prior conviction for violating the FFDCA may be prosecuted as a felony under 21 U.S.C. § 333(a)(2). Separately, it is also a felony to knowingly import a drug in violation of the "American goods returned" provision of 21 U.S.C. § 381(d)(1). *See* 21 U.S.C. § 333(b)(1)(A). In addition, those who can be found civilly and criminally liable include all who *cause* a prohibited act under the FFDCA. 21 U.S.C. § 331 ("The following acts and the causing thereof are hereby prohibited").

To date, FDA has focused its enforcement resources on those who commercialize the practice of importing drugs into the United States from abroad. As a matter of enforcement discretion, FDA generally has not seized drugs from those who have taken buses across the border and then brought foreign drugs back into the United States for their own personal use. Instead, FDA has attempted to educate such citizens about the safety risks associated with consuming foreign drugs. Nevertheless, FDA retains the authority to bring an enforcement action in any case in which a provision of the FFDCA has been violated.

Federal Preemption

Federal preemption of state law is grounded in the Supremacy Clause of the United States Constitution. U.S. Const. art. VI, cl. 2. The Supremacy Cause states that: "This Constitution, and the Laws of the United States which shall be made in pursuance thereof . . . shall be the supreme Law of the Land; and the Judges in every State shall be bound thereby, any Thing in the Constitution or Laws of any State to the Contrary notwithstanding." U.S. Const. art. VI, cl. 2.

The Supreme Court has held that,under the Supremacy Clause, the enforcement of a state regulation may be pre-empted by federal law in several circumstances: first, when Congress, in enacting a federal statute, has expressed a clear intent to preempt state law; second, when it is clear, despite the absence of explicit preemptive language, that Congress has intended, by legislating comprehensively, to occupy an entire field of

regulation and has thereby left no room for the States to supplement federal law; and finally, when compliance with both state and federal law is impossible, or when state law stands as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress. *Capital Cities Cable, Inc. v. Crisp, 467 US 691, 698-99 (1984)* (quotation marks and citations omitted); *see also English v. General Electric Co.*, 496 US 72, 78-79 (1990); *Association of Int'l Auto Mfrs., Inc. v. Abrams*, 84 F.3d 602, 607 (2nd Cir. 1996).

Courts have thus held that federal law preempts state law when, *inter alia*, Congress has intended to occupy a field of regulation comprehensively (termed "field preemption") and when the federal law and the state law actually conflict (termed "implied conflict preemption"). *See English v. General Electric Co.*, 496 US at 78-79; *Choate v. Champion Home Builders Co.*, 222 F.3d 788, 792 (10th Cir. 2000).

Field Preemption

Congressional intent to occupy a field comprehensively can be shown any of three ways: 1) when, based on the pervasiveness of the federal regulation, it may be inferred that Congress "left no room for the States to supplement it"; 2) if the federal statute "touch[es] a field in which the federal interest is so dominant that the federal system will be assumed to preclude enforcement of state laws on the same subject"; or 3) when the state regulation "may produce a result inconsistent with the objective of the federal statute." *Rice v. Santa Fe Elevator Corp.*, 331 US 218, 230 (1947).

In the instant matter, Congress set forth a comprehensive importation scheme in the FFDCA that strictly limits the types of prescription drugs that are allowed to be introduced into domestic commerce. For example, the "American goods returned" provision (21 U.S.C. § 381(d)(1)) was enacted in 1988 as part of the federal Prescription Drug Marketing Act. PL. 100-293 (April 22, 1988). In enacting the law, Congress cited the explicit goal of limiting the flow of drugs into the United States from abroad. In section 2 of the bill, Congress found, "[l]large amounts of drugs are being reimported into the United States as American goods returned. These imports are a health and safety risk to American consumers because they may have become subpotent or adulterated during foreign handling and shipping." *Id.* Clearly, Congress enacted section 381(d)(1) and the other import provisions in the FFDCA with the goal of controlling the types of drugs that could be legally imported into the United States. The federal scheme is comprehensive in that it promulgates national standards that are to be applied equally to all ports of entry, regardless of the states in which they are situated. By definition, the scheme cannot allow the individual states to enact laws that erode the federal standards; otherwise, importers could simply circumvent the federal law by routing all their unapproved drugs into the state (or states) that allowed such imports. Licensure of Canadian pharmacies by the state of Rhode Island would be inconsistent with the plain objectives of the FFDCA if such licensure authorized those Canadian pharmacies to ship into the United States drugs that violate the provisions of the FFDCA.

Implied Conflict Preemption

Implied conflict preemption can be shown in two ways: (1) where it is impossible to comply with both federal and state law; or (2) where the state law stands as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress. *See English v. General Electric Co.*, 496 US at 79.

In the instant matter, if the state were to enact import legislation that contravened the provisions of the FFDCA, those importing the drugs would find it impossible to comply with both the state and the federal law. Indeed, the drugs imported pursuant to the state law would still be illegal under federal law (*see* 21 U.S.C. §§ 331, 352, 353, 355, and 381), and those importing the drugs would be subject to civil or criminal liability in the federal courts (21 U.S.C. §§ 331, 332, and 333).

In addition, a state law authorizing the importation of drugs would frustrate the Congressional objectives enshrined in the import provisions of the FFDCA. As noted, Congress clarified the purpose behind 21 U.S.C. § 381(d)(1) when it passed the Prescription Drug Marketing Act. It concluded that American consumers are best protected by a "closed" drug system that strictly limits the types of products that may be imported into the United States. Any effort by the State of Rhode Island to allow imports that conflict with that scheme would stand as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress as expressed in the FFDCA.

Conclusion

I hope that the preceding discussion is helpful to you. The licensure of Canadian pharmacies by the State of Rhode Island will not only result in violations of federal law, it will put citizens at risk. In our experience, many drugs obtained from foreign sources that purport and appear to be the same as FDA-approved prescription drugs have been of unknown quality and origin. FDA approves a drug based on scientific data submitted by the drug sponsor to demonstrate that the drug is safe and effective. We cannot provide adequate assurance to the American public that the drug products delivered to consumers in the United States from foreign countries are the same products approved by FDA. Accordingly, the FFDCA strictly limits the types of prescription drugs that may be imported into the United States. Any state law that legalizes imports in contravention of the FFDCA would be preempted by federal law. Moreover, those importing drugs in violation of the FFDCA would be subject to liability under that statute, regardless of whether the importation was otherwise sanctioned by the state.

We are aware that the high cost of some prescription drugs is a serious public health issue, and we have taken several steps in recent months to help reduce the cost of drugs in the United States without opening our borders to the potential dangers of foreign

unapproved pharmaceuticals. These steps include new initiatives to accelerate approval of innovative medical procedures and drug therapies, changes to our regulations to reduce litigation that has been shown to delay unnecessarily access to more affordable generic drugs, and proposals to increase agency resources for the review and approval of generic drugs – products that are often far less expensive than brand name products in the U.S., and generally less expensive than the generic drugs sold elsewhere in the industrialized world. Also, the Medicare prescription drug discount card provides millions of America's seniors with discounts and coverage for their prescription medicines.

If you need additional information, please feel free to contact me.

Sincerely,

William K. Hubbard
Associate Commissioner for Policy and Planning

Footnotes

1 We will limit our discussion to drugs imported from Canada because the Rhode Island law is so limited. The legal analysis is the same for drugs imported from any foreign country.

CC: Governor of Rhode Island
Rhode Island General Assembly
Rhode Island Board of Pharmacy

ATTACHMENT E

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Prescription Drugs | Safety Risks of Reimportation Outweigh Benefits, Giuliani Partners Report Finds
[Apr 12, 2005]

The safety and security risks of purchasing lower-cost prescription drugs from other countries "far outweigh any alleged benefits" for U.S. residents, according to a report released Monday by consulting firm Giuliani Partners for the Pharmaceutical Research and Manufacturers of America, *CQ HealthBeat* reports. According to the report, Internet pharmacies are not regulated and widening the range of sources through which U.S. residents can purchase prescription drugs would make it more difficult to guarantee the drugs' authenticity and to determine their chain of custody. The report also found that mechanisms to electronically track prescription drugs are not yet ready for systemwide implementation. According to the report, implementing a safe system to import medications would cost billions of dollars. Former New York City Mayor Rudolph Giuliani (R), CEO and Chair of Giuliani Partners, in a PhRMA release said, "Several credible sources have identified links between counterfeit goods, including pharmaceuticals, and organized criminals and terrorist groups. It is not difficult to imagine a scenario in which terrorist groups could use this system to either finance operations or, worse, as a vehicle of attack." PhRMA President and CEO Billy Tauzin said that the report "underscores the dangers" of reimporting prescription drugs (*CQ HealthBeat*, 4/11).

EXAMINATION AND ASSESSMENT OF PRESCRIPTION DRUG IMPORTATION FROM FOREIGN SOURCES TO THE UNITED STATES

April 2005

GIULIANI
PARTNERS

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INTRODUCTION

Prescription medicines are a key component to this nation's healthcare system. As new medicines are developed, people are living longer, healthier lives. And because it is literally a matter of life and death, every effort must be made to protect this nation's medicine supply. To that end, a comprehensive system has been implemented at the federal and state levels to ensure that the medicines that are approved are safe and effective and that the processes for their manufacture, distribution and sale are as tightly controlled as possible in order to keep them safe and effective. And while the United States does have an excellent system, often referred to as the "gold standard," some weaknesses do exist and they, in turn, create vulnerabilities that can be exploited. Common sense dictates that when weaknesses are identified in critical systems, those weaknesses should be addressed before possible harm results. Unfortunately, the current debate regarding the importation of prescription drugs from foreign sources has diverted attention from where it should be; attention is not appropriately focused on addressing the problems that currently challenge those who are responsible for keeping America's medicines safe and minimizing the risk for potential harm.

Giuliani Partners LLC was retained by the Pharmaceutical Researchers and Manufacturers of America (PhRMA) to evaluate the risks associated with the importation of non-FDA approved medicines from foreign sources. After conducting a preliminary, independent review of these issues, in May 2004 an Interim Report, entitled an "Examination and Assessment of Prescription Drug Importation from Foreign Sources to the United States," was submitted to the Health and Human Services Task Force. It was also submitted to two Congressional committees studying the issues associated with importation – the Senate Judiciary Committee and the United States Senate Permanent Subcommittee on Investigations of the Committee on Governmental Affairs. That report found that counterfeit, diluted or adulterated drugs are already entering the United States and that the existing pharmaceutical system is vulnerable to significant exploitation by drug traffickers, organized criminals and terrorists. The serious problems identified in the existing system should be addressed first before any type of importation is authorized.

After the issuance of the Interim Report, Giuliani Partners continued its review of the safety issues associated with the importation of non-FDA approved medicines from foreign sources. This report summarizes the preliminary findings outlined in the Interim Report, includes new information and offers several recommendations to address some of the issues identified. Based upon what has been learned, there is real reason for serious concern regarding the safety of the nation's medicine supply if commercial importation is permitted. To do so would be fraught with risk and could seriously compromise a system that is already weakened. Efforts should be dedicated to addressing the issues within the existing system first while at the same time finding alternative ways to provide safe, effective and affordable medicines to those who need them.

EXECUTIVE SUMMARY

Much of the reason for the focus on importation of prescription medicines from foreign sources stems from the sometimes significant differences in the cost of such medicines in the United States versus foreign countries. Ensuring that all Americans have access to safe, effective and affordable prescription medicines must be a priority. However, based upon the findings in this review, safety will surely be compromised if current efforts to broadly legalize importation are successful. The United States cannot afford to go forward with such a program unless it has determined with absolute certainty that the nation's medicine supply is adequately protected. The press for legislative action to open the borders should be halted until the issues presented can be sufficiently resolved. To do otherwise would create serious risk to the nation's medicine supply.

At the conclusion of the preliminary review, a number of things quickly became evident:

- There are significant risks associated with the importation of medicines from foreign sources.
- Loopholes and problems in the existing drug distribution system need to be addressed.
- An importation system that can assure that medicines being imported are safe and effective does not appear to exist.
- Most surprisingly, the nation's medicine supply is vulnerable to exploitation by organized criminals, drug traffickers and terrorists.

We should not contemplate opening our borders to threats to our medicine supply when in all other aspects we are searching for ways to tighten the security of our borders.

The review also revealed that access to safe, effective and affordable medicines for all Americans is a critical issue and that, due to price controls in other countries, Americans do pay more for many of their prescription medicines. These matters related to affordability and access should be addressed. However, if the health and safety of Americans are truly paramount, then importation of prescription drugs is not the answer. Shortcomings in the existing system related to safety should be addressed and the medical and healthcare professions, as well as consumers, must be educated about various options that currently exist to access more affordable medicines.

This report and the preceding Interim Report discuss a number of findings regarding the safety issues associated with the importation of non-FDA approved medicines from foreign sources. In addition, this document briefly summarizes the law

regarding importation, and the findings of the report recently issued by the Health and Human Services Task Force on Drug Importation. Further, although not the primary focus of this review, in light of the fact that the price of prescription medicines in the United States is an incentive for people to turn to foreign sources, this report briefly discusses several studies regarding the economic implications of such a program.

Those findings can be summarized as follows:

- **Importation is illegal.** The law currently prohibits the importation of prescription drugs from foreign sources unless done by the manufacturer from an FDA-approved facility.

- **Unapproved drugs have already compromised the system.** Non-FDA-approved drugs are already getting into the United States, as evidenced by inspections at various airport mail facilities. Random inspections found that 86% to 88% of the suspected drug parcels examined contained non-FDA approved medicines from such countries as Pakistan, Mexico, Brazil, the Netherlands and Canada. In addition, the World Health Organization, the FDA and pharmaceutical companies indicate that the number of counterfeit drug cases is on the rise. By expanding the sources for drugs, it will be harder to ensure authenticity and chain of custody. The risk to patient/consumers of receiving some of that counterfeit product increases proportionally.

- **There are problems with the existing system.** The weaknesses in the current drug distribution system are well documented. For example, no uniform mechanism, i.e., pedigree of chain of custody, has been implemented to track medicines from the point of manufacture to the point of sale. There are reported issues with the "secondary" drug distribution market and those responsible for oversight of the system do not have sufficient resources to conduct adequate inspections or effectively monitor the system.

- **Troubling questions are raised about remedies proposed in pending importation legislation.** Saying that a commercial importation program is safe does not make it so. Many of the safety features being discussed in the context of pending importation legislation are not necessarily reliable. For example, meaningful ways to "track and trace" medicines electronically, while being used successfully in a few places in the system, are still a few years away from system wide implementation. Further, it is estimated that the FDA resources required to implement a safe system will cost billions. Even if the resources were available, it is questioned whether the FDA would have the necessary authority to perform the required inspections in other countries. We cannot and should not rely on other countries to perform these tasks for us. As was stated in the HHS Task Force Report and by Canada as well, foreign governments are primarily

concerned with the safety and effectiveness of the drugs sold to their own citizens, not necessarily those that are being exported to other countries.

- **The Internet mail-order pharmacy business has exposed a number of safety concerns.** Given that Internet pharmacies are not regulated, ordering prescription drugs in this manner is fraught with risk unless the consumer/patient is able to verify that he or she is dealing with a legitimate pharmacy. Many Internet pharmacies seek to avoid liability by requiring patients to sign waivers.

- **Importation could have significant implications for Canada.** That country does not have supply sufficient to provide for its residents and Americans as well. The Canadian Minister of Health has stated that Canada cannot be the drugstore for the United States and that the Canadian government is contemplating measures to limit Canadian Internet pharmacy sales.

- **Drugs are already coming from foreign sources.** Several of the large Canadian Internet pharmacies have stated publicly that they are already filling prescriptions with drugs from foreign countries and that if the Canadian government does limit their business, they will move their operations to Europe. Patients cannot assume that the drugs they receive from such sources are identical to what they would get in the United States.

- **We must learn from experience regarding the actions of organized criminals, drug traffickers and terrorists.** The present system of importation, inspection and distribution is vulnerable to exploitation and abuse by drug traffickers, organized criminals and terrorists. Several credible sources have identified links between counterfeit goods, including pharmaceuticals, and organized criminals and terrorist groups. Based upon what was learned about the existing system, it is not difficult to imagine a scenario in which terrorist groups could use this system to either finance their operations or, worse, as a vehicle of attack.

- **Savings to consumers may not necessarily be achieved in the long run.** Although not the primary focus of this review, several studies that examined the economic implications of parallel trade, price control and/or commercial importation schemes, were reviewed. They raise troubling issues. Generally, no data could be located to support the contention that there is any economic benefit of legalized importation to consumers in the United States in the long run. Such programs will likely have a negative impact on the investment in research and development by pharmaceutical companies, which in turn could lead to the development of fewer new and innovative medicines. Two other studies examined the economic implications of such programs in the states of Michigan and Massachusetts and both studies projected job loss and reductions in personal income.

In order to appreciate more fully the implications of authorizing a commercial importation program in the United States, a few points perhaps merit some clarification. Generally speaking, under the importation schemes currently being discussed, prescription drugs would be purchased from certain foreign countries, such as Canada or the countries that are part of the European Union (EU). Many, if not all of those countries have systems in place to regulate the price of prescription medicines in their respective countries and those prices do vary. Since these price differentials exist, prescription drugs are traded among those countries comprising the EU. The practice is referred to as "parallel trading." In essence, licensed traders buy medicines in one country where the prices are lower and then sell them in another country at a higher price. Because there are costs associated with this process, e.g., related to transportation, repackaging and distribution, there are mark ups in the price of the medicines.

In order to give a frame of reference regarding the volume of drugs that are being parallel traded, a document published by the Social Market Foundation, which cites the European Association of Euro-Pharmaceutical Companies that estimated that 140 million packs of medicines were parallel traded in 2002 within the EU Internal market and that 70% of that trade is in the United Kingdom. Since commercial importation into the United States would appear to take on similar characteristics to parallel trading, increases in foreign drug prices can be anticipated thereby reducing the overall savings. Another aspect of this process is troubling. The more often prescription drugs change hands, the more difficult it becomes to verify custody at each step and the easier it becomes to tamper with the product or introduce counterfeit drugs into the supply.

Several recommendations are also included. Based upon what was learned during this review, a number of steps should be considered to ensure that every possible effort is made to protect this nation's medicine supply. The questions and threats related to the safety of imported medicines are real and should not be dismissed. Accordingly, the following recommendations are offered:

- **Fix the existing system.** The safety of this nation's medicine supply cannot be assured without investing significant resources into an already overburdened system. The vulnerabilities in the current system should be addressed in order to maintain the "gold standard." The FDA, Customs and Border Protection and other regulatory entities should be provided with the authority and the resources necessary to ensure that the "gold standard" is not compromised further. In addition, other systemic issues should be addressed, including the implementation of an effective pedigree system.

- **DHS should conduct a threat and vulnerability assessment.** Given the critical role that medicines play in the overall healthcare of the people of this country, a

threat and vulnerability assessment of the nation's medicine supply should be conducted by the Department of Homeland Security.

- **Conduct an education campaign regarding access to cheaper, safer medicines.** At the same time as efforts are underway to address the safety issues associated with the current system, doctors, healthcare professionals and consumers need to be better educated regarding the options available to access cheaper medicines, such as drug discount cards or other patient assistance programs.

- **New efforts should be undertaken to track potential problems with drugs obtained from foreign sources.** There is a need to assess the extent to which people are being harmed as a result of importing drugs from foreign sources. Currently, there is no formal mechanism in place to quantify the problem. Efforts should be undertaken by the healthcare and medical profession to identify the problem. For example, consideration should be given to modifying emergency room, medical examiner and doctor protocols, urging that the following types of questions be asked: from where are the prescription medicines being purchased and are they available to be tested? Additionally, consideration should be given to modifying the FDA's "MedWatch" system, which tracks adverse events involving FDA-approved products, in order to capture additional information related to this issue.

- **Better educate consumers about risks associated with drugs from foreign sources.** Consumers must be made more aware of the risks associated with importing medicines from foreign sources. Not only is there a potential risk from the compromised quality of product they may be receiving, but also there may be serious health implications if their doctors and/or pharmacists are not aware of all of the medicines they are taking. In addition, because current legislative proposals concerning importation extend beyond Canada, for example proposing importation from 25 or more countries, a study should be undertaken, similar to that which was conducted by the HHS Task Force regarding Canada, to assess the feasibility and the risks associated with a broader program. Patient safety requires no less.

- **Create greater access to more affordably priced medicines.** Access to safe, effective and affordable medicines is a significant issue for many Americans, particularly the uninsured and the underinsured, and it should be addressed; but importation is not the answer. As a mechanism to reduce reliance on importation to create greater access at more affordable prices, there needs to be a candid discussion among the pharmaceutical companies, the health care industry, governments and international trade organizations, consumer groups and other

interested parties regarding the cost and accessibility of prescription medicines in the United States and abroad.

Importation from foreign sources clearly invites greater risk to a system that is already compromised. We need to take appropriate steps to address the problems that currently challenge those responsible for ensuring the safety of the nation's medicine supply – close the loopholes, get the resources to those who need them, give developing technologies like those that are capable of ensuring that each pill is authentic and traceable, a chance to be implemented system wide and, in the meantime, find other ways to bring safe and affordable medicines to those who need them. Simply put, patient safety must come first.

Most importantly, it is hoped that this report will raise the level of concern with regard to the risks our medicine supply faces already. Repeatedly, Congress has recognized the need for a regulatory system to ensure Americans receive safe and effective medicines and that the nation's medicine supply is adequately protected - from the earliest stages of development through the approval process to the distribution and sale to patients and consumers. The risks associated with importation of medicines from foreign sources are well documented. Until the existing issues are addressed, it seems illogical to disregard the warnings and open an already vulnerable system to potentially harmful medicines. Under the present circumstances, why would Congress now deviate from its past practice and contemplate introducing a system that cannot, with certainty, guarantee the safety of the nation's medicine supply. That is not to say that the issue of access to safe and affordable medicines should not be addressed; it must be.

THE BACKDROP

THE LAW

Millions of Americans are engaged in the importation of non-FDA approved medicines from foreign countries and may not fully appreciate that certain aspects of their conduct may be against the law. Historically, the federal regulation of the prescription drug industry began in 1938 when Congress passed the Food Drug and Cosmetic Act (FDCA). Its key provision required that all drugs be cleared for safety by the FDA prior to distribution. It was passed in response to the disaster involving the elixir sulfanilamide in 1937, which killed 107 people when antifreeze was used as a solvent for the drug.

The FDCA makes it illegal to distribute or import an unapproved drug. The Prescription Drug Marketing Act (PDMA) of 1987, passed in response to a concern about counterfeit medicines being diverted into the market, made it illegal for anyone other than the original manufacturer to re-import an approved drug that was manufactured in the United States and then shipped overseas. As a result of these laws and other steps taken

by Congress, an extensive system of regulation currently governs the manufacture, distribution and sale of prescription drugs in the United States and, with limited exception, ensures that the American medicine supply is safe and effective. This system, often referred to as the "gold standard," essentially establishes a closed system of drug distribution – meaning that, among other things, any medicines distributed in the United States must be FDA-approved.

Notwithstanding this prohibition against importation, the FDA exercises its discretion with regard to the importation of certain unapproved drugs by individuals. Referred to as the "personal use exemption," the FDA, in its Regulatory Procedures Manual, indicates that "FDA personnel may use their discretion to allow the entry of shipments of violative FDA regulated products when the quantity and purpose are clearly for personal use and the product does not present an unreasonable risk to the user." The personal use exemption was intended for drugs that had not been approved for use in the U.S. but were being used to treat a serious condition for which other treatments were not available. It does not apply to the importation of drugs available in the United States, the importation of unapproved foreign versions of drugs available in the United States, or to the re-importation of approved drugs in violation of the PDMA.

Congress has passed other laws since the PDMA which demonstrate its acknowledgment that this nation's medicine supply must be protected. In 2000, Congress enacted the Medicine Equity and Drug Safety Act, certain provisions of which were subsequently amended by the Medicare Prescription Drug Improvement and Modernization Act of 2003. Each of these laws contains provisions that would authorize the importation of medicines from foreign sources provided the Secretary of Health and Human Services (HHS) certifies that such action will pose no additional risk to the public's health and safety and will result in significant cost savings to the consumer. Since the enactment of these laws, neither the Secretary of HHS under the Clinton administration nor the successors under the Bush administration ever made such a certification.

States have also enacted laws and implemented regulations to provide additional safeguards for the nation's medicine supply. For example, most states have established licensing systems for distributors, pharmacists, and pharmacies. Current importation practices circumvent these laws and regulations adopted by the appropriate state Boards of Pharmacy.

Notwithstanding the above-referenced legal restrictions, the report prepared by the United States Department of Health and Human Services Drug Task Force which will be discussed in greater detail below estimated that two million Americans purchased approximately $700 million worth of prescription drugs from Canada in 2003. The report estimates that similar amounts were purchased from other foreign countries, primarily coming in the mail. Further, a number of states and municipalities continue to promote

purchasing from Canada and other foreign sources. A recent news story reported that 28 states and the District of Columbia considered drug importation measures last year. Examples include:

- The State of Rhode Island, which passed a law permitting the purchase of drugs from Canada by giving the State Board of Pharmacy the authority to license Canadian pharmacies in the same manner that it licenses other out-of-state mail order pharmacies;

- The Governor of Oklahoma, who recently proposed a plan to be submitted to the State's legislature that would allow state residents to buy lower-cost prescription drugs from Canada and other nations;

- Five states - Illinois, Wisconsin, Kansas, Missouri and Vermont - through a website, I-SaveRX.net, have joined together with CanaRX, a pharmacy benefits manager, to facilitate the purchase of prescription drugs from Canada, Ireland and the United Kingdom; and

- Montgomery County in Maryland which passed a local law permitting importation of prescription drugs from Canada.

Thus far, the FDA has been reluctant to take formal action against any state or municipality that has instituted such programs. Instead, it has sent letters to those entities advising them of the safety risks associated with importing medicines from foreign sources and outlining how such programs may violate federal law.

SUMMARY OF INTERIM REPORT

As noted above, Giuliani Partners issued an Interim Report in May 2004 to the Health and Human Services Task Force and stated that, based upon what had been learned to that point, there are already safety risks associated with the importation of non-FDA approved medicines from foreign sources. In addition, under the current distribution and regulatory system, those risks are likely to increase if importation is legalized. It would be extremely difficult to assure the safety of America's medicine supply under such a program. The following is a summary of the findings from that report, a copy of which is attached to this report as Attachment A.

Non-FDA Approved Drugs Are Already Coming into the U.S.

- FDA random inspections at several mail facilities revealed that 86% – 88% of the packages examined contained non-FDA approved drugs.

- During a visit to the JFK Airport Mail Facility, controlled substances, injectables, and medicines with sensitive storage requirements delivered from the Netherlands, Brazil, and Pakistan were discovered.

- The FDA, the World Health Organization and pharmaceutical companies report that counterfeit cases are on the rise.

- Although difficult to assess and monitor, there are a number of reported incidents of adverse effects involving people who took medicines with questionable origins.

Weaknesses Exist In The Current System

- The volume of parcels coming into this country (estimated to be greater than 10 million annually) coupled with insufficient resources (the FDA has only approximately 100 investigators to handle this nationwide) makes meaningful inspection by the FDA almost impossible.

- At the JFK Airport Mail Facility, only 1%-2% of the 40,000 packages received daily are inspected.

- There is no uniform mechanism, i.e., a chain of custody or "pedigree," to track the medicine from point of manufacture to point of sale.

- Wholesalers and distributors are regulated by the states with no uniform interstate standards (there are reportedly more than 6000 secondary wholesalers).

- A Florida Grand Jury report released in February 2003 found an overwhelming need for tighter regulation and oversight of the pharmaceutical distribution system. More specifically, the report concluded that oversight of the distribution system is lax, product quality is compromised, health risks are significant, funding for oversight agencies is inadequate, and incentives for counterfeiting and diversion are considerable.

- There are challenges associated with the oversight and enforcement of current laws with regard to ensuring that medicines being purchased or sold in this country are FDA-approved.

Internet Pharmacies Are Not Regulated

- When placing orders over the Internet, there is no way to ensure product quality or origin.

- Many Internet pharmacies do not employ doctors; some do not require prescriptions and many require patients to sign waivers in order to have their prescriptions filled.

Importation Would Appear to Have Significant Implications for Canada

- The Canadian government made it clear in correspondence to The Washington Post that it would not be responsible for the safety and quality of prescription drugs exported from Canada into the United States or any other country.

- Canada does not have the infrastructure and sufficient supply to provide for its residents and Americans as well. In fact, Canadian pharmacists report difficulties in sourcing the supply of medicines.

    - The United States fills 3.1 billion prescriptions annually versus 300 million in Canada (US population – 293 million versus Canada – 32.5 million).

There is a Potential for Exploitation by Narcotics Traffickers, Organized Criminals and Terrorists

- Although much has been done since September 11, 2001 to protect America's borders, there has not been enough focus on providing additional security for the nation's medicine supply system and it remains vulnerable as a potential target.

- Various studies have documented the links between counterfeit products and terrorist organizations, which engage in such activity to finance their operations.

THE HHS TASK FORCE REPORT

Since the issuance of the Interim Report mentioned above, a comprehensive report was issued by the United States Surgeon General regarding the importation of prescription drugs from Canada. The Surgeon General and other experts concluded that the safety and effectiveness of America's medicine supply could not be ensured if drugs are imported from foreign sources. The Medicare Prescription Drug Improvement and Modernization Act passed in December 2003 required the Secretary of Health and Human Services to convene a Task Force on Drug Importation to explore how drug importation might be conducted safely and what would be its potential impact on the health of American patients, medical costs, and the development of new medicines. In its report, the Task Force recognized that access to drugs that are safe and effective as well as affordable is a critical policy goal and there is a "difficult balance" between the need for affordable prescription drugs and the concerns over potential safety hazards that many imported drugs pose. The Task Force also acknowledged that "safety should not be

sacrificed for affordability." In December 2004, the Task Force issued its report[1] and in its Executive Summary identified the key findings as follows:

- The current system of drug regulation has been effective but is facing new threats; it should be modified "only with great care" to ensure continued high standards of safety and effectiveness of the US drug supply.

- There are significant risks associated with the way individuals are currently importing drugs.

- It would be extraordinarily difficult and costly for personal importation to be implemented in a way that ensures the safety and effectiveness of the imported drugs.

- Overall national savings from legalized commercial importation will likely be a small percentage of total drug spending and developing and implementing such a program would incur significant costs and require significant additional authorities.

- The public expectation that most imported drugs are less expensive than American drugs is not generally true.

- Legalized importation will likely adversely affect the future development of new drugs for American consumers.

- The effects of legalized importation on intellectual property rights are uncertain but likely to be significant.

- Legalized importation raises liability concerns for consumers, manufacturers, distributors, pharmacies, and other entities.

The work of the Surgeon General and the HHS Task Force is comprehensive and well documented. Its findings, which are thoughtful and well supported, should not be ignored by those engaged in the debate regarding importation.

FOLLOW UP TO THE INTERIM REPORT

After issuance of the Interim Report, Giuliani Partners continued its review of the safety issues associated with the importation of non-FDA approved medicines from foreign sources. This section outlines additional information regarding issues discussed

[1] "Report on Prescription Drug Importation," HHS Task Force on Drug Importation, U.S. Department of Health & Human Services, December, 2004.

in the first report as well as new findings. Research conducted since the issuance of the Interim Report reinforces safety concerns, and the volume of evidence supporting a position against importation of medicines from foreign sources continues to mount.

More About Internet Pharmacies

The information learned during this review strongly indicates that the purchase of prescription drugs over the Internet can be fraught with risk. That is not to say that all Internet pharmacies are bad; some are legitimate. Unless consumers have the ability to verify that they are dealing with a legitimate pharmacy that dispenses FDA-approved medicines, they are potentially putting themselves in harm's way. The facts are overwhelming; for example, although there are some pharmacies that have a sound Internet business, there are hundreds of "rogue" or very questionable Internet sites that are not what they purport to be. Internet sites claiming to be based in Canada may actually be located someplace else. One news report cited an example involving the drug Accutane, which is used to treat acne and requires careful doctor monitoring. It was ordered over the Internet without a prescription; it was shipped from Pakistan, the instructions were in Greek and the foil blister pack was broken on arrival. Other examples from the FDA set forth below (see page 17) further illustrate this point.

In addition, Internet pharmacies may utilize questionable business practices. In evaluating eight different Canadian pharmacies being evaluated for participation in the Minnesota Governor's prescription drug website, the Minnesota Board of Pharmacy prepared a report which noted that four of the eight pharmacies visited did not provide "acceptable pharmacy services." (It should be noted that none of these pharmacies was selected to participate in the Governor's program.) The report also included a number of observations indicating that safety standards among the pharmacies were not uniform and that quality control appeared to be an issue for several of the pharmacies. If what has been learned to date regarding personal importation using the Internet is any indication of what is to come if commercial importation is authorized, then this nation's medicine supply could be subject to compromise.

The following highlights additional findings regarding the Internet sale of prescription drugs.

- State programs facilitating the importation of drugs from Canada have not been without incident. In Wisconsin, a state-sponsored website facilitates the purchase of drugs from three mail order pharmacies in Canada. A report issued in August 2004 by the Pharmacy Society of Wisconsin noted that analyses of reports provided to the state from the Canadian pharmacies indicated that some of the drugs being imported did not comply with the requirements of the program. For example, some were improperly shipped (e.g., no refrigeration) and others were unapproved generics. One news report quoted the executive director of the

Society as saying that "almost a third of the drugs the Canadian pharmacies have dispensed were not (FDA) approved..." In addition, during the summer of 2004 the FDA conducted its own review of the packages coming from the Internet pharmacies participating in the Wisconsin program. Over a five-day period, the FDA found that almost 70% of the packages sent to Wisconsin consumers contained drugs that violated the agreement between the State and the Canadian Internet pharmacies.

- During the summer of 2004, the Government Accounting Office (GAO) issued two reports concerning this issue; both were presented to the Chairman of Permanent Subcommittee on Investigations, Committee on Government Affairs, U.S. Senate.

    - The first report, issued in June and entitled "Internet Pharmacies – Some Pose Risk for Consumers," detailed the findings from a study wherein the GAO placed orders over the Internet for a number of different drugs. It placed 90 orders for 13 distinct drugs with a mix of pharmacies, some U.S.-based sites, some Canadian-based sites and some "other foreign" sites. The GAO received 68 samples of 11 distinct drugs. Many of the problems identified were among drug samples received from the "other foreign" sites. The problems included the following: generally no prescription was required to order, many of the drugs were not properly labeled, many were not properly packaged or shipped, many were non-FDA approved drugs and two samples were counterfeit, having a lesser amount of the required active ingredient, and two samples had "significantly different chemical compositions" than the products ordered. Further, 16 of the 18 samples from the Canadian pharmacies were unapproved for sale in the U.S. for labeling and packaging reasons. This report suggests that as more and more Canadian Internet pharmacies seek to move their operations to Europe or other foreign countries and/or fill their prescriptions with drugs from foreign sources, the risks of receiving non-FDA approved or counterfeit drugs increases.

    - The second report, issued in July 2004 and entitled "Prescription Drugs – Preliminary Observations on Efforts to Enforce the Prohibitions on Personal Importation," identified problems encountered by the FDA, Customs and Border Protection and other federal agencies in monitoring the purchase of drugs over the Internet and shipped through the mail. The report acknowledges that the volume of non-FDA approved drugs coming into the U.S. is very large and increasing, that the authorities do not have the requisite resources to inspect a significant number of shipments coming into the country and that the ability to inspect the packages is hindered by the cumbersome processing requirements. As a result, tens of

thousands of shipments have been delivered to consumers even though they may contain drugs that pose health risks. This report also discussed the results of an analysis done by a Customs and Border Protection (CBP) laboratory in which 180 drugs coming through the mail were intercepted by CBP and the FDA. Of these, 5% of the drugs contained no active ingredient, 28% contained controlled substances that were prohibited for import and 68% were non-FDA approved.

- The FDA continued in its efforts to identify risks associated with the purchase of drugs over the Internet. In July 2004 the FDA, in a news release, delivered the results of analyses it had performed on "Canadian generic" versions of Viagra, Lipitor and Ambien that had been purchased from a website (since none of the drugs has a U.S. approved generic, all were unapproved). One, Ambien, was "super-potent," containing too much active ingredient, another, the "generic" Lipitor, was sub-potent, containing on average only 57% of the active ingredient stated on the label and the last, the "generic" Viagra, contained too little of the active ingredient and had an unacceptable level of impurities. Additionally, at a Senate hearing in July 2004, the FDA cited three examples that are illustrative of the point that a consumer cannot be assured of the veracity of the statements contained on the websites from which purchases are being made (the FDA had conducted a survey of Internet sites that appeared to be Canadian and analyzed a random sample of 106 sites): one Internet site advertised as being located in British Columbia, but the registrant was actually in the Czech Republic; another said it was located in Winnepeg, but the registrant was in Ho Chi Minh City, Viet Nam; and yet another purporting to be located in Canada, was registered in China, the drug ordered came in a package with a Dallas postmark and a Miami return address, the credit card was billed to St. Kitts and the phone number was in Belize.

- In testimony before the Senate Committee on Governmental Affairs on July 22, 2004, DEA Administrator Karen Tandy stated that "rogue Internet pharmacies pose a significant threat to lives and health across the country" and that in an "import blitz" conducted at international mail facilities by a task force comprised of several federal agencies, of 325 packages sampled, 132 contained controlled substances that had illegally arrived from Spain, India, the Netherlands, Belgium, Romania, Slovenia, Mexico, Argentina, and Brazil.

- The U.S. Department of Justice recently issued a press release regarding the conviction and sentencing of a California man for his role in operating one of the largest Internet pharmacy schemes ever prosecuted. The man operated an Internet pharmacy that did not require prescriptions in order to purchase drugs. Customers merely had to fill out a questionnaire and pay $35 for a doctor's consultation; however there was no doctor involved in the operation. The drugs were labeled

as "generic" even though some had no approved generic equivalent and contained active ingredients for Viagra, Cialis, Levitra and other drugs. It was reported that the drugs were manufactured in Mexico and contained ingredients that were shipped from China and India. As part of this press release, Michael Garcia, Assistant Secretary for U.S. Immigration and Customs Enforcement of the Department of Homeland Security, stated "The reality is, the quality and content of drugs sold over the Internet is a big question mark." In the same press release, another federal law enforcement official commented "illegal pharmaceutical distribution is a growing problem..."

- An article in the Sarasota Herald-Tribune recently reported that a mail order pharmacy, Canada Pharmacy Direct Inc., operating in that city was sending authorization forms to its customers seeking their approval to import drugs from Europe, New Zealand, and Australia. The same article recounted a story of a man who had ordered an anti-depressant from Canada that was shipped from Vanuatu, an island in the South Pacific. Reportedly, the box's label also mentioned both Australia and New Zealand. The medicine was ordered through a business in New Jersey.

- As was indicated by the information learned by the FDA, many of the websites claiming to be Canadian Internet pharmacies contain false or misleading information and may be conducting their operations using questionable business practices. Giuliani Partners learned from one independent review of a number of websites that claimed to be Canadian pharmacies that several were not what they claimed to be. Six websites in the Ontario region were randomly selected and the registered business addresses were visited. Surprisingly, each location turned out to be a private residence, one of which appeared to be a "call center" or location used solely for taking orders, given the equipment that was present within and around the residence. It remains unclear where the actual business was being conducted and where the drugs were coming from to fill the orders being placed.

It bears repeating, given all of the issues that were identified in the Interim Report and the information presented in this document regarding the purchase of prescription drugs over the Internet, significant safety concerns are evident. Consumers should be made more aware of the risks they are undertaking when they go online to make such purchases. As was stated in the HHS Task Force report: "Safety should not be sacrificed for affordability."

More About Counterfeits

As was noted in the Interim Report, counterfeit drugs continue to be found within the United States medicine supply as well as in other foreign countries. A U.S. News and World Report article on this subject stated that the drug market "safety net is increasingly

full of holes." Before any expansion of our drug distribution system is seriously contemplated, more should be done to identify such products and tighten the country's supply chain in order to prevent counterfeits from reaching pharmacy shelves. The following highlights additional information regarding counterfeit drugs.

- Notable cases of counterfeit drugs continue to compromise America's drug distribution system. Most recently, in an FDA Talk Paper issued in July 2004, the agency warned the public about counterfeit versions of the drugs Zocor (simvastatin) that contained no active ingredient and Carisoprodol, which had a different potency from the authentic version, being imported from Mexico by some Americans. Another case involved counterfeit Viagra that was found in two pharmacies in California in June 2004. The bad product was originally discovered by a patient, who notified Pfizer after becoming suspicious of the packaging. The second incident was discovered by a pharmacist who was alerted to the first case.

- For the first time in many years, England reported the discovery of several cases of counterfeit medicines. In late August 2004 the United Kingdom Medicines and Healthcare Products Regulatory Agency (MHPA) issued a warning about counterfeit Cialis, which had been found in circulation; one week later, the MHPA issued another drug alert and recall of an obesity drug, Redistill. In addition, a University of London study that analyzed samples of Viagra sold on the Internet and estimated that around half of the Viagra sold on the Internet could be counterfeit. As will be discussed later, this becomes important because many of the Canadian Internet pharmacies have publicly stated that they are sourcing some of their supply from England and other foreign countries.

- A news article reported that two Florida men recently plead guilty to federal conspiracy charges for admittedly running a large Internet pharmacy that sold counterfeit Viagra made by a San Diego based operation. It was reported that at least some of the pills were being manufactured in India.

More About Canada

Recent events concerning the implications of the "cross border drug trade" on Canada's medicine supply have received a great deal of media attention in the last few months. For the first time since mail order pharmacies began selling drugs to Americans from Canada, the Canadian government is publicly expressing its concerns about the impact of this business on the Canadian drug supply. Additionally, the Canadian government is considering taking steps to protect its supply. Given the apparent reluctance on the part of the Canadian government to continue to support this business, the importation of prescription drugs from Canada may not remain a viable option for those seeking to open the borders of the United States to drugs from that country.

Canada does not have the medicine supply or the infrastructure in its current pharmaceutical drug distribution system to supply the United States with its prescription medicine needs. This fact coupled with the information set forth below leads to the more obvious conclusion that the United States should address the issues associated with the access to safe and affordable medicines within its own borders. The following is a summary of the more significant recent events in Canada:

- The Canadian Minister of Health stated in a speech given at the Harvard Medical School on November 10, 2004 that "...Canada cannot be the drugstore of the United States." He also stated that that it was difficult for him to appreciate how a small country like Canada could satisfy the prescription drug needs of America without putting the Canadian supply "at serious risk." Such statements were a marked departure for the Canadian government. Prior to this, the government had been relatively silent on the issue, stating that it was monitoring the situation. These statements were also unusual because in Canada, healthcare is a provincial responsibility and the federal government does not typically get involved in provincial affairs.

- As a follow-up to his remarks at Harvard, the Canadian Minister of Health has indicated that he and the Canadian government are considering proposals to make it illegal for pharmacists to fill prescriptions for patients who have not been seen in person by a Canadian doctor; to prevent filling of prescriptions for foreigners who are not in Canada and to ban certain drugs from being exported.

- The Canadian Pharmacists Association released the findings of a study entitled "Administrative Burden on Canadian Pharmacists Due to Drug Shortages" in November 2004. Of the 218 community pharmacists that responded to the survey, 80% indicated that they had difficulty filling prescriptions and that drug shortages had become more frequent during the preceding 12 months. While the study acknowledged that there may be a number of variables causing a drug shortage, the cross border drug trade was identified as a possible factor.

- Canadian doctors are being penalized for inappropriately signing prescriptions for U.S. patients. One doctor from Surrey, British Columbia was suspended by the British Columbia College of Physicians and Surgeons for two years after admitting that he signed thousands of prescriptions for U.S. patients without first seeing them. Although it is not illegal for doctors to sign prescriptions for patients they have not personally examined, it is reported that most of Canada's 10 provinces and two territories have adopted professional standards, through the appropriate regulatory bodies, precluding such activity. Another doctor from Toronto who also co-signed thousands of prescriptions for an Internet pharmacy without first seeing the patients was recently found guilty of professional misconduct by the College of Physicians and Surgeons of Ontario.

- Most significantly, Canadian Internet pharmacies have publicly stated that they are moving their business to Europe; Examples include:

    - Internet pharmacist Darren Jorgenson, founder and chairman of canadameds.com said he "is dispensing drugs to Americans from almost 30 different countries including England, Malta, Australia, New Zealand, and Chile. It doesn't matter to Americans." In a more recent news article, Mr. Jorgenson stated that 50% of the prescriptions being filled by his pharmacy were coming from international pharmacies, primarily in Israel, Britain, Ireland and Germany. He also said they were ready to fill all of their prescriptions in this manner if the changes are made to the Canadian law. In fact, his website states "Not just from Canada anymore! Choose your country and your savings."

    - Another mail order pharmacy, TheCanadaPharmacy.com, was offering drugs from British pharmacies as early as last spring and was looking to add inventory from Australia, New Zealand, Israel and Chile. Similarly, news reports state that Mediplan Health Consulting Inc. of Manitoba is filling prescriptions with drugs from the British Commonwealth.

    - Another Canadian pharmacy, CanadaRX, has set up a distribution warehouse in Freeport in the Bahamas. It is reported that it was established to buy prescription drugs from European wholesalers for sale to Americans. A Boston Globe reporter who visited the operation noted that the shipping methods being used "are designed to evade detection by the US authorities." It was also reported that the drugs being shipped to Americans contained labels that were in French, Spanish and Italian.

    - Interestingly, although Ireland has been mentioned as one source of supply, one news report noted that the Irish Medical Board has indicated that it was not aware of any pharmacies that are participating in such a program and to do so without the proper licenses would be illegal; in fact the mail order of prescription products is illegal in Ireland. Some news reports indicated, however, that drugs may be lawfully shipped to other countries in Europe and then sourced to Americans who are making purchases over the Internet through Canada.

More About the Potential Exploitation by Organized Criminals, Drug Traffickers and Terrorists

As noted in the Interim Report, given the vulnerabilities that are present in the existing system, the potential exists for the nation's medicine supply to be exploited by organized criminals or drug traffickers or to be used as a vehicle for terrorist activity. Those shortcomings identified in the drug manufacture and distribution system must be realistically assessed, as does the fact that these systems are vulnerable to exploitation by terrorists as well as other criminal groups.

Terrorist groups, organized criminals and drug traffickers have already infiltrated the high-profit, low-risk counterfeit goods market to finance their operations. Recent articles in Business Week and Harper's Bazaar highlighted the links between counterfeit goods and terrorists and other crime groups. Unfortunately, the current prescription drug market poses few challenges for organizations that seek to develop counterfeit drugs or to divert legitimate product. There is considerable money to made in the prescription drug business (in 2002, the U.S. spent more than $162 billion on prescription drugs), the risk of getting caught is minimal, and even if caught, the penalties are low.

Further review has only enhanced the belief that the system is vulnerable to exploitation. Since the issuance of the Interim Report, the following information or activities have occurred or been discovered.

- In testimony before the United States House Committee on International Relations, Interpol Secretary Ronald K. Noble stated that the "the link between organized crime groups and counterfeit goods is well established" and that "intellectual property crime is becoming the preferred method of funding for a number of terrorist groups." Noble also said, "There are enough examples now of the funding of terrorist groups in this way for us to worry about the threat to public safety." He went on to say, "Law enforcement agencies have to recognize that Intellectual Property Crime is not a victimless crime. Because of the growing evidence that terrorist groups sometimes fund their activities using the proceeds, it must be seen as a very serious crime with important implications for public safety and security." Noble characterized the links between intellectual property crime and terrorist financing as either having "direct involvement" – the terrorist group is involved directly in the manufacture, distribution and/or sale of the counterfeit goods and use the proceeds to fund its activities - or "indirect involvement" – sympathizers are involved in the counterfeiting activities and channel funding to the terrorists groups to fund activities.

  News reports stated that Interpol documents presented to the U.S. House of Representatives Committee on International Relations indicated that a wide range of groups – including Al-Qaeda - benefit from funds raised by sympathizers.

The examples included: Al-Qaeda (counterfeit shampoos, creams, colognes and perfumes); Hezbollah (Interpol was aware of three cases involving intellectual property crime and terrorist funding in South America); Chechen separatists (counterfeit CDs); ethnic Albanian extremists in Kosovo (consumer goods such as CDs, DVDs, clothes, shoes, and computer software); paramilitaries in Northern Ireland (counterfeit cigarette trafficking); and North African radical fundamentalist terrorists in Europe. Each of these groups has been found to profit from the production or sale of counterfeit goods. Reports indicate that counterfeit products include pirated CDs and DVDs, clothing, computer software, cigarettes and pharmaceuticals. Mr. Noble also concluded that intellectual property crime is a low risk – high return activity due to the low penalties if caught and the high return in relation to the initial investment.

- The acting head of the Food and Drug Administration, in August 2004, stated in an interview that he was very concerned about terrorists tampering with the prescription drug supply of the United States, referring specifically to illegally imported drugs. At that time, however, a spokesman from the Department of Homeland Security indicated that although it is aware that Al Qaeda and other terrorist groups have studied agro terrorism, DHS had not received any specific information regarding a threat to the nation's food or drug supply.

- In testimony before the U.S. Senate Committee on Banking, Housing and Urban Affairs during a hearing on Terrorist Financing, Michael J. Garcia, Assistant Secretary, U.S. Immigration and Customs Enforcement (ICE), Department of Homeland Security, stated, in the context of discussing actions being taken by ICE to address terrorist financing, that ICE targets "methods that terrorist and other criminal organizations could use to earn funds through investigations of intellectual property rights violations, counterfeit pharmaceuticals, human smuggling, commercial fraud, export violations, and cybercrime."

- The Alliance Against Counterfeiting and Piracy, based out of the United Kingdom and comprised of members and organizations interested in combating intellectual property crime, issued a report entitled "Proving the Connection – Links Between Intellectual Property Theft and Organised Crime." The report states that there is strong evidence that "...organised crime [is] controlling, exploiting and benefiting from intellectual property fraud." It includes several examples to support the conclusion and cites to the UK's National Criminal Intelligence Service 2002 UK Threat Assessment which states "[m]any serious and organized criminals are involved, either in the manufacture of counterfeit products, or in their distribution, attracted by their high profits and low risk of detection, and no doubt conscious of the fact that the penalties for intellectual property crime offences are rarely more than minimal." The report also cites the Organised Crime Task Force in Northern Ireland and its Threat Assessment 2002 which reported that given the scale of

intellectual property theft in Northern Ireland (the Police Service of Northern Ireland seized counterfeit goods worth 6.7 million pounds in 2002) and the nature of criminality in that country, "it is inconceivable that terrorist organisations are not directly complicit." The Alliance report states that this Threat Assessment states that 34% of the organised crime groups in Northern Ireland were involved in product counterfeiting.

- The International Anti-counterfeiting Coalition, in a publication "Facts on Fakes" noted that the "[l]ow risk of prosecution and enormous profit potential have made criminal counterfeiting an attractive enterprise for organized crime groups." In addition, it cited a number of examples of cases which draw connections between organized crime and terrorist groups and counterfeiting, indicating that such groups use the sale of counterfeit goods to raise and launder money. Some of those examples involve counterfeit cigarettes, CDs as well as other commercial goods. A few are discussed below:

    - One BBC article discusses an investigation conducted by an Italian financial newspaper which reported that connections were found between a large shipment of counterfeit goods and the terrorist group, Al Qaeda. The shipment contained approximately 8 tons of counterfeit shampoo, face creams, Vaseline, cologne and perfume. It was being transported from Dubai to Britain through Demark and was seized in Copenhagen. The European Commission Customs Coordination Office confirmed that the man who had dispatched the goods had links to Bin Laden's group. In addition, a UN monitoring group indicated that Al Qaeda does in fact keep part of its funds in banks in Dubai.

    - An October 2002 Associated Press article reported that "U.S. authorities have several investigations under way examining evidence suggesting that Hezbollah, Hamas and other terror networks might be selling counterfeit products to pay for their worldwide activities. Terrorists are benefiting from counterfeit merchandise schemes..." quoted a U.S. government advisory. That same report noted that counterfeit operations in South America, near the tri-border region (Paraguay, Brazil and Argentina), may have been used to raise money to support terrorist operations and groups. It was reported as part of the AP story that counterfeit CDs were being sold to raise money for Hezbollah.

In the fall of 2004, a book, A Sick Business – Counterfeit Medicines and Organized Crime written by Graham Satchwell, a former detective Superintendent from the United Kingdom, was released. It documents an investigation he conducted for the Stockholm Network into the links between counterfeit medicines and organized crime and terrorism. He identifies a number of cases

that show a clear link between counterfeit medicines and organized crime and terrorism. Mr. Satchwell also identifies a number of issues with the current prescription drug market in the United Kingdom and Europe. For example, the book discusses parallel trade in the United Kingdom and Europe and mentions some of the risks associated with the practice. Mr. Satchwell notes that parallel trading of prescription medicines as it currently exists and the repackaging that is often necessary allows for the introduction of counterfeit goods, creates the potential for errors in translation as the drugs are traded among various countries. Also, given the process, i.e., multiple handling, the "sell by" dates could expire before reaching the consumer. He concludes that the more pharmaceuticals that are parallel traded the greater the risk of the introduction of counterfeits and that there is not sufficient attention being paid to this issue in the United Kingdom or Europe.

Along the same line, the President's budget provides for increases in funding related to bioterrorism and this month, Interpol hosted its first global conference on preventing bioterrorism. Furthermore, the Director of the Federal Bureau of Investigation, Robert S. Mueller III, stated in his testimony before the United States Senate Committee on Intelligence, when discussing the FBI's currents views regarding threats against the United States and how the organization is responding, that second among the three areas of greatest concern to the FBI is the "growing body of sensitive reporting that continues to show Al Qa'ida's clear intention to obtain and ultimately use some form of chemical, biological, radiological, nuclear or high-energy explosives (CBRNE) material in its attacks against America." And finally, a recent editorial in The New York Times regarding "Our Necessary Insecurity" noted, "the anthrax attacks of the fall of 2001 only began to suggest the devastating power of biological weapons. While officials are all too aware of the mortality rate that would follow an attack with weapons grade anthrax, smallpox or the plague, controls are still spotty. Lethal pathogens are too often stored in insecure laboratories."

The President's budget also proposes cuts to many of the FDA's inspection programs, including a 5.8% cut in foreign drug plant inspections. It seems contradictory to open the borders in a way that will make the nation's medicine supply less safe while at the same time devoting resources to protecting our borders from other threats.

While government officials continue to look for ways to secure American borders, on a daily basis tens of thousands of mail parcels and courier packages containing shipments of suspected prescription drugs ordered from the Internet go unchecked through the approximately 355 "ports of entry" into the United States. They are not inspected for a few reasons. For example, some of those operating Internet pharmacies have devised methods to conceal the contents of what is being shipped, and given the volume, those responsible for monitoring these imports simply do not have the resources to inspect even a fraction of the parcels in a meaningful way. Consequently, the drugs

being imported could be safe, but also they could be adulterated, unapproved, or counterfeit. Another fact to consider is the areas of the world that demonstrate an increase in the level of activity as it relates to counterfeit prescription drugs: China, Eastern Europe, South America, and certain parts of Asia, for example, Pakistan and India. In these areas intellectual property rights are compromised, counterfeiting is rife and terrorists and other crime groups often work together in furtherance of their respective goals. History has shown that terrorist groups often infiltrate an existing business network in order to finance their operations. It is not difficult to imagine that the Internet drug trade could be one such vehicle to either finance their operations or use as a method of attack.

Since we already know, for example, that the former Soviet Union devoted great effort to developing a ballistic delivery system for pathogens and that terrorists are capable of identifying weaknesses, like those that resulted in the September 11th attacks, it is not far-fetched to imagine terrorists deploying the easy flow of corrupted medicines. It is critical that existing issues with respect to the drug distribution system be addressed and that similar to the steps that are being taken to protect this nation's borders, steps should be undertaken to protect the nation's medicine supply.

Reports Show Questionable Economic Benefit From Importation

Although the economic implications relative to importation were not the primary focus of this review, it is difficult to discuss importation without addressing the cost of prescription medicines in some form or manner. Most would agree that the reason so many Americans, whether elected representatives or consumers, are turning to importation as the solution to the problem of the cost of prescription medicines in the United States is that due to price controls certain drugs are cheaper in Canada and other countries. On a case-by-case basis, that may be true. However, a number of studies indicate that the adoption of a system that resembles parallel trade and/or price controls, programs that, to simplify, are functionally equivalent to commercial importation, would not necessarily produce savings for patients similar to those being enjoyed by individuals importing prescription medicines independently. On the contrary, some studies found that patients would experience little to no savings. Instead, for example, the potential savings may go to the "middlemen," i.e., those involved in the distribution of the drugs, or to other third parties.

In addition, it has been reported that since it is likely that commercial importation would result in revenue losses for pharmaceutical companies, there would be a resulting negative impact on research and development in the long term. Fewer new and innovative medicines would be developed to treat existing and future ailments. And as stated in the HHS report, this would result in "reducing benefits to future drug consumers and adversely affecting public health." Finally, studies have found that commercial importation could also have a potentially negative impact on local economies. Reduced

investments in research and development could have an effect on how the pharmaceutical and biotechnology industries currently run their operations and could translate into lost jobs, and losses in personal income and tax revenues.

The following summarizes, in a very general way, the findings of some of these studies or reports. This discussion is not intended to be detailed or exhaustive since the pricing of prescription medicines in this country and around the world is a complicated issue, but it is intended to demonstrate a point: even though many of those who support a commercial importation program state that such a program will generate significant cost savings for consumers, the studies reviewed do not support this contention.

- Savings to consumers would be only one to two percent of their total drug spending, with most of the benefits going instead to third party purchasers like insurance companies and HMOs.[2]

- Patients receive little to no savings from parallel trade; parallel traders take in more of the profits as compared to others involved in the business; orders for prescription medicines from the manufacturers decline appreciably in destination countries; and source countries can experience product shortages.[3]

- Importation of prescription medicines from foreign sources could reduce incentives to invest in research and development (one study found a reduction in R&D spending by as much as 25% to 30%), thereby causing a reduction in the future supply of new drugs.[4]

- Price controls reduce revenues for drug companies, thereby discouraging investments in research and development, reducing the number of new medicines, and, in turn, impacting the health and longevity of Americans.[5]

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[2] "Report on Prescription Drug Importation." Department of Health and Human Services. December 2004 and "Would Prescription Drug Importation Reduce US Drug Spending?" The Congressional Budget Office. April 29, 2004.

[3] Panos Kanavos, PhD., Joab Costa-i-Font, PhD., Sherry Merkur, PhD., and Marin Gemmill, MA. "The Economic Impact of Parallel Trade in European Member States: A Stakeholder Analysis." The London School of Economics. January 2004.

[4] John A. Vernon, Ph.D. testimony before the US Senate Committee on Health, Education, Labor and Pensions hearing on "Importation of Prescription Drugs." May 20, 2004 and "Pharmaceutical Price Controls in OECD Countries – Implications for US Consumers, Pricing, Research and Development, and Innovation." The US Department of Commerce International Trade Administration. December 2004.

[5] John A. Vernon, Rexford E. Santerre, and Carmelo Giacotto "Are Price Controls Good for your Health?" The Manhattan Institute. December 2004 and Jacob Arfwedson. "Reimportation (Parallel Trade) in Pharmaceuticals" The Institute for Policy Innovation. July 15, 2004.

- Importation would result in a significant reduction (estimated to be a drop of $14.8 billion in the first 12 years after implementation) in pharmaceutical and biotechnology research and development leading to a decrease in the number of new drugs approved on an annual basis (an estimated 70% reduction in the first 12 years). A specific look at the impact on the state of Massachusetts, where an estimated 10% of the nation's pharmaceutical and biotechnology research dollars are spent, finds a loss of more than 3,900 jobs and a drop in economic activity worth $247 million by 2010. Similar findings were reported in a study that focused on the implications of such a program in Michigan.[6]

- Per capita spending on pharmaceuticals in Europe is 60% less than in the U.S. These savings, however, are not without consequence as the pharmaceutical research industry has shifted from Europe to the U.S. Similar research investments were made in the U.S. ($9 billion) as in Europe ($10 billion) in 1992. By 2002, however, the U.S. had outstripped Europe as the recipient of investment dollars ($26 billion as opposed to $21 billion in Europe). Drug launches followed a similar trend: Europe launched 81 new products between 1993 and 1997, while the U.S. launched 48. From 1998 to 2000, Europe launched 44, while the U.S. launched 85.[7]

Setting aside the safety issues for a moment, it remains unclear that a commercial importation program will yield the anticipated benefits; however, it may have a number of significant consequences. Those findings regarding the legalization of an importation or price control program include: that consumers may not necessarily realize a meaningful cost savings in the long run; that it will have a negative impact on the revenues of the pharmaceutical companies; that as a result, there will be reduced incentive to invest in research and development; that in turn, there will be fewer drugs on the market; and with fewer new and innovative drugs on the market, the health and longevity of Americans will be negatively affected. Further, reduced investments in research and development may result in lost jobs and income. Given that importation might curtail the research and development of future medicines over the long term, yielding significant societal and monetary costs, the short term savings that may be realized from importation, if any, should be carefully weighed against the long term costs.

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[6] David G. Tuerck, John Barrett, Douglas Giuffre, and Zaur Rzakhanov. "The Impact of Drug Reimporation and Price Controls: The US and Massachusetts." The Institute for Policy Innovation. September 9, 2004 and Dr. Dean G. Smith, "Prescription Drug Importation, Investment and Employment in Michigan." Department of Health Management & Policy. The University of Michigan. August 18, 2004.
[7] Jim Gilbert and Paul Rosenberg, Bain & Company, Inc. "Addressing the Innovation Divide." World Economic Forum. Davos, Switzerland. January 22, 2004

RECOMMENDATIONS

Based upon the findings, a number of steps should be considered in order to ensure that every possible effort is made to adequately protect this nation's medicine supply. The questions and issues related to the safety of imported medicines are real and should not be dismissed. Accordingly, the following recommendations are offered:

- The safety of this nation's medicine supply cannot be assured without investing significant resources into an already overburdened system. Thus, the vulnerabilities that exist in the current system should be addressed. The FDA, Customs and Border Protection and other regulatory entities should be provided with the authority and the resources necessary to ensure that the "gold standard" is not compromised further. For example:

    - An effective pedigree requirement should be implemented – a system needs to be implemented that provides for the documentation and verification of each transaction involving the sale, transportation, exchange and/or distribution of prescription medicines from point of manufacture to point of sale. In the absence of the federal system, states may also wish to consider passing laws requiring such pedigrees. See, for example, Florida's law, which includes a paper pedigree system and/or the California law, which requires electronic pedigrees for dangerous drugs by 2007. Additionally, every effort should be made to develop and implement system-wide RFID or other electronic "track and trace" technologies, such as the program being used by Purdue Pharma L.P. and Wal-Mart.

    - The "secondary wholesale" market as well as repackaging operations should be reviewed and consideration should be given to strengthening federal requirements for wholesalers and distributors.

    - Consideration should be given to improved enforcement efforts and enhancing or increasing the penalties for counterfeiting or otherwise tampering with the nation's medicine supply.

    - Consideration should be given to developing and implementing uniform standards for the operation of Internet pharmacies – such as the program developed by the National Association of Boards of Pharmacy VIPPS (Verified Internet Pharmacy Practice Sites) Program.

- Given the critical role that medicines play in the overall health care of the people of this country, a threat and vulnerability assessment of the nation's medicine supply should be conducted by the Department of Homeland Security. In

February 2003 The National Strategy for The Protection of Critical Infrastructures and Key Assets was released by the President. The document identified a number of America's critical infrastructures and key assets and outlined guiding principles for protecting those entities from terrorist attack. Public Health was identified among the critical infrastructure sectors that had "major protection initiatives" identified. It did not appear from the discussion of the challenges and initiatives set forth in the report that particular consideration was given to the safety and security of the nation's medicine supply. This assessment should be conducted in concert with other relevant agencies and should be undertaken as quickly as possible.

- At the same time as efforts are underway to address the safety issues associated with the current system, doctors, healthcare professionals and consumers need to be better educated regarding the options that are available to access cheaper medicines, such as drug discount cards or other patient assistance programs. Examples include:

    - The Medicare Discount Card – This is authorized by the Medicare Prescription Drug Improvement and Modernization Act of 2003 and is designed to give immediate relief to Medicare-eligible seniors and disabled persons.

    - Discount Programs Operated by States, Municipalities and Pharmaceutical Companies – Approximately 49 states, Washington D.C. and many municipalities have programs that guide individuals to lower cost prescription drugs that do not involve importation. In addition, there are a number of industry sponsored websites that assist patients or health care providers with locating cheaper medicines. Examples include:

        - HelpingPatients.org is an interactive website that helps to direct patients to patient assistance programs that would be most helpful to them. It is a comprehensive, one stop link to thousands of medicines offered through hundreds of patient assistance programs sponsored by pharmaceutical companies, governments, and local organizations.

        - TogetherRX Access Plan – offers discounts of 25% to 40% on 275 products for people younger than 65 who do not have prescription insurance or Medicare and meet certain income limits.

- Comparison Shopping Programs – Several states and organizations have programs that offer price comparisons on prescription drugs and that may assist patients locate the lowest cost prescription medicine in a geographically convenient location.

- Greater consideration should be given to use of generic alternatives.

- There is a need to develop a system to assess whether, and the extent to which, people are being harmed as a result of importing drugs from foreign sources. Currently, there is no formal mechanism in place to adequately quantify the problem. Thus, an effort should be undertaken by the healthcare and medical profession to attempt to identify the scope of the problem. For example, consideration should be given to modifying emergency room, medical examiner and doctor protocols urging that the following questions be asked. Where are the prescription medicines being purchased and are they available for testing. Included within this assessment should be an effort, as difficult as it might be, to determine whether a disease has progressed because the product was ineffective. In addition, consideration should be given to modifying the FDA's "MedWatch" system, which tracks adverse events involving FDA-approved products, in order to capture additional information related to this issue.

- Consumers must be made more aware of the risks associated with importing medicines from foreign sources. Not only is there a risk from the compromised quality of the product they may be receiving, but also there may be serious heath implications if their doctors and/or pharmacists are not aware of all of the medicines they are taking. In addition, because current legislative proposals extend beyond Canada, for example, proposing importation from 25 or more countries, a study should be undertaken, similar to that which was conducted by the HHS Task Force regarding Canada, to assess the feasibility and the risks associated with such a program. Patient safety requires no less.

- Access to safe, effective and affordable medicines is a significant issue for many Americans, particularly the uninsured and the underinsured, and it should be addressed; but importation is not the answer. In order to reduce reliance on importation and create greater access at more affordable prices, there needs to be a candid discussion among the pharmaceutical companies, the health care industry, governments and trade organizations, consumer groups and other interested parties regarding the cost and accessibility of prescription medicines in the United States and abroad.

This report is not the first to include recommendations to address the issues raised regarding the vulnerabilities in the existing system, the issues associated with counterfeit goods worldwide or the risks associated with importing drugs from foreign sources. For example, the FDA's Counterfeit Drug Task Force issued a report last year entitled "Combating Counterfeit Drugs: A Report of the Food and Drug Administration" which contained several recommendations worthy of consideration; a Florida Grand Jury convened to study the safety of prescription drugs in Florida issued a report containing a number of recommendations related to improving the drug distribution system in that state as well as around the country; and although not specific to pharmaceuticals, the World Customs Organization and Interpol have been working on a series of proposals to combat counterfeiting worldwide. Each merits further consideration and attention.

CONCLUSION

The review completed by Giuliani Partners identified a number of serious risks associated with the importation of non-FDA approved medicines from foreign sources. The evidence is overwhelming. The information and findings clearly demonstrate that this country should not establish a commercial importation system. It would compromise patient safety and expose the nation's medicine supply to exploitation by organized criminals and terrorists. All Americans deserve access to safe, effective and affordable prescription medicines. But it became very clear during this review that safety and effectiveness cannot be assured through an importation program.

Careful consideration should be given to the following:

- The weaknesses in the existing system are well documented. Not only this report but the HHS Task Force and others have identified a number of problems that must be addressed to maintain the "gold standard."

- Incidents involving counterfeit drugs are on the rise and the World Health Organization estimates that as much as 10% of the world's medicine supply is counterfeit. By expanding the sources for drugs, it will be harder to ensure authenticity and chain of custody. The risk to patient/consumers of receiving some of that counterfeit product increases proportionally.

- The Internet mail-order pharmacy business has exposed a number of safety concerns, from the quality and source of the product being ordered to the difficulties associated with oversight.

- The Canadian government has expressed concerns about the impact of the cross border drug trade on its supply and has stated that Canada cannot serve as America's drugstore. Further, more and more Canadian Internet pharmacies have publicly stated that they are filling orders with drugs from other countries.

Patients cannot assume that the drugs they receive are identical to what they would get in the United States.

- We must learn from experience regarding the actions of organized criminals, drug traffickers and terrorists. Such groups have already infiltrated the high-profit, low-risk counterfeit goods market to finance their operations. Given the shortcomings identified in the existing drug manufacture and distribution system, it could be vulnerable to exploitation by terrorists and other criminal groups.

- Saying that a commercial importation program is safe does not make it so. Many of the safety features being discussed in the context of pending importation legislation are not necessarily reliable:

    - There currently exists no national pedigree system, notwithstanding the fact that the law has been in place for more than 15 years. Meaningful ways to "track and trace" medicines electronically, while being used successfully in a few places in the system, are still a few years away from system wide implementation (estimates range from 18 months to several years).

    - Existing anti-counterfeiting technology is a delaying tactic at best, since advances in technologies enable counterfeiters to produce better copies of products and packaging in a more timely fashion.

    - It is estimated that the FDA resources required to implement a safe system will cost billions. Even if the resources were available, it is questioned whether the FDA would have the necessary authority to perform the required inspections in other countries. We cannot and should not rely on other countries to perform these tasks for us. As was stated in the HHS Task Force Report and by Canada as well, foreign governments are primarily concerned with the safety and effectiveness of the drugs sold to their own citizens, not necessarily those that are being exported to other countries.

- Furthermore, studies find that the primary reason for importing medicines from foreign sources - saving consumers money on the cost of their prescription medicines – may not necessarily be achieved in the long run.

Based upon what has been learned during this review, importation from foreign sources is likely to result in increased risk, including increased opportunity for the introduction of counterfeit and other sub-standard medicines into the nation's medicine supply. It is evident that the risks are too great and that there are simply too many unanswered questions and outstanding issues to contemplate such a program.

Fix the existing system. Ensure that it is not vulnerable to exploitation by terrorists and other criminal elements. Utilize existing discount programs to provide patients with the medicines they need. And relevant parties should engage in a candid discussion about the cost of prescription medicines in the U.S. and abroad. Importation of non-FDA approved prescription drugs from foreign sources is not the answer.

GIULIANI
PARTNERS

Giuliani Partners LLC
Examination and Assessment of
Prescription Drug Importation From Foreign Sources
To the United States

Interim Findings
May 11, 2004

INTRODUCTION

The availability of safe, effective and reasonably priced medications for all Americans is at the center of an important, ongoing debate regarding our health care system. As the costs of medicines have increased, so has the focus of pricing on this debate. Individuals and even local and State governments have sought alternative means to obtain necessary medicines at lower costs, and these initiatives have further narrowed the debate to the value of importing Canadian or foreign medicines into the United States.

However, the safety and efficacy of these same imported medicines has received less attention and focus and is often overshadowed or even ignored by the pricing issue. From the outset, there is little dispute that the high price of many prescription medicines becomes an impediment to access. And while the price of today's medicines exist in part to provide for the development of tomorrow's cure, patient access should be expanded by exploring methods for lowering costs for those in need.

Giuliani Partners LLC has been retained by the Pharmaceutical Research and Manufacturers of America (PhRMA) to evaluate the risks, if any, associated with the importation of Canadian and foreign medicines.

In recognition of the public health implications associated with importation, and at the request of Congress, the United States Department of Health & Human Services has convened a Task Force on Drug Importation to examine these very concerns. Acknowledging the importance of this issue to the public, the Task Force is working with great alacrity to provide its recommendations to HHS. Giuliani Partners LLC will be providing the Task Force with a more detailed report encompassing our preliminary findings and conclusions as part of our effort to inform this critical debate and to assist the Task Force in its work. For now, we have made a series of interim findings that are worth discussing today to widen the lens through which the issue of the importation of drugs is viewed, and consequently address the equally important issues of safety and risk in the Task Force's assessment.

It is important to note from the outset that there appears to be a fundamental misunderstanding about the source of the less expensive drugs at the center of this discussion. Initially, this debate was framed around "re-importation" – in other words, the importation (from Canada) of medicines manufactured under U.S. Food and Drug Administration (FDA) oversight and now available at a lower cost via Canada. Under such a system, a patient could reasonably assume that the medicine was safely and properly manufactured under FDA oversight without corruption in the supply chain. However, that is not necessarily what is occurring. Instead, U.S. patients are receiving medicines from foreign countries (albeit ordered through Canada or sources purporting to be Canadian based) that were manufactured or re-packaged without any oversight by the FDA or Health Canada (the Canadian FDA counterpart).

Indeed, several U.S. States that provide links to websites for their citizens to order "Canadian" drugs have graphic disclaimers disavowing any warranty about the product and relinquishing the state government from any legal liability with regard to the product or care from the on-line pharmacy. In some instances, the Canadian pharmacy website requires the patient to sign a waiver that denies the patient any legal recourse in the U.S. for harm caused by these imported drugs. The current U.S. regulatory process, while not perfect, protects patients seeking medicines from U.S. pharmacies. This raises an important question that must be reviewed when assessing the relative risks associated with obtaining imported medicines against the potential rewards of lower prices.

Product Quality: What Is In Our Medicine?

When a patient seeks to fill a particular prescription for a particular medicine, there is an assumption that the medicine is in the exact form, quality, potency and dosage as directed by the patient's physician. Anything less constitutes a risk to that patient's health and well-being.

Based upon our review to date, we have found that some patients who believe they are purchasing re-imported Canadian medicines are in fact receiving non-FDA approved drugs from foreign countries that are not at all what they claim to be. There is significant evidence that patients have received drugs through the Internet that are past their expiration date, are sub-potent (or, in some cases, more potent than indicated), contain the wrong dose, are contaminated or clearly counterfeited, are not properly stored or shipped (i.e. medicines that require constant refrigeration or others that must be protected from freezing) among other problems. We have found that medicines ordered over the Internet that purport to be manufactured under FDA oversight or delivered through Canadian pharmacies are in fact manufactured in countries such as Pakistan, China, Iran, Singapore and many others. The fundamental question of product quality and integrity must be at the center of this important discussion.

Set forth below is an outline of the review we have undertaken. Significant questions are raised regarding the level of safety for patients and indeed for our nation from the relaxation of importation controls. It is vital that the Task Force and others carefully and thoughtfully consider all of these legitimate concerns so that our health care system can be as safe, effective and accessible as possible.

SYSTEMIC ISSUES

The American system for manufacturing, distributing and selling prescription medicines is significantly regulated and often referred to as the "gold standard." Notwithstanding this fact, however, there are identifiable weaknesses in this process that can compromise the quality and integrity of our medicine supply.

The Distribution Chain

On its face it appears that the distribution chain for prescription medicines in the United States is fairly straightforward – manufacturers sell their products to wholesalers, who in turn sell the products to retail pharmacies or stores, who in turn dispense medicines to patients with prescriptions. It is not until the system is studied in greater detail that one begins to appreciate both the complexities and the vulnerability of the distribution chain and the potential for exploitation or abuse.

Some contributing factors are as follows:

- Wholesalers or distributors are primarily regulated by the states with no uniform standards across state borders. States have a comparatively small number of investigators to monitor the licensed wholesalers; thus, given the sheer number of wholesalers, oversight is minimal.

- There are thousands of "secondary" pharmaceutical wholesalers in addition to McKesson, AmerisourceBergen and Cardinal Health (the "big three") involved in the distribution of prescription medicines. As reported in The Washington Post, there are more than 6,500 small wholesalers nationwide.

- There is no uniform mechanism, i.e., a chain of custody or "pedigree," to track the medicine from point of manufacture to point of sale; the FDA has not implemented the pedigree requirement that was mandated by law in 1988.

- Repackaging is a vulnerable point in the process and can provide an opportunity for counterfeit or non-FDA approved products to compromise the system.

Report of the Florida Grand Jury

Two years ago the State of Florida convened a statewide Grand Jury to examine the safety of prescription drugs in Florida and to analyze the sale and resale of prescription drugs in the wholesale market. The report, released in February 2003, found an overwhelming need for tighter regulation and oversight of the pharmaceutical distribution industry. Many of those interviewed by Giuliani Partners indicated that the problems identified in the Florida Grand Jury Report are pervasive throughout the United States. A summary of the Grand Jury's findings follows.

- Oversight of the system is lax.
  - Minimal background checks are required for licensing wholesalers and warehouse operators were found to be uneducated amateurs, some with criminal records.
  - Corrupt wholesalers are neither investigated nor prosecuted.
  - Despite existing requirements, drugs are being distributed with either incomplete or, in many cases, non-existent pedigree papers to document the products' supply chain history.
  - Inspection of wholesaler operations by the appropriate authorities and oversight by responsible agencies is spotty at best.

- Funding for oversight agencies is inadequate.
  - The Florida Bureau of Statewide Pharmacy Services employs only nine field inspectors to inspect 422 wholesalers statewide.

- Product quality is compromised.
  - Widespread problems with the quality and integrity of the secondary wholesale drug supply were found to include:
    - expired drugs re-labeled with falsely extended dates
    - previously dispensed medicines
    - illegally imported drugs
    - sub-potent drugs
    - drugs that contained an entirely different substance from the one listed on the container's label

- Health risks are significant.
  - The mainstream market is compromised by corrupt, secondary wholesalers. Diverted drugs are often combined with counterfeit medicines or re-labeled or repackaged. Then, these compromised drugs enter the mainstream market through corrupt secondary wholesalers and are dispensed by legitimate pharmacies, hospitals or clinics. By way of example, a father in Michigan who thought he was injecting his son with a

growth hormone later found that the vials actually contained insulin. These drugs were traced to a legitimate pharmacy in Orlando, Florida.

- Incentives for counterfeiting and diversion are considerable.
    - The huge profits derived from these activities rival those of illicit narcotics traffickers, while the penalties are minor by comparison.

Challenges to Oversight and Enforcement

There are challenges associated with the oversight and enforcement of our current laws with regard to ensuring that medicines being purchased or sold in this country are FDA-approved, safe and effective.

- The current volume of parcels of drugs coming into this country through the mail (it is estimated to be more than 10 million packages annually) and the increasing volume of Internet purchases make meaningful inspection by the FDA almost impossible.

- The FDA has less than 100 investigators to deal with drug importation issues nationwide, and its investigative authority is limited relative to its ever-increasing law enforcement responsibilities. For example, the FDA has no administrative subpoena authority in order to facilitate the conduct of its investigations; thus it must either partner with another investigative agency or request subpoenas from the local United States Attorney's office.

- Investigating and prosecuting counterfeit drug cases or illegal Internet sales cases are not, with few exceptions, a priority for the federal or state law enforcement agencies.

- The penalties are comparatively low for engaging in this kind of activity – the current penalties for FDA violations are approximately 3 years.

- The technologies being advanced as mechanisms to ensure an imported drug shipment is safe and effective are not foolproof, and, in some instances, not yet available.
    - Electronic Track and Trace – most agree that these technologies, e.g., using bar coding or radio frequency identification (RFID) chips that could track drug products in real time throughout the system and then provide an electronic pedigree, are still very costly when available.
    - Counterfeit resistant technologies that include covert and overt packaging and labeling techniques, such as holograms, watermarks, color shifting inks or fluorescent inks, as well as chemical agents, are widely used by the

industry already. However, they can be easily duplicated and, therefore, must be changed on a periodic basis.
  - "Unit of Use" packaging, which is a container closure system designed to hold a specific quantity of drug product for a specific use and dispensed to a patient without any modification except for appropriate labeling, does eliminate the need for some repackaging; however, there are packaging and cost issues for the manufacturers, and some drugs do not lend themselves to such packaging.
  - Authentication testing, while not a technology *per se*, is also an option when determining the integrity of a pharmaceutical product. It is a complicated, time consuming and costly process, however, and can be performed only by the original manufacturer. There are no available tests that can be conducted "in the field" to ascertain whether a product is real or fake.

These factors, among others, make it a high profit, low risk business for the counterfeiters or those involved in circumventing the laws in supplying medicines outside the traditional distribution chain, and, therefore, it may be appealing to organized crime and terrorist organizations.

PRODUCT QUALITY

Weaknesses in the existing system already threaten the quality and integrity of the nation's drug supply. Despite best efforts, the evidence we have seen thus far supports the notion that the drug supply is indeed vulnerable. Some examples are as follows:

Random Examinations Conducted by the FDA and U.S. Customs and Border Protection

The FDA and U.S Customs and Border Protection conducted a number of random inspections or "blitzes" at several mail ports in the fall and early winter of 2003.

- In the first inspection, 1,153 drug products were examined and 1,019 or 88% were not approved by the FDA; the drugs came from countries such as India, Thailand, and the Philippines.

- In the second exam, 1,982 parcels were examined and 1,728 or 87% were not approved; 16% of those shipments were from Mexico.

- Many of the drugs examined during these visits were non-FDA approved for many reasons, including:
  - improper labeling, e.g., there were no instructions for proper use;
  - the presence of controlled substances;

- potentially recalled drugs, e.g., drugs that had been withdrawn from the market for safety reasons;
- animal drugs not approved for human use;
- drugs requiring risk management and/or restricted distribution (e.g., initial screening or periodic monitoring); drugs with clinically significant drug interactions; or drugs requiring careful dosing; and
- required special storage conditions for certain drugs were violated.

Portal Visits

In order to gain an appreciation for the scope of the problem, United States mail facilities were visited to observe the volume and nature of the packages allegedly containing prescription drugs entering the United States. A number of the observations follow.

John F. Kennedy Airport Mail Facility

At the invitation of United States Senator Norm Coleman, former New York City Mayor Rudolph W. Giuliani and former New York City Police Commissioner, Bernard B. Kerik, accompanied the Senator on a visit in March, 2004 to the US Mail facility located at JFK Airport. Customs officials advised that approximately 40,000 packages of suspected drug shipments are received each day from the postal service for review and inspection. Based upon information, the FDA focuses on "countries of interest" and visually inspects 500 to 700 parcels per day. Thus, the majority of packages are sent on to the addressee uninspected. The following was learned:

- Drugs purported to be Xanax, Valium (Diazepam), Lorazapam, Vicodin (all controlled substances) and Lupron were observed; there were numerous packages from the Netherlands, Brazil, Pakistan, as well as other countries.

- Many of the drugs contained in the parcels were non-FDA approved because they were inappropriately packaged, expired, mislabeled or otherwise noncompliant.

- The sheer volume of shipments overwhelms Customs and FDA; FDA has only 6 staff members assigned to JFK.

- Although much of what is inspected is non-FDA approved, few parcels are actually detained. The processing requirements to detain a shipment are cumbersome and time consuming. The rules require the FDA to send a notice to the addressee of the package. If the person does not respond or the response is insufficient, the package must then be returned to the sender (manufacturer). This process varies significantly from the way controlled substances or narcotics are handled. Such drugs can be destroyed without further processing.

Miami International Mail Branch Facility Visit in March 2003

Giuliani Partners was provided with a Congressional staff report regarding a similar review of the Miami facility in March 2003. The findings of the bipartisan Congressional report were consistent with the findings of this review:

- Congressional staff witnessed "thousands of shipments of foreign drugs" being processed; the packages were from countries such as Honduras, Costa Rica as well as Great Britain; and the packages purportedly contained "valium" (diazepam), Reteina (Ritalin), Zolipedem, and Ciprofloxacin.

- The volume of drugs coming through the mail facilities is too great to allow for any meaningful inspection.

- Parcels are only visually inspected; there is no testing as to the quality or integrity of the product.

- FDA and Customs detain very limited numbers of questionable drugs coming into the facility because of the cumbersome nature of the detention process.

The Increase in Counterfeit Drugs

- Most of those interviewed by Giuliani Partners agreed that:

    - The number of incidents involving counterfeit medicines is increasing;
    - The increased use of Internet sale and purchase is exacerbating the problem;
    - The counterfeiting techniques are becoming more sophisticated and harder to detect;
    - There are vulnerabilities in the current distribution system that contribute to the problem; and
    - Opening the borders for wholesale importation will worsen the problem.

- The former Commissioner of the FDA, Dr. Mark McClellen, testified before the U.S. Senate Committee on Commerce, Science and Transportation on March 11, 2004 that the FDA has seen its number of counterfeit drug investigations increase four-fold since the late 1990's. "Although counterfeiting was once a rare event, we are increasingly seeing large supplies of counterfeit versions of finished drugs being manufactured and distributed by well funded and elaborately organized networks."

- On its website, the World Health Organization (WHO) states that while the true extent of the problem of counterfeit drugs is difficult to know or measure, they have estimated that at least 8% – 10% of the world's total drug supply is counterfeit.

- An August 30, 2002 Washington Post story cites the Shenzhen Evening News in reporting that an estimated 192,000 people died in China in 2001 because of counterfeit drugs. Another news story reported that as much as 50% of China's drug supply is counterfeit (Investor's Business Daily dated October 20, 2003).

Reported Incidents of Adverse Effects

Without question, the most frequently asked question by proponents of importation is "who is really being harmed by the purchase of medicines from outside of the United States?" There appears to be no easy answer to the question. Because receipt of imported medicines is unregulated, there are no systems in place to effectively monitor whether injuries result from the taking of compromised medicines. When complications arise from taking imported medicines and a patient does consult with his or her doctor or reports to an emergency room, no one is asking the question 'where do you purchase your prescription medicines?" Patients are also reluctant to report adverse reactions that may be attributable to medicines illegally purchased from outside the country.

Given these circumstances, coupled with the systemic challenges discussed earlier, it is difficult to ascertain the actual source of an imported drug. The following are some examples of actual incidents where people taking medicines with undocumented origins were adversely affected as a direct result of taking the prescription drugs. These cases represent the dangers of obtaining drugs from sources outside of the United States' closed system.

- In La Mesa, California, Ryan T. Haight, 18, died in his bedroom of an overdose after taking narcotics obtained on the Internet. After his death, his parents found a bottle of the painkiller Vicodin in his room with a label from an out-of-state pharmacy. An investigation by federal drug agents showed that the teenager had been ordering addictive drugs online and paying with a debit card his parents gave him to buy baseball cards on eBay. (Washington Post, October 19, 2003)

- In Sacramento, California, James Lewis, 47, a former triathlete, shopped the world for painkillers that flowed unimpeded from pharmacies in South Africa, Thailand and Spain. His wife discovered him dead of an overdose on the living room couch. (Washington Post, October 19, 2003)

- A 15-year-old paraplegic boy went into convulsions and died after taking a non-FDA approved drug called Lincocin which had been smuggled in from Mexico. (Los Angeles Times, March 10, 2001)

- Juris Abolins, 43, used painkillers off and on for years to treat pain from kidney stones. His roommate found him slumped on his bedroom floor dead. An autopsy revealed the presence of controlled substances in his blood stream. Relatives found a Federal Express slip for drugs purchased from a website in Tijuana, Mexico. (Washington Post, October 19, 2003)

THE INTERNET

Over the past several years, hundreds of websites have appeared on the Internet selling prescription medicines. While some sites provide legitimate prescription services, many sites are illegitimate and pose significant risks to all patients who use them.

Private Investigation Regarding Internet Purchases

A security and investigative firm based out of New York City, Beau Dietl & Associates, conducted an investigation regarding the importation of foreign medicines and reported its findings in December 2003. The results were disturbing:

- More than 1400 websites were identified as selling prescription drugs.

- 352 of those sites did not require a prescription when ordering.

- 142 of 170 orders were placed without a prescription and at the time of the report, 79 orders were filled without a prescription.

- Many of the medicines received were not only shipped in improper packaging but came from foreign countries such as Pakistan.

- An order for Ciprofloxacin was placed, received and tested. It was determined to be only 65% potent.

- The investigation found that website operators were often difficult to identify and trace; and some of those identified were found to have questionable backgrounds:
    - One website owner/operator was a convicted felon;
    - Other website owners could not be traced because the registration information was false;
    - Many sites failed to comply with legal requirements – doctors wrote prescriptions without ever meeting the patient; and one Internet doctor was a convicted sex offender.

- Websites were easily established with no minimum qualifications, standards, or oversight.

- Once the websites were established, emails were received from various suppliers offering to provide medications from "several countries," or "bulk meds from Pakistan" for resale in the U.S. market.

The results of this investigation offer a troubling snapshot of the nature of the Internet pharmaceutical business.

The CASA White Paper

The National Center on Addiction and Substance Abuse at Columbia University, under the direction of Joseph Califano, former Secretary of the Department of Health, Education and Welfare, the predecessor of the U.S. Department of Health and Human Services, released a study in February 2004 regarding the sale of controlled, dangerous and addictive prescription drugs in America. It looked particularly at Internet sales and teamed with the same New York City investigative firm to conduct the review. CASA characterized its findings as "alarming."

During a one-week period of observation, the firm identified a total of 495 web sites offering Schedules II through V controlled substance prescription drugs. Examples of the controlled substances available online included painkillers, stimulants, and nervous system depressants.

- Of the 157 sites selling controlled substance prescription drugs on the Internet
    - 90% (141) did not require a prescription
    - 4% (7) required that a faxed prescription
    - 2% (3) required that a mailed prescription
    - 4% (6) made no mention of prescriptions

- Of the sites, 47% disclosed that the drugs would be coming from outside the United States; 28% stated the drugs would be shipped from a US pharmacy; and 25% gave no indication where the drugs would be coming from.

- The analysis determined that there were no mechanisms in place to block children from purchasing these drugs.

Canada – The Implications of Importation

It is generally agreed that prescription medicines purchased by Canadians in a Canadian drug store are safe and effective. Like the United States, Canada has a system

of regulatory controls over its medicine supply. However, the same cannot be said for the drugs that are being imported to Canada and then exported. In fact, the Canadian government is not inspecting those medicines that are being imported to Canada and then exported to the United States. The Canadian government has clearly stated that it would not be responsible for the safety and quality of prescription drugs exported from Canada into the United States or any other country. Furthermore, the Canadian Food and Drug Act does not apply to any packaged food, drug, cosmetic or device not manufactured for consumption in Canada and not sold for consumption in Canada.

With respect to the question of drug supply capacity, it is undisputed that Canada does not have supply sufficient to provide for its residents and Americans as well. (In 2002, 3.1 billion prescriptions were filled in the U.S. compared to 335 million prescriptions filled in Canada.)

According to information provided by Industry Canada, a department of the Canadian Federal Government, from September 2002 to September 2003, there was a significant increase in drugs imported into Canada from the following countries:

- Singapore up 30%
- Ecuador up 198%
- China up 43%
- Iran up 2,753%
- Argentina up 221%
- South Africa up 84%
- Thailand up 52%

Prudential Financial, Inc. released similar findings, stating that Canadian Internet pharmacies were increasingly obtaining their product from other countries such as Bulgaria (exports to Canada up 300%), Singapore (up 101%), Argentina (up 171%), South Africa (up 114%), Pakistan (up 196%), as well as others. Further, some Canadian pharmacies, such as Canadameds.com, have publicly indicated that because of the increasing demand from the United States, they are turning to Great Britain for prescription drugs.

THE POTENTIAL FOR EXPLOITATION BY NARCOTICS TRAFFICKERS, ORGANIZED CRIMINALS AND TERRORISTS

The terrorist attacks of September 11, 2001 demonstrated how vulnerable this country is to those who have total disregard for human life or who mean us harm. Since that time, the United States has invested billions of dollars to protect our borders. Despite all that has been done, we have not focused on the vulnerability of the nation's medicine supply as a potential target. The present controlled system of importation and

inspection is open to exploitation and abuse. Any further removal of controls, much less the total opening of the borders to foreign drugs, would create a situation that terrorists, drug dealers and organized criminals might well use to their advantage. It seems counter-intuitive to contemplate opening our borders with regard to our medicine supply when in all other aspects of border security and protection, we as a country are looking for ways to tighten security.

A July 22, 1998 story in Insurance Day, while reporting on pill piracy and the World Health Organization's efforts to confront pharmaceutical fraud, stated that "Interpol believes that this aspect of the drug trade is closely connected with the narcotics cartels and that the profits generated by it are in part used to finance international terrorism." The article further stated that Interpol had been following the global counterfeit drug racket for some time and based its belief on evidence uncovered by police in North America and Western Europe.

Further, in her book, Funding Evil, How Terrorism is Financed – and How to Stop It, Rachel Ehrenfeld makes numerous references to the fact that terrorists use counterfeiting activities as a means to fund their terrorist acts. While counterfeit prescription drugs are not specifically referenced, the use of illegal drugs to fund such activities is well documented.

GlobalOptions Inc. identified the potential terrorist threats to America's medical supply in its work, An Analysis of Terrorist Threats to America's Medicine Supply. In sum, it identified three potential threats. First, the "mere infiltration of terrorists in the counterfeit drug market poses a threat to the public." Terrorists could easily produce and sell harmful prescription drugs. Second, terrorist groups could use the profits raised through the sale of counterfeit or diverted drugs to fund their activities. And third, terrorists could use poisoned drugs as a method of attack or, worse, as a weapon of mass destruction.

This study cited numerous examples of links between counterfeiting activities of various types and terrorist groups, where such groups were using the proceeds from these sales to fund their terrorist activities. In particular, the authors pointed to the following:

- The activities of the Irish Republican Army in the early 1990's in Florida that included the manufacture of a counterfeit drug product used to treat livestock. Proceeds from this operation were used to purchase guns;

- An international drug ring raised millions of dollars for Hezballah. The report states that the terrorist group's operatives legitimately purchased large quantities of pseudoephedrine in Canada, smuggled it into the United States, and produced "speed."

THE CONCLUSION

After conducting a preliminary, independent review of the issues associated with the wholesale importation of prescription medicines, it is evident that the existing pharmaceutical system is open to significant exploitation of counterfeit, diluted or adulterated drugs coming into the United States. The limitations of our system should be addressed before it is opened to wholesale importation.

The Health and Human Services Task Force on Drug Importation is currently considering all of these issues. The Task Force should be allowed to complete its mission as Congress directed before any major statutory changes are contemplated. Given the seriousness of this issue and its implications for the health and safety of Americans, a thorough and well-informed analysis is necessary.

Our interim findings can be summarized as follows:

- Although the current pharmaceutical manufacturing and distribution system is comprehensive and regulated, counterfeit or otherwise adulterated products still penetrate the market.
- There are serious questions as to the quality and safety of the medicine products coming into the United States from foreign sources.
- There are no minimum standards and little or no regulation regarding the operations of Internet pharmacies.
- There are identifiable weaknesses in the current pharmaceutical distribution chain (e.g., the "secondary" wholesale distribution market and the lack of a drug pedigree)
- The agencies responsible for enforcing the existing laws and regulations are already overwhelmed with the current volume of non-FDA approved prescription medicines coming into the United States.
- The potential exists for the use of the nation's medicine supply as a vehicle for terrorist activity.
- There are serious implications for Canadians with the current demand on their drug supply.

As noted previously, this review and these findings are preliminary. However, the issues discussed herein strongly suggest that no action be forced on the FDA or other government oversight agencies until the HHS Task Force has completed its analysis. In

the meantime, the public should be made aware of the risks associated with importing medicines from outside the United States. As the importation debate continues, it is vital that all aspects of this important public health issue be carefully assessed. We should not minimize the potential risks surrounding importation.

ATTACHMENT F

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Patricia F. Harris
Executive Officer
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Re: Automated Dispensing Device "Temporary Waiver"

Dear Ms. Harris:

I am the attorney for the Pharmacy Defense Fund. Mr. Fred Mayer, President of the Fund and has requested that I investigate issues related to the December 6, 2004 "Temporary Waiver" issued to Long's Drugs for the unlimited and unregulated installation of automated dispensing devices ("Devices"), and the approval of the amendment of CCR Title 16, Section 1717 to allow the devices in all California pharmacies.

The development surrounding this waiver concerns both PDF and the Board of Pharmacists Planning Services, Inc., made up of local pharmacists in both large and small pharmacies. The concerns fall into several areas. My client is concerned that the waiver itself is inadequately thought out and planned and is overly broad in scope, thereby jeopardizing the health of California patients. In addition, there is a general concern regarding the speed with which the State Board has acted and is proceeding with the Long's waiver and amendment of Section 1717, and the pending request for a similar waiver from Safeway.

I would like to first address the concern's regarding the terms of the waiver. The following areas coincide with those referred to in the wavier letter:

1. Limitation to Refills Only. The variance requires that the Devise be used for refills only. However, there are no provisions requiring Pharmacist supervision of the data entry or depositing of medicines into the Device to insure that this provision is not mistakenly violated

2. Patient's Choice. The second condition of the variance (that it be the patient's choice to use the Device) makes no mention of how the patient will know of this choice. It does not require that the patient be advised verbally or in writing, or even that there be a sign anywhere near the Device advising of this choice. The Device itself does not need any sign warning that the patient has the right not to use the machine, nor is there a requirement that the software somehow advise the patient of this right. In reality, during those hours that the pharmacy is closed, there really is no choice for the patient other than to come back at another time.

3. "Reasonable Proximity". This vague requirement gives to the store the option to put the Device as far away from the pharmacy departments as they want. It is inappropriate for patients to be going to the isle where liquor is sold or near the sandwich line or where the birthday cards are kept to obtain their medications. This type of latitude will further remove the pharmacist from the dispensing process. In addition, it removes the patient from the view of those notices and warnings that are traditionally posted at pharmacies, and further removes them from the consultation area of the pharmacy.

4. Security. The condition that the Device be secure from access by "unauthorized individuals" is also incredibly vague. I am not sure if that means that the whole device must be secured in such a way that it cannot be removed from the store premises or it means that only pharmacy personnel can have access to the interior of the Device. Does this mean that a Store Manager may access the Device to retrieve transaction information? Will a store Manager have Administrative access to the software? Or perhaps to the medicines themselves? This condition should, at the very least, require that all access to the Device be by pharmacy personnel who are authorized to handle medications.

5. Consultation Option. Is it the Board's position that a "means ...to obtain a consultation" is the retailer putting up a sign advising the patient to come back during regular pharmacy hours if they want a consult, or that they can call a number from the pay phone outside the store to speak to a pharmacist? There is no requirement that the patient even be advised that they are entitled to a consultation or how to obtain a consultation should they want one. There is no requirement that there be a phone installed in the Device or that there be one near the device. Since there is no requirement that there be a pharmacist available by phone during all hours the Device is accessible to the patient, even advising of the right to a consultation is a sham as no one will be available to consult. Once again, reality makes this condition useless: people who are there and want a consultation will not go to the trouble to obtain one. The retailer has successfully put up another barrier to consultation.

6. Need for Counseling. The variance prohibits the use of the Device if the pharmacist determines that counseling is required. While a review of the medications that have been given to the patient by that pharmacy can be reviewed on the pharmacy computer, that will not tell a pharmacist that the patient is jaundiced, or acting strangely or otherwise is suffering from side effects of a prescribed medicine from the pharmacy or a medicine from another pharmacy. A pharmacist or their assistant who sees this type of condition face to face is more likely to review medications and their effect than someone who is dropping medicine into a slot in a machine. How will the use of these Devices give the pharmacist the information needed to determine if counseling is even necessary?

Of additional concern is that the waiver appears to be a blanket waiver allowing Long's to install Devices in all of its California stores (approximately 400). This is hardly a "pilot program" as that term would be understood by anyone. When considered with the current Safeway wavier pending before the Board, it is simply an overly broad, wholesale acceptance of the Long's and Safeway business plans to reduce their costs, without any testing or evaluation at all. My clients are concerned when this attention to the needs of these retailers appears to be of more concern than the health of Californians.

The intent of the State Board in approving the Long's "temporary waiver" is made more obvious by the rapid steps taken to approve a change in the regulations and the upcoming hearing on a similar waiver applied for by Safeway. Taken together, it is clear that the Board has abandoned any pretense of a "temporary" or limited testing and evaluation of the proposed Devices. The Board does not know if or how the Devices will work in California and does not make any pretense of restricting their use to determine how they may work. Rather, it has already granted a wholesale waiver to Long's and is considering granting a waiver to Safeway, which I am told together constitute approximately fully *one quarter* of the pharmacies in California. This is certainly not a pilot program.

Effective this date I am starting my investigation into both the content and source of the background material the Board had in its possession to support that this waiver is in the interests of California patients and was a viable, safe process to institute. Since PDF does not consider the placement of these Devices into approximately 25% of the pharmacies to be either "temporary" or a form of testing, I will proceed under the assumption the Board, either as an entity are as individuals, has determined to proceed with the wholesale installation of these Devices without testing and evaluation as to their safety. Compliance with both the word and spirit of California law, and the Board's obligation to protect the citizens of this State from unsafe practices will be the measure against which we look at these matters.

PDF and PPSI strongly object to the Long's waiver as approved and to the amendment of regulations even before the Devices are tested and their safety evaluated and the expansion of this expanding this experiment to even more pharmacies through the Safeway or other waivers that may have been or will be applied for.

Please present this letter in its entirety to the Board before its upcoming meeting.

Sincerely,

LAW OFFICES OF JEFFREY A. MOSS

By: _____
JEFFREY A. MOSS, ESQ.

JAM/tim

cc: Gov. Arnold Schwarzenegger
Senator Carole Migden
Assemblyman Joe Nation
Fred Mayer, PDF
PPSI

ATTACHMENT G

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

March 4, 2005

Patricia Harris
Executive Officer
California State Board of Pharmacy

RE: Inspection Report: Long's Drug Store #247-Scriptcenter

As requested, an inspection of the Long's Drug Store, #247, located at 2662 Del Mar Heights Road in Del Mar, California was conducted on Friday, March 4, 2005, to determine the operational status of the Scriptcenter automated refill device installed as a pilot program for dispensing certain select refill medications (photos 1 & 2).

This project was approved by the board and provided a temporary waiver to California Code of Regulations Section 1717. The Scriptcenter became operational at Long's Drug Store #247 on December 2, 2004.

Specifically, the following operational parameters were observed:

- Limitations to Refills Only
- Patient's Choice
- Reasonable Proximity
- Security
- Consultation Options
- Need for Counseling

During the inspection, I interviewed Pharmacist-in-Charge Panteha Dowlatshahi Kelly, Bob Hansen, Vice-President, Asteres Corporation and David Fenner, Asteres Project Manager. Mr. Hansen and Mr. Fenner happened to be at the pharmacy during the inspection as part of the on-going monitoring program during the initial test phase. Neither PIC Kelly, Mr. Hansen, or Mr. Fenner were contacted prior to conducting the inspection.

Limitations to Refills Only:

The Scriptcenter is designed and dedicated to providing only select refillable medications. During the course of the inspection, I asked the pharmacist-in-charge (PIC) to describe the operations of the Scriptcenter and what processes were in place to prevent dispensing drugs from the Scriptcenter that would require consultation. The PIC stated that to avoid inadvertent placement of "new" medications into the device, only those prescriptions with a prescription numerical suffix ending in .000 are processed into the device. The Long's computer system (ADX) will not allow any medication without the correct suffix to be processed into the Scriptcenter. A bar code is produced and attached to the bag containing the medication. This bar code is scanned for identification and only then can the medication be dispensed from the

device (photos 3, 4, 5, 6). The PIC further described that a pharmacist is responsible for conducting the final check of all medications to be dispensed from the Scriptcenter for compliance with the requirement that only unchanged refilled medications are approved.

The PIC also provided copies of the Asteres Scriptcenter Training Instruction manual (attachment 1), the Scriptcenter Quick Reference Guide (attachment 2), and a copy of the Long's Drugs Scriptcenter In-Store Training manual (attachment 3).

It was my observation that the staff appeared to be well trained in the processing of prescriptions into the Scriptcenter, and there were adequate safeguards in place to identify the correct drugs that could be dispensed from the device.

Patient's Choice:

The PIC was asked to describe what processes are used to identify patients whose refilled medications are available in the Scriptcenter. The PIC stated that patients are provided a choice of obtaining their medications through the Scriptcenter or not. An enrollment form is stored on the Scriptcenter (photo 7) that patients can read and complete if they are interested in obtaining their routine refilled medications from the device (attachment 4). Patients are asked to provide unique a security password and a log-in ID code that will be used to access their medications from the Scriptcenter. There is a written acknowledgement on the application form that is signed by the patient which authorizes Long's to place their refilled prescriptions into the Scriptcenter and further advises the patient that not all of their prescriptions may be eligible for the service. The patient signs the completed form and is given to the pharmacist and their confidential information is entered into the computer system. The patient keeps the bottom portion of the form which contains their password and Log-in ID code (which is not provided to the pharmacy). There is also an additional advisement at the bottom of the portion retained by the patient that states *"Prescriptions that are oversized, unusually shaped, or that require refrigeration or consultation will not be available for pick-up in the Scriptcenter. These items will be available at the pharmacy counter."*

When asked how successful or not the program has been, the PIC and Mr. Hansen stated that since inception of the program on December 2, 2004, Long's has enrolled approximately 600 plus patients and has dispensed approximately 1000 plus refilled prescriptions from the Scriptcenter. There have been approximately 15 patients who have opted to drop from the program. The reasons cited were varied and some were related to the inconvenience of utilizing their ATM or credit card twice in the store for purchases not related to the Scriptcenter. The PIC provided a copy of the in-store patient satisfaction survey questionnaire (attachment 5 and photo 8) and a copy of the survey results were provided by Mr. Hansen (attachment 6). A review of the results showed that many of the patients found the Scriptcenter to be a convenience and were satisfied with the service.

I conducted a separate interview of customers utilizing the Scriptcenter during the inspection. Statements from these patients were similar to the survey results in claiming convenience for obtaining the medications. One patient stated that a "no-so computer literate person" might have difficulty early on but did not feel it was a major issue. I asked the patients if they felt there was

enough information provided that should a question arise on their refilled medications that they had ample opportunity to speak with a pharmacist during and off hours ?. The patient said yes and pointed at a sign next to the ScriptCenter which listed two phone numbers for 24 hours pharmacies that could be accessed to answer any questions (photo 9).

I asked the PIC if ethnic groups not fluent in English could utilize the Scriptcenter and was informed by Mr. Hansen that English was on the only language offered at this time and that plans were being designed to provide multi-language accessibility.

Reasonable Proximity:

When I approached the pharmacy area, I observed that the Scripcenter was located at one end of the pharmacy cashier counter (photo 10, 11). The front of the device was accessible to the patients and there appeared to be ample signage identifying the Scriptcenter . The rear of the device where the drugs are loaded was in the back of the pharmacy cashier counter and directly accessible by the pharmacy staff during operational hours (photo 12, 13, 14). Immediately behind the Scriptcenter was the will-call or pick-up shelf for medications not suitable for the Scriptcenter or for patient not enrolled in the program. During off hours, a retractable door descends to block off the prescription area; however, the Scriptcenter is then located outside of the secured area during off hours (photo 15, 16). Access to the rear of the cabinet is only done by pharmacy staff and requires computer access to unlock the cabinet. No keys are used.

Security:

As described above under Reasonable Proximity, the Scriptcenter is located within the pharmacy area and accessible and controlled by the pharmacy staff. I asked the PIC to demonstrate the process to access the Scriptcenter to load and unload the device with medication. The PIC stated only the pharmacy staff can access the device and it is computer controlled requiring the pharmacist or pharmacy technician to enter an individual specific log-in ID code and a password. According to the PIC and from my observations, no one outside the pharmacy staff and only the licensed pharmacy staff have access codes into the device. I observed that the Scriptcenter was constructed of steel with steel rear doors that unlocked only by the correct computer access codes (photo 17). I attempted to pull open the doors and was not able to gain access. Once opened, the bin boxes containing the medications are accessible (photo 18, 19, 20). The doors are manually closed and an audible click is heard when the doors are relocked and made secure. I asked Mr. Hansen how much the Scriptcenter weighed and he said 1300 pounds unloaded. I also observed to large bolts visible from the back of the device and under the rear doors (photo 21) which attached the Scriptcenter to the floor for seismic safety purposes and to prevent intentional removal (which is doubtful based upon the 1300 pound weight). There is an additional security feature located at the front of the Scriptcenter which is a video unit that is activated each time an access code is entered onto the keyboard and creates a video record of the person accessing the device (photo 22). Also, the keyboard screen on which the patient enters their access code and prescription number can only been seen by the user. A patient standing to the right or left of the screen at an angle cannot clearly see the screen nor any information entered by the patient (photos 23, 24).

Consultation:

I asked the PIC for the hours of operation and was informed the pharmacy was open Monday thru Friday from 8am to 10pm, Saturday from 9am to 7pm and Sunday from 10am to 6pm. During these hours the PIC stated a pharmacist is always available to answer any questions regarding medications obtained from the Scriptcenter. As described under Patient Choice, a notification in the form of a statement is provided to the patient at the time of enrollment that advises drugs requiring consultation would not be available in the Scriptcenter. The PIC also stated that a new access window is planned immediately adjacent to the Scriptcenter that will be used by patients who have difficulty obtaining or have questions with their Scriptcenter provided refilled medications. Patients will step up to the window and will be serviced by a pharmacy clerk without having to stand in line behind other patients. In the event a refill medication requires patient consultation or discussion, a message would appear on the screen notifying the patient to contact the pharmacist in order to obtain their medication(s).

During off hours, the PIC stated that there are two 24 hour Long's pharmacies nearby that will answer questions. I noticed a large information board next to the Scriptcenter that identified the two pharmacies and their telephone numbers (photo 25, 26). Mr. Hansen added that Long's was planning to attach a telephone onto the Scriptcenter that will provide direct access to the other pharmacies during off hours. The intent of the Scriptcenter is to provide access to refill medications that patients must take on a chronic basis and are unchanged from refill to refill. Current pharmacy rules and regulations does not require consultation for these types of refilled medication; however pharmacy rules and regulations states any changes in refill medication directions, strength, dosage etc are considered "new" medications and require consultation. According to the PIC, none of these drugs are eligible for the Scriptcenter refill dispensing process.

Need for Counseling:

As stated above, refill medications and new prescriptions that require consultation are not placed in the Scriptcenter for automated dispensing. These prescriptions are filled and placed in the will-call/pick-up area and consultation is provided at the time the patient or the patient's representative asks for the prescription(s). The usual practice for obtaining refilled medications that do not require consultation is from the pharmacy clerk or pharmacy technician at the front counter of the pharmacy. Neither of these pharmacy staff employees are capable of, nor have they been trained in diagnosing a patient's condition just from observing the patient during the short interval of time it takes to pick up refill medications from the pharmacy. Additionally, providing refill and new medication from a mail order service also eliminates direct pharmacy staff contact but is allowable under current pharmacy rules and regulations as long as the patient is provided an opportunity to obtain consultation via a telephone number (California Code of Regulations, Section 1707.2 Subdivision 2). From inspection of the processes used by Long's and the Scriptcenter, I did not observe any variance from current California Pharmacy Rules and Regulations.

Findings:

An inspection of the Long's Drugs #247 at 2662 Del Mar Heights Road in Del Mal, California for the implementation of the Scriptcenter automated refill dispensing device revealed compliance with current California Pharmacy Rules and Regulations in regards to limitations on only refill medications not requiring consultation, notice to provide consultation, security and patient choice. The pharmacy staff appeared to be well trained in utilizing the Scriptcenter device.

Recommendations:

1. From the observations and interviews of patients conducted during the inspection, it is recommended that the term "close proximity" used in granting the waiver for CCR 1717, be more defined to mean "within the immediate vicinity" of the licensed location. Locating the device within the pharmacy with the front in the public area and the back accessed only from the licensed area, or at the very least located at the pharmacy cashier counter as observed at the Long's pharmacy maintains the professional relationship between the patient and the pharmacist, and allows the staff to answer and resolve problems associated with obtaining the refilled medications without leaving the pharmacy area unattended. In addition, patients have the expectation the device would be located in the pharmacy area and not in some remote location in another part of the business. Despite the fact it is an automated process, nevertheless, the function it provides is a practice of pharmacy and should be accessible by patients and staff in the pharmacy area.
2. The board strongly recommend that pharmacies who plan to install Scriptcenter units also concurrently install direct telephone access to a pharmacy and made available to patients during off hours to answer any questions from the enrolled patients to expedite patient/pharmacist contact.

Respectfully submitted,

Dennis L. Ming, Pharm.D.
Supervising Inspector

Proposed Regulation Change to Allow the Use of a Device to Dispense Refill Prescriptions (Approved at October 2005 Board Meeting – Pending Notice of a Regulation Hearing)

Add Section 1713

§1713 Receipt and Delivery of Prescriptions

(a) Except as otherwise provided in this Division, no licensee shall participate in any arrangement or agreement, whereby prescriptions, or prescription medications, may be left at, picked up from, accepted by, or delivered to any place not licensed as a retail pharmacy.[1]
(b) A licensee may pick up prescriptions at the office or home of the prescriber or pick up or deliver prescriptions or prescription medications at the office of or a residence designated by the patient or at the hospital, institution, medical office or clinic at which the patient receives health care services.[2]
(c) A patient or the patient's agent may deposit a prescription in a secure container that is at the same address or adjoining the licensed pharmacy premises. The pharmacy shall be responsible for the security and confidentiality of the prescriptions deposited in the container.
(d)A pharmacy may use a device to dispense refilled prescriptions provided:

(1) The patient chooses to use the device .
(2) The device is located in reasonable proximity to the licensed pharmacy premises.
(3) The device has a means to identify the patient and only release that patient's prescriptions.
(4) The device is secure from access by unauthorized individuals.
(5) The pharmacy provides a means for the patient to obtain a consultation with a pharmacist if requested by the patient.
(6) The pharmacy is responsible for the prescriptions stored in the device.

§1717. ~~Pharmaceutical~~ Pharmacy Practice.

(a) No medication shall be dispensed on prescription except in a new container which conforms with standards established in the official compendia.
Notwithstanding the above, a pharmacist may dispense and refill a prescription for non-liquid oral products in a clean multiple-drug patient medication package (patient med pak), provided:

(1) a patient med pak is reused only for the same patient;
(2) no more than a one-month supply is dispensed at one time; and
(3) each patient med pak bears an auxiliary label which reads, "store in a cool, dry place."

(b) In addition to the requirements of Business and Professions Code Section 4040 ~~4036, Business and Professions Code~~, the following information shall be maintained for each prescription on file and shall be readily retrievable:

(1) The date dispensed, and the name or initials of the dispensing pharmacist. All prescriptions filled or refilled by an intern pharmacist must also be initialed by the supervising pharmacist ~~preceptor~~ before they are dispensed.
(2) The brand name of the drug or device; or if a generic drug or device is dispensed, the distributor's name which appears on the commercial package label; and
(3) If a prescription for a drug or device is refilled, a record of each refill, quantity dispensed, if different, and the initials or name of the dispensing pharmacist.
(4) A new prescription must be created if there is a change in the drug, strength, prescriber or directions for use, unless a complete record of all such changes is otherwise maintained.

---

[1] Moved from 1717 (e).
[2] Moved from 1717 (e).

(c) Promptly upon receipt of an orally transmitted prescription, the pharmacist shall reduce it to writing, and initial it, and identify it as an orally transmitted prescription. If the prescription is then dispensed by another pharmacist, the dispensing pharmacist shall also initial the prescription to identify him or herself. All orally transmitted prescriptions shall be received and transcribed by a pharmacist prior to compounding, filling, dispensing, or furnishing.
Chart orders as defined in Section 4019 of the Business and Professions Code are not subject to the provisions of this subsection.
(d) A pharmacist may furnish a drug or device pursuant to a written or oral order from a prescriber licensed in a State other than California in accordance with Business and Professions Code Section 4005.
(e) ~~No licensee shall participate in any arrangement or agreement, whereby prescriptions, or prescription medications, may be left at, picked up from, accepted by, or delivered to any place not licensed as a retail pharmacy.~~
~~However, a licensee may pick up prescriptions at the office or home of the prescriber or pick up or deliver prescriptions or prescription medications at the office of or a residence designated by the patient or at the hospital, institution, medical office or clinic at which the patient receives health care services. The Board may in its sole discretion waive this application of the regulation for good cause shown.~~
~~(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, 1306.26.
Prescriptions for other dangerous drugs which are not controlled substances may also be transferred by direct communication between pharmacists or by the receiving pharmacist's access to prescriptions or electronic files that have been created or verified by a pharmacist at the transferring pharmacy. The receiving pharmacist shall create a written prescription; identifying it as a transferred prescription; and record the date of transfer and the original prescription number. When a prescription transfer is accomplished via direct access by the receiving pharmacist, the receiving pharmacist shall notify the transferring pharmacy of the transfer. A pharmacist at the transferring pharmacy shall then assure that there is a record of the prescription as having been transferred, and the date of transfer. Each pharmacy shall maintain inventory accountability and pharmacist accountability and dispense in accordance with the provisions of Section 1716.
Information maintained by each pharmacy shall at least include:

(1) Identification of pharmacist(s) transferring information;
(2) Name and identification code or address of the pharmacy from which the prescription was received or to which the prescription was transferred, as appropriate;
(3) Original date and last dispensing date;
(4) Number of refills and date originally authorized;
(5) Number of refills remaining but not dispensed;
(6) Number of refills transferred.

~~(g)~~ (f) The pharmacy must have written procedures that identify each individual pharmacist responsible for the filling of a prescription and a corresponding entry of information into an automated data processing system, or a manual record system, and the pharmacist shall create in his/her handwriting or through hand-initializing a record of such filling, not later than the beginning of the pharmacy's next operating day. Such record shall be maintained for at least three years.

Authority cited: Sections 4005, 4075 and 4114, Business and Professions Code. Reference: Sections 4005, 4019, 4027, 4050, 4051, 4052, 4075, 4114, 4116, 4117 and 4342, Business and Professions Code.

ATTACHMENT H

Longs ScriptCenter®

A PATIENT DELIVERY SYSTEM

ScriptCenter Features

- Holds up to 500 prescriptions
- Automatically identifies if prescription needs to be "returned to stock"
- Allows for real time inventory tracking
- Allows for real time reporting

Security of ScriptCenter

- Located in pharmacy area
- Access to unit through a locked door and Pharmacist maintains key to open
- Only Pharmacy Personnel can access unit
  - Access requires pharmacy staff to sign onto the Longs computer system
  - Then, additional sign-on to access ScriptCenter Program required
- Access by patients and staff tracked—access report can be printed on demand

Security (cont'd)

- As patient inputs information into ScriptCenter, screen not readable from side
- Camera takes 2 videos of person using ScriptCenter
  - As person logs in
  - As prescription is picked up
- System PREVENTS A NEW PRESCRIPTION from being placed into the ScriptCenter

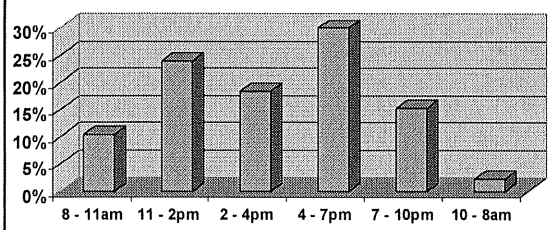
What is the ScriptCenter Process?

- ALL prescriptions are filled as usual, including pharmacist verification of ALL prescriptions
- If prescription is designated for input into ScriptCenter, placed into ScriptCenter bag
- Bar code "marries up" bag and prescription
- Bags loaded onto trays in any order
- Trays placed directly into ScriptCenter

How Do Patients Use the ScriptCenter?

- Patient "opts-in" and pre-registers
- When Patient picks up a prescription:
  - Enters ID and Password into ScriptCenter
  - Selects prescription(s) to be picked up
  - Authorizes payment and signs for 3rd party payer authorization
  - Removes prescription(s) from bin and takes receipt

Prescription Pick Up By Time of Day



Consultation

- A special "Lane" for questions by patients using ScriptCenter being established
- Sign posted next to ScriptCenter gives phone numbers and locations of nearby 24 hour Longs pharmacies
- Notice posted on unit itself advises of phone numbers and locations of nearby 24 hour Longs pharmacies

Consultation (cont'd)

- Flyer being included in bag, advising patients of availability of consultation by a pharmacist
- Can create database of drugs that won't be placed into ScriptCenter

Training and Education

- Success depends on level of training and education
  - Staff Training
  - Patient Education

Longs Drug Stores

General Offices: 141 North Civic Drive, P.O. Box 5222, Walnut Creek, California 94596 (925) 937-1170

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2005 APR -1 AM 10: 24

March 29, 2005

RECEIVED BY CALIF.
BOARD OF PHARMACY
2005 APR -1 AM 10: 25

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

RE: REQUEST FOR APPEARANCE AT APRIL BOARD MEETING

Dear Ms. Harris:

At its October 2004 meeting, members of the California Board of Pharmacy approved a waiver, requested by Longs Drug Stores, to install and utilize automated patient delivery units in its stores. In December 2004, we successfully installed the first Asteres Unit in our Oceanside store.

Recently several questions and concerns about patient delivery units have been raised in the media and in letters to the Board. To address these concerns, as well as also provide an update to Board members regarding operation of the unit, Longs Drug Stores would like to do a presentation at the April Board of Pharmacy meeting. In the presentation we plan to include information on the patient delivery system location, how we are monitoring and auditing the unit, privacy and security features the unit provides, training conducted before the unit went live, and quantification of when patients are using the unit. We also want to share comments, received from patients who have used the unit, with Board members.

The presentation will take approximately 15 minutes and as always, we will try to address any questions that may arise. Prior to the meeting, I will provide you with information that we would like to have included in the Board packet.

Should you have any questions, please do not hesitate to contact me.

Sincerely,

Orriette A. Quandt

Orriette A. Quandt, PharmD
Corporate Pharmacy Compliance Manager
Longs Drug Stores

ATTACHMENT I

State of California | Department of Consumer Affairs

Memorandum

To: Dana Winterrowd | Date: February 28, 2005

From: Virginia Herold

Subject: Request for Legal Opinion: Naturopathic Doctors

The board requests a Legal Opinion regarding the overlay of the duties authorized to naturopathic doctors by SB 907 and Pharmacy Law.

The version of SB 907 enacted (Burton, Chapter 485, Statutes of 2003) creates several questions. This year, the naturopathic doctors are pursuing cleanup legislation to amend various code sections in the Business and Professions Code containing Pharmacy Law. Understandably, they only want to do this once.

As such, could your opinion please consider:

1. Under section 3627(c) and (d) -- can naturopathic doctors can prescribe dangerous drugs before the required report and formulary recommendations are provided to the Legislature 1/1/06? If so, what dangerous drugs or all of them? It seems that the Legislature intended that a formulary of prescription drugs be developed for naturopathic doctors by this section, not any prescription drug (or otherwise, why require the formulary recommendations in the first place?).

2. Under section 3640 (c) and (d) -- can a naturopathic doctor write an order for a pharmacy to compound or inject the listed items in (c)?

   We are advising pharmacies that there must be a prescription written by a prescriber for any drug compounded by a pharmacy, even if compounded only from OTC ingredients.

   Can the naturopathic doctor do this only under protocol as required by 3640.5?

3. Under section 3640.7 -- testosterone is a Schedule III medication. As such, can a naturopathic doctor write a prescription for testosterone:
   (a) independently, without a supervising physician
   (b) without a DEA number issued to him or her as a naturopathic doctor

   Staff believes that the Schedule III classification of testosterone removes it from the very general list of hormones in 3640.7, and makes it subject to the prescribing requirements of 3640.5(f) and of the Health and Safety Code. Testosterone is a Schedule III drug, not merely a hormone or a dangerous drug. This is in accordance with why controlled drugs are

scheduled and treated differently from all other dangerous drugs in the Business and Professions Code and Health and Safety Code.

Because the naturopathic doctors are highly interested in removing all legislative impediments to their prescribing and they have a contract lobbyist ready to move with a legislative proposal, I ask for you to complete this opinion as soon as possible.

Thank you.

Virginia Herold
Assistant Executive Officer

cc: Patricia Harris

Necessity for Pharmacist to Check Automation/Robotic Dispensing

The Board of Pharmacy recently reviewed a request from McKesson Automation, Inc. (McKesson) to approve a proposed protocol for use in hospital and institutional pharmacies that would not require licensed pharmacists to check every medication dispensed by its automated dispensing system, ROBOT-Rx. McKesson proposed a protocol whereby a pharmacist would check 100 percent of the medications packaged by the ROBOT-Rx on a daily basis for at least 30 days after the ROBOT-RX is deployed. After the 30 days, the pharmacist would then taper off to sampling only 5-10 percent of the doses dispensed.

Pharmacy Law is silent on the question about how a pharmacist must check medication dispensed from automated delivery systems, aside from those provisions relating to placement of such a system in nonprofit or free clinics (Business & Professions Code [B&PC] section 4186). There is no statute or regulation specifically requiring that a pharmacist check every dose dispensed by an automated drug delivery system located in an inpatient setting, nor is there any statute or regulation absolving the dispensing pharmacist of this responsibility. Because of this silence, McKesson concluded that it is within the Board's discretion to approve a protocol that would apply specifically to ROBOT-Rx technology.

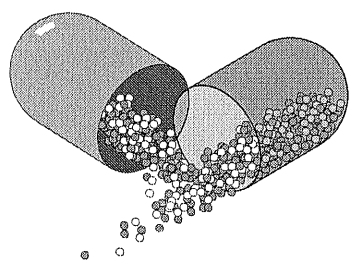
In denying McKesson's request, the Board considered the opinions of its counsel, which follow, in relevant part:

The Board has no relevant statutory authority to approve a protocol, and to do so may constitute an impermissible underground regulation. Under current law, it is the responsibility of individual licensees to determine the level of error risk they are willing to assume, and the steps they take to reduce or eliminate that risk.

Pharmacy Law is violated where a prescription is dispensed in an insufficiently or inaccurately labeled container (B&PC sections 4076-4078), where the drug dispensed deviates from requirements of a prescription (Title 16, California Code of Regulations [CCR] section 1716), or where the prescription is dispensed containing significant errors, omissions, irregularities, uncertainties, ambiguities, or alterations (CCR section 1761). These provisions apply to all dispensing, regardless of the setting.

Any licensee that chooses to implement a reduced-error-checking protocol like that suggested by McKesson is assuming the risk of any errors that result. Even if such errors are less likely with the ROBOT-Rx system, the licensee is responsible for any errors that do occur. It may therefore be a risk for licensees to implement a protocol that increases the chance of such an error, however minor, by eliminating 100 percent of the human double-checking that could perhaps catch and correct those few errors made by the machine(s). Any licensee implementing such a protocol will be subject to discipline for any errors that do occur (as would any licensee responsible for errors from any other delivery system). It is possible the severity of the violation may even be greater where the error could have been caught had not such a sampling protocol been in place.

In the absence of any statutes or regulations exempting a dispensing pharmacist or pharmacy working with an automated drug delivery system from the general requirements pertaining to prescription accuracy and propriety of drug delivery, it is the responsibility of the dispensing pharmacist and pharmacy to ensure 100 percent accuracy of the dispensing. Licensees electing to save costs by reducing their level of error checking do so at their own risk and that of the patient.



Naturopathic Doctors Added to Prescriber List

Section 3640.5 of the Business & Professions Code authorizes naturopathic doctors (NDs) to furnish or order Schedule III-V drugs, and emergency regulations authorizing NDs to prescribe have recently been approved.

Licensing of NDs by the Bureau of Naturopathic Medicine has begun and will be limited to those who have completed educational and other licensing requirements. Licensed NDs will function in accordance with standardized procedures or protocols developed with his or her supervising physician and surgeon.

Prescriptions written by NDs must contain:

- The printed or stamped name, license number and **furnishing number** of the ND,
- The ND's federal controlled substances registration number, if the prescription is for a controlled substance. This requirement may be met by stamping the ND's federal registration number on the prescription.
- The signature of the ND.

Updated information regarding this issue will be published in this newsletter when it becomes available.

ATTACHMENT J

California State Board of Pharmacy
400 R Street, Suite 4070, Sacramento, California 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

WHAT TO LOOK FOR ON THE NEW TAMPER-RESISTANT PRESCRIPTION FORMS

Beginning January 1, 2005, written prescriptions for controlled substances must be on tamper-resistant security prescription forms that have been preprinted by a Board-approved printer and must contain specific elements (Health & Safety Code Section 11162.1 et seq.). There is no single specific format, size or color for the security prescription forms, so pharmacists need to be aware of the required elements for such forms. Security features are used to prevent fraud or diversion.

DESCRIPTION OF SECURITY FEATURES

The law requires a description of the security features be printed on each security form. Some forms describe each feature in a list on the back of the prescription; however, some forms describe features in "warning bands" across the face or along the edge of the prescription. The description should tell what and where the features are on the form and how to test them. (click here to view samples)

Other security feature components are:

1. **Latent Repetitive Void Pattern**— the word "void" must appear in a pattern across the entire face of the security prescription form if it is scanned, photocopied, or faxed. Consequently, if a prescription is to be faxed, prescribers are encouraged to use plain paper prescription forms (not security prescription forms) for this purpose. A pharmacist receiving a "void" faxed prescription should always use his or her professional judgment when filling the prescription and contact the prescriber anytime there are questions concerning a prescription's validity (just as a pharmacist would do with any prescription).
2. **Watermark**— a printed watermark consisting of the words, "California Security Prescription," must be printed on the backside of the prescription blank. The watermark is often very light but can be seen by holding the form at an angle.
3. **Chemical Void**—A protection that prevents alteration by chemical washing. Any area of the security form that is exposed to ink solvents (e.g., acetone) will cause a "void" pattern to appear or will appear heavily stained. This feature is important to prevent unauthorized changes to a security form after the prescriber has written the prescription.
4. **Thermochromic Ink Feature**—a feature (e.g., a symbol or text) printed in thermochromic ink. Such a feature will change color or disappear temporarily when exposed to heat, such as rubbing briskly with your fingers or with hot breath. An important aspect of this ink is that the feature returns to its original color when it cools.
5. **Opaque Writing** —An area of opaque writing so that the writing disappears if the prescription is lightened.

6. **Quantity Check-off Boxes**—Six quantity check-off boxes must be printed on the form with specific quantity range choices as illustrated on the right (see *Computer Generated Prescriptions Using Institution Forms* below for a limited exception to this rule.). This feature is important to prevent alteration of the quantity ordered after the prescription is written. The prescriber checks the box next to the quantity range that matches the number of tablets or capsules prescribed for each prescription written. On forms with only one set of check boxes but includes multiple prescriptions on one form, the appropriate quantity range for each prescription written should be checked. If the quantity of two or more prescriptions falls into the same quantity range, the range is checked only once.

☐ 1-24
☐ 25-49
☐ 50-74
☐ 75-100
☐ 151 and over
Unit _____

7. **Unit Designation** —In conjunction with the quantity check-off boxes referenced above, there must be a space for designating the drug form or unit if the prescribed drug is not in tablet or capsule form (e.g., "ml" for milliliter, "sol" for solution, etc).

8. **Single or Multiple Drug Statements** – The new security prescription forms come in two prescription formats: a single drug format and a multiple drug format. The single drug format has the following statement printed on the form:

   - "Prescription is void if more than one controlled substance prescription is written per blank. (click here to view sample)

   The multiple drug format has the following printed on the form:

   - "Prescription is void if the number of drugs prescribed is not noted" and a line provided for the prescriber to write in or circle the number of drugs prescribed. Note: Although the board would prefer multiple drug forms to be sectioned for each drug prescribed and include quantity check-off boxes, refill, and do not substitute instructions for each section, it is not required. (click here to view sample)

9. **"Do Not Substitute" Check Box** – The statement "Do Not Substitute" must appear on the form, and if checked off, indicates the prescriber's order not to substitute the drug prescribed. The prescriber must also personally initial the check box to confirm.

10. **Form Batch Numbers**—Every batch of security forms must have a unique lot number printed on the forms and each form within that batch is numbered sequentially, beginning with numeral one.

PREPRINTED PRESCRIBER REQUIREMENTS AND LIMITED EXCEPTIONS FOR LICENSED HEALTH CARE FACILITIES

Preprinted Prescriber Information —Controlled substance security prescription forms must be preprinted with the name, category of licensure (e.g., MD, DDS, etc), license number, and federal controlled substance registration number of the prescriber, by a board-approved security printer. In addition, the prescriber's address and phone number is required to be on the form to be a valid prescription; however, this information can be preprinted (preferred), handwritten, or stamped on the form. Multiple prescribers, even multiple addresses, with check boxes are allowed. (click here to view sample)

Preprinted Forms for Licensed Health Care Facilities - The "institution" style form is an option available to licensed health care facilities only. A "licensed health care facility" means a facility licensed pursuant to Article 1 (commencing with section 1250) of Chapter 2 of Division 2 of the California Health and Safety Code, such as, a general 24-hour acute care hospital, acute psychiatric hospital, skilled nursing facility, or intermediate care facility. Qualified licensed health care facilities that wish to use the "institution" style forms, must designate a prescriber to order forms, receive delivery, distribute the forms to authorized prescribers within the facility, and record the names, federal controlled substance registration numbers, license numbers, and quantity of forms issued to each. The facility must maintain the records for three years. (click here to view sample)

- **Forms for Institutional Use**— The institutional style forms must be ordered from an approved printer and include all of the same security features. The "designated prescriber's" name, category of licensure, license number, and federal controlled substance registration number must be preprinted on the institution style form, as well as, the facility's name, address, category of licensure, and Department of Health Services issued license number. A blank area is provided for the actual prescriber within the facility to write or stamp his or her name, category of licensure, license number, and federal controlled substance registration number when the prescription is written. It is important to note that a prescription written on an institutional style form is not valid without the actual prescriber information filled in on the form.

  a) **Computer Generated Prescriptions Using Institution Forms** – A special provision for licensed health care facilities that computer generate prescriptions to print on "institution" style laser or dot matrix forms have the following exceptions:

     - Computer generated institution style forms do not require the quantity check-off boxes;
     - The facility's "designated prescriber" is not required to maintain a record of the prescriber's to whom the institution style computer generated prescription forms are distributed to within the facility; and
     - The computer software can print the actual prescriber's name, category of licensure, DEA number, and license number on the form, as well as, the date the prescription is written. The actual prescriber must sign the prescription.

     Note: These exceptions do not apply to laser or dot matrix controlled substance prescription forms for use by an individual prescriber, group practice, clinic, surgery center, or any other outpatient setting.

If you have questions concerning the validity of a prescription, treat the prescription like any other questionable prescription—call the prescriber to verify. If the form does not contain the proper features, it may indicate that it was not printed by a Board–approved printer. Such prescriptions should be reported to the Department of Justice, Bureau of Narcotic Enforcement at (916) 319-9062.

Prescriber, Group Practice, or Clinic Security Prescription Form Sample in Single Drug Format

• VOID APPEARS WHEN COPIED • REVERSE RX • MICROPRINT SIGNATURE LINE • CA WATERMARK

Z999999-0001

Group Practice Name ❒ Prescriber Name, Category of Licensure, DEA Number, State License Number
Address ❒ Prescriber Name, Category of Licensure, DEA Number, State License Number
City, State Zip ❒ Prescriber Name, Category of Licensure, DEA Number, State License Number
Telephone Number ❒ Prescriber Name, Category of Licensure, DEA Number, State License Number

Name _____ DOB _____
Address _____ Sex: ❒ M ❒ F

SAMPLE ONLY – ACTUAL FORM DESIGNS WILL VARY

Quantity:
❒ 1–24
❒ 25–49
❒ 50–74
❒ 75–100
❒ 101–150
❒ 151 – over

Unit _____
Refills: 0 – 1- -2 – 3- -4- -5
❒ Do Not Substitute
Initials_____

X _____ Date _____

Prescription is void if more than one controlled substance is written per blank

• THERMOCHROMIC INK SYMBOL • QUANTITY CHECK BOXES • CHEMICAL VOID PROTECTION

Batch/Lot Numbers – Unique batch and sequential lot numbers assigned by approved security printers. Not tracked by the State,

Opaque Writing fades or disappears when photocopied repeatedly

Six quantity check boxes allow quick confirmation that the quantity prescribed has not been altered.

Refills – CII drugs cannot be refilled, only CIII – V can be refilled.

Do Not Substitute – prescriber must check box and initial

Statement that Identifies form as a **single drug** prescription form

Thermochromic ink feature changes color or disappears temporarily with hot breath or when rubbed briskly. It slowly returns to normal as it cools.

Microprint Signature Line – seen only with a magnifier and becomes a solid line when copied, faxes or scanned.

Description of security features in warning bands on face or listed on back of prescription.

Alternatively, prescribers may order a form designed to write multiple prescriptions on one form. See the next form sample using a multiple drug prescription format. 12/04

SAMPLE BACKSIDE OF SECURITY PRESCRIPTION FORM

Security Features:

- RX logo disappears or changes color temporarily with hot breath or when rubbed briskly with finger.
- Opaque Rx fades or disappears with repeated attempts to lighten prescription on copier.
- Microprinted text signature line becomes solid line when copied.
- California Security Prescription watermark on back.
- Repetitive VOID pattern appears across face when copied.
- VOID pattern or stain appears where attempts are made to chemically alter the prescription.
- Quantity range checked confirms quantity prescribed.
- Unique batch number and each form sequentially numbered.
- Order not to substitute.
- Single drug prescription format.
- Preprinted prescriber information.

SAMPLE ONLY – ACTUAL FORM DESIGNS WILL VARY

- **California Security Prescription Watermark** printed in opaque ink– hold at an angle to view.
- **Description of Security Features** (may be on the face of prescription in warning bands instead, see blue bands on sample forms)

INSTITUTION STYLE SECURITY PRESCRIPTION FORM SAMPLE IN A MULTIPLE DRUG FORMAT

Institution forms can only be used by health care facilities licensed under Health & Safety Code section 1250. Generally, these are 24-hour acute care hospitals, skilled nursing facilities, etc. The forms are preprinted with the facility and the facility's "designated prescriber" information as indicated below. The actual prescriber information will be printed, handwritten, or stamped on the form when the prescription is written.

• CA WATERMARK

Institution's State License Number 9999999-0001
Institution Name
Address
City, State Zip
Designated Prescriber: Designated Prescriber Name, Category of Licensure, DEA Number, State License Number

Prescriber Name & Category of Licensure | **DEA Number** | **State License Number** | **Telephone Number**

Name _____ DOB _____
Address _____ Sex: ❒ M ❒ F

1)
Quantity: ❒ 1–24 ❒ 25–49 ❒ 50–74 ❒ 75–100 ❒ 101–150 ❒ 151 – over
Unit _____ Refills: 0 – 1- -2 – 3- -4- -5
❒ Do Not Substitute Initials _____

2)
SAMPLE ONLY – ACTUAL FORMS WILL VARY
Quantity: ❒ 1–24 ❒ 25–49 ❒ 50–74 ❒ 75–100 ❒ 101–150 ❒ 151 – over
Unit _____ Refills: 0 – 1- -2 – 3- -4- -5
❒ Do Not Substitute Initials _____

3)
Quantity: ❒ 1–24 ❒ 25–49 ❒ 50–74 ❒ 75–100 ❒ 101–150 ❒ 151 – over
Unit _____ Refills: 0 – 1- -2 – 3- -4- -5
❒ Do Not Substitute Initials _____

X _____ Date _____

Prescription is void if the number of drugs is not noted: _____

• THERMOCHROMIC INK SYMBOL • QUANTITY CHECK BOXES • CHEMICAL VOID PROTECTION

- **Batch/Lot Numbers** – Unique batch and sequential lot numbers assigned by approved security printers. Numbers are not tracked by the State.
- **Actual Prescriber** – the prescription is not valid without the actual prescriber information filled in.
- **Opaque Writing** fades or disappears when photocopied repeatedly to lighten.
- **Six quantity check boxes** allow quick confirmation that the quantity prescribed has not been altered.
- **Do Not Substitute** – if desired, prescriber must check box and initial
- **Refills** – CII drugs cannot be refilled, only CIII – V can be refilled.
- **Description of security features** in warning bands on face or listed on back of prescription. (see sample of backside)
- **Thermochromic ink** feature changes color or disappears temporarily with hot breath or when rubbed briskly. It slowly returns to normal as it cools.
- **Statement** allows multiple prescriptions on one form. Prescribers must note the number of drugs prescribed.

Alternatively, institutions may order a form designed to write only one controlled substance. See the previous form sample using a single drug prescription format.

ATTACHMENT K

California, 2004

The Disease Prevention Demonstration Project (DPDP)

PURPOSE OF THE NEW PHARMACY ACCESS LEGISLATION

To prevent the spread of HIV, hepatitis, and other blood-borne diseases among injection drug users (IDUs), their sexual partners, and their children.

SUMMARY

Senate Bill (SB) 1159, subject to authorization by a county or city, creates the Disease Prevention Demonstration Project (DPDP), a collaboration between pharmacies and local and state health officials, and authorizes pharmacists in licensed pharmacies, who have registered with their local health department, to sell ten or fewer hypodermic needles or syringes for human use without a prescription. This provision sunsets on December 31, 2010. SB 1159 requires pharmacies that make such sales to undertake prescribed activities including offering safe syringe disposal programs to ensure that these hypodermic needles and syringes are disposed of in an appropriate manner, and providing written information or verbal counseling on how to access drug treatment and testing and treatment of human immunodeficiency virus (HIV) and hepatitis C virus (HCV). SB 1159 authorizes a person to possess up to ten hypodermic needles or syringes if acquired through an authorized source and deletes both the identity requirement and the requirement that a pharmacist keep detailed records of nonprescription sales of hypodermic needles and syringes. SB 1159 requires that the Department of Health Services (DHS) evaluate the effects of allowing the sale of hypodermic needles or syringes without a prescription, and submit a report to the Governor and Legislature by January 15, 2010.

WHAT DOES SB 1159 DO?

General Components:

- Establishes the DPDP, a collaboration between pharmacies and local and state health officials, to evaluate the long-term desirability of allowing licensed pharmacists to furnish or sell nonprescription hypodermic needles or syringes to prevent the spread of blood-borne pathogens, including HIV and HCV.

Pharmacy Components:

- Authorizes a licensed pharmacist, until December 31, 2010, to sell or furnish ten or fewer hypodermic needles or syringes to a person 18 years or older for human use without a prescription if the pharmacist works for a pharmacy that is registered with the local health department for DPDP.

- Requires participating pharmacies to:
    - 1) register with their local health department and certify that they will provide the purchaser with written information or verbal

counseling on all of the following: how to access drug treatment; how to access testing and treatment for HIV and HCV; and, how to safely dispose of sharps waste;
  - 2) store hypodermic needles and syringes so that they are available only to authorized personnel; and
  - 3) provide for the safe disposal of hypodermic needles and syringes through one or more of the following options: providing an on-site safe hypodermic needle and syringe collection and disposal program; furnishing or making available for purchase mail-back sharps disposal containers that meet state and federal standards; and furnishing or making available for purchase personal sharps disposal containers.

- Deletes the current requirement that a pharmacist keep detailed records of nonprescription sale of hypodermic needles and syringes and delete the requirement that a signature and address be obtained from the person to whom the needle or syringe was furnished.

IDU-Medical Patient Components:

- Allows a person who is 18 years or older to purchase ten or fewer hypodermic needles or syringes without a prescription at pharmacies that registered with a local DPDP

- Authorizes, from January 1, 2005 until December 31, 2010, a person to possess ten or fewer hypodermic needles or syringes if acquired through an authorized source.

- Makes it unlawful to discard or dispose a hypodermic needle or syringe upon the grounds of a playground, beach, park, or any public or private elementary, vocational, junior high, or high school. SB 1159 would make a knowing violation of this prohibition a crime, punishable by a fine ($200-2,000), imprisonment (up to 6 months), or both.

- Exempts syringes that have been appropriately containerized for safe disposal from paraphernalia statutes, i.e., those syringes cannot be used as evidence of possession of drug paraphernalia. (A permanent change in law does not sunset in 2010.)

DHS Components:

- Requires DHS to convene an uncompensated advisory panel comprised of specialists, representatives, and stakeholders from the State, health, pharmacy, law enforcement, and waste management communities.

- Requires DHS, in conjunction with the advisory panel, to evaluate the effects of allowing licensed pharmacists to furnish or sell a limited number

of hypodermic needles or syringes without prescription, and provide a report to the Governor and the Legislature on or before January 15, 2010. The report shall include, but need not be limited to, the effect of nonprescription hypodermic needle or syringe sale on all of the following: 1) hypodermic needle or syringe sharing practices among those who inject illegal drugs; 2) rates of disease infection caused by hypodermic needle or syringe sharing; 3) needle stick injuries to law enforcement officers and waste management employees; 4) drug crime or other crime in the vicinity of pharmacies; 5) safe or unsafe discard of used hypodermic needles or syringes; and 6) rates of injection of illegal drugs.

- SB 1159 encourages DHS to seek funding from private and federal sources to pay for the evaluation.

Local Health Department Components:

- Require local health departments to:
  - 1) maintain a list of all pharmacies that have registered under DPDP;
  - 2) make available to pharmacies written information that may be provided or reproduced to be provided in writing or orally by the pharmacy to the customer at the time of furnishing or sale of nonprescription hypodermic needles or syringes. This information will include: how to access drug treatment; how to access testing and treatment for HIV and HCV; and how to safely dispose of sharps waste.

ATTACHMENT L

First Name	Last Name	County	Agency	Address	City	State	Zip	Phone	Email	Implemented?
Christine	Lieverman	Contra Costa	Contra Costa DPH					(925) 313-6786	cleiverm@hsd.co.contra-costa.ca.us	yes
Kate	Kraxenberg	Yuba	Yuba					(530) 749-6786	kkraxberger@co.yuba.ca.us	yes
Patricia	Calloway	Alameda	Alameda					510) 873-6503		yes
Steven	Simon	L.A. city	City of Los Angeles					(213) 485-6320		yes
Leslie	Goodfriend		Santa Cruz DPH					(831) 454-4313	leslie.goodfriend@health.co.santa-cruz.ca.us	yes
Anna	Long	Los Angeles	LA County Dept. of Health Services	313 N. Figueroa Street, Room 909	Los Angeles	CA	90012	(213) 240-8036	along@ladhs.org	no
no contact			City of West Hollywood							yes
Frima	Stewart	Marin	Marin					(415)507-4062	fstewart@co.marin.ca.us	
		San Francisco								yes
Valerie	Rose		San Francisco DPH	25 Van Ness Ave., suite 500	San Francisco	CA	94102	(415) 554-9023	valerie.rose@sfdph.org	

ATTACHMENT M

NABP Convenes Task Force on E-Pedigree Requirements

NABP's Task Force to Develop Recommendations for Electronic Pedigree Requirements convened via conference call on January 14, 2005, to examine current regulation, statutes, legislation, and other pertinent information regarding electronic pedigrees for the wholesale distribution of prescription drugs. After convening, the Task Force provided recommendations to the NABP Executive Committee concerning the necessary components, elements, and requirements for e-pedigrees. The final recommendations, with the Executive Committee's approval, will be available on NABP's Web site, www.nabp.net, at the end of the first quarter in 2005.

NABP President Donna M. Horn appointed this Task Force to gain consensus from state boards of pharmacy and other applicable regulatory agencies regarding the regulatory rules and components of e-pedigrees. Currently, some states have statutorily implemented and adopted regulations concerning e-pedigrees. As more and more states move in this direction and e-pedigree transactions occur across jurisdictions, it is necessary to establish uniform regulatory components for data elements required within the e-pedigree.

The Task Force members include Joshua Bolin, director, Indiana Board of Pharmacy; Patricia F. Harris, executive officer, California State Board of Pharmacy; William Harvey, acting executive director/chief inspector, New Mexico Board of Pharmacy; Jerry Hill, bureau chief of pharmacy services, Florida Department of Health; Lloyd K. Jessen, executive director/secretary, Iowa Board of Pharmacy Examiners; Elizabeth Scott Russell, executive director, Virginia Board of Pharmacy; and Richard M. Ritota, program manager, Food and Drug Safety Program, Consumer and Environmental Health Services, New Jersey Department of Health.

Following are the recommendations that the Task Force submitted to the Executive Committee for consideration.

To effectively deter counterfeiting and diversion, the Task Force recommended that e-pedigrees document all transactions and distributions of a product – starting from the product's manufacturer until final sale or distribution to the pharmacy or other entity dispensing or administering the product to the patient or end user. The complete recording of a product's chain of custody minimizes the risk of unscrupulous wholesale distributors and pharmacies illegitimately laundering products. The Task Force considered pharmacies' concerns regarding the costs associated with implementing such technology, but noted that information from the technology industry indicates that in the future such technology will be more affordable.

The Task Force determined that the implementation timeline proposed by Food and Drug Administration's Task Force Report on Counterfeit Drugs, which targets 2007 as the implementation

(continued on page 87)

Task Force Recommended E-Pedigree Data Elements

Prescription Drug Product	Transaction Information
Prescription Drug Name (proprietary and established name)	Name, Address, Telephone Number, and E-mail Address (if available), VAWD™ Number (if applicable), and State License Number of Each Entity Involved in the Chain of the Prescription Drug's Custody
Amount of Prescription Drug (container size and number of containers)	Name and Address of Each Person Certifying Delivery or Receipt of the Prescription Drug
Dosage Form/Dosage Strength	Certification That Each Recipient Has Authenticated the Pedigree
Lot/Control Numbers with Expiration Dates	A Certification From the Licensed Entity That the Information Contained in the Pedigree is True
Name of the Manufacturer and Repackager (if applicable) of the Finished Dosage Form	Sales Invoice Number
National Drug Code Number (optional)	Date of Transaction (Including Delivery and Receipt)

NABP's 101st Annual Meeting Registration Form and Program Available Online

Registration forms and program schedules for NABP's 101st Annual Meeting, May 21-24, 2005, at the Sheraton New Orleans Hotel in New Orleans, LA, are available on NABP's Web site at www.nabp.net. Just click on the links under Special Items or Meetings.

Themed "A Medley for Patient Safety: Accreditation, Self Assessment, Quality Care," NABP's 101st Annual Meeting features the Association's business sessions, timely and relevant continuing education programming, the annual Meet the Candidates session, the Welcome Reception, and Annual Awards Dinner as well as the Fun Run/Walk and the optional spouse/guest Louisiana Swamp Tour.

NABP has arranged a special meeting rate of $179 with the Sheraton New Orleans Hotel for single/double occupancy plus applicable taxes. To guarantee your accommodations, contact the Sheraton New Orleans Hotel directly at 504/525-2500, through their central reservation system at 1-888/627-7033, or via fax at 504/561-0178. All major credit cards are accepted. All reservations must be received by **April 22, 2005**. Be sure to mention that you are attending NABP's 101st Annual Meeting.

Air travel and rental car rates are available through NABP's designated travel agency, Options Travel, at 1-800/544-8785. When calling Options Travel, identify yourself as a registrant of NABP's 101st Annual Meeting and mention our special code, *NABP101*.

For more information about the 101st Annual Meeting program, contact the NABP Meetings Desk at 847/391-4406 or e-mail custserv@nabp.net.

New Orleans Facts

Site of NABP's
101st Annual Meeting
May 21-24, 2005
Sheraton New Orleans Hotel
New Orleans, LA

No trip to New Orleans is complete without a stop at the Café Du Monde to taste the eatery's world-famous beignets (pronounced "ben-yays"). These square pieces of fried dough, caked with powdered sugar, are believed to have been brought to New Orleans by French Ursuline nuns in 1727. The recipe remains the same to this day – beignets are hand rolled, deep fried, and then covered with heaping amounts of sugar.

Try the traditional New Orleans order – a café au lait (half coffee, half milk) and beignets (or doughnuts, as the locals call them) – while at the Café Du Monde.

The original Café Du Monde was established in the New Orleans French Market in 1862 and is open 24 hours a day, seven days a week, with the exception of Christmas Day and when there is a threat of a hurricane. A second Café Du Monde was opened in 1985; currently, there are seven Café Du Mondes in the New Orleans area.

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Source:
www.neworleansonline.com/pr/releases/prsall/pr_facts.html

E-Pedigree Task Force

(continued from page 71)

date for full adoption of the Radio Frequency Identification and Electronic Product Code e-pedigrees, is realistic and practical. As such, NABP's Task Force recommends that e-pedigrees be implemented by December 31, 2007. In the event that necessary technology is unavailable for implementing e-pedigree programs, the Task Force suggested that a phase-in approach to such technology may be warranted.

Uniform data elements for e-pedigrees were also discussed at the Task Force meeting. The Task Force discussed various state and federal mandated components of electronic and paper pedigrees and identified basic common components. Please see the chart on page 71 for a complete list of the Task Force's recommended e-pedigree data elements.

For more information about NABP's Task Force to Develop Recommendations for Electronic Pedigree Requirements, please e-mail custserv@nabp.net.

States Develop Wholesale Distributor Legislation, NABP Offers Guidance

Effectively combating counterfeit prescription drugs requires action on many different fronts, with electronic pedigrees being a primary means to securing the drug distribution system. The increasing availability and affordability of track and trace technology utilizing radio frequency identification, or RFID, makes the present legislative effort a perfect means to implement electronic pedigrees into the drug distribution system. Several states agree with this assessment and have passed or are developing legislation mandating the use of e-pedigrees. NABP strongly believes in the incorporation of e-pedigrees and the state boards of pharmacy and related state departments have been utilizing the Association's Model Rules for the Licensure of Wholesale Distributors, which is part of the *Model State Pharmacy Act and Model Rules of the National Association of Boards of Pharmacy*, as they develop regulations and legislation.

In February 2004, NABP released its first revision to the Model Rules for the Licensure of Wholesale Distributors and, subsequently, another revision was released in March 2005. In the revised Model Rules, Section 10 (Recordkeeping) calls for the implementation of e-pedigrees by December 31, 2007:

> Effective December 31, 2007, all Wholesale Distributors, whether located in or out-of-State, whether an Authorized Distributor or not, must provide and maintain an electronic Pedigree developed in accordance with standards and requirements of the Board, for all Prescription Drugs received and distributed.

Over the past few months, NABP has been advising several state boards of pharmacy and applicable state regulatory agencies on language for e-pedigree provisions contained in wholesale distributor legislation. NABP's activities include testifying to boards regarding e-pedigree provisions, submitting comments on various states' proposed legislation and regulatory initiatives, and attending state board of pharmacy meetings. While attending meetings, NABP provides board members with background on the counterfeiting issue and the Association's Model Rules.

NABP's revised Model Rules calls for increased licensure requirements for wholesale distributors including background checks, on-site inspections, and re-licensure every three years. In addition, the Prohibited Acts (Section 11) and Criminal Acts (Section 12) sections of the Model Rules incorporate more significant penalties for entities involved in prescription drug diversion and counterfeiting.

"As states move to strengthen the drug distribution system, each state must identify its own needs; however, it is important that all 50 states adopt wholesale distributor legislation that is similar to ensure that unscrupulous wholesale distributors are put out of business," explains NABP President Donna M. Horn. "If all 50 states

adopt uniform legislation based on NABP's Model Rules, they will effectively align their requirements to make it more difficult for wholesale distributors to circumvent laws by moving their businesses to another state with less stringent requirements. In addition, it will be easier for legitimate wholesale distributors to comply with each state's regulations."

In addition to these activities, NABP's Task Force to Develop Recommendations for Electronic Pedigree Requirements convened on January 14, 2005, to provide NABP's Executive Committee with recommendations concerning the necessary components, elements, and requirements for e-pedigrees (see "NABP Convenes Task Force on E-Pedigree Requirements" on page 71).

States and E-Pedigrees

Pedigree requirements for non-authorized distributors of record (ADRs) were first addressed in the Prescription Drug Marketing Act of 1987; subsequent federal regulations requiring pedigrees have been stayed most recently until December 2006. Currently, states have begun to incorporate pedigree mandates into their own regulations (see chart on page 81). While Florida and California will be the first states to impose pedigree requirements that provide incentive to wholesale distributors to implement e-pedigrees instead of paper pedigrees, Nevada led the way in 2001 with legislation mandating paper pedigrees for all prescription drugs from those wholesale distributors that are not ADRs. Nevada also required extensive wholesale distributor licensure applications and criminal background checks. Since then, Florida and California have also passed stringent legislation regarding pedigrees and wholesale distributors.

> . . . Florida's Bureau of Statewide Pharmaceutical Services reported that approximately 55 of the 1,458 permitted wholesalers in the state passed suspicious pedigree papers, bought or sold drugs without pedigree papers, or had permits but no record or conduction of legitimate business.

In July 2003, Florida passed legislation requiring, effective July 1, 2006, pedigrees recording ". . . each distribution of any given legend drug, from sale by a pharmaceutical manufacturer, through acquisition and sale by any wholesaler or repackager, until final sale to a pharmacy or other person administering or dispensing the drug." During the interim, pedigrees must be passed for all "specified drugs," which include those drugs the state has found to be at high risk for diversion or counterfeiting. In addition, those wholesalers that are not ADRs must pass a pedigree for any transaction – even those involving prescription drugs that are not "specified." By July 2006, however, all wholesale distributors – including those with ADR status – must provide pedigrees.

Before the law pertaining to pedigrees was passed, the Florida Legislature's Office of Program Policy Analysis and Government Accountability studied the problem of counterfeit drugs and diversion. The resulting report confirmed that state regulatory and law enforcement agencies had observed a significant increase in the incidence of counterfeit and diverted drugs. According to the report, Florida's Bureau of

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Pedigree Legislation

(continued from page 77)

Statewide Pharmaceutical Services reported that approximately 55 of the 1,458 permitted wholesalers in the state passed suspicious pedigree papers, bought or sold drugs without pedigree papers, or had permits but no record or conduction of legitimate business. The Bureau linked three major weaknesses to the increasing problem of diversion and counterfeiting in Florida, one of which was that "inadequate safeguards for current drug wholesaler permit requirements make it easy for unscrupulous individuals to invade Florida's wholesale market."

California has also passed legislation in an attempt to eliminate the threat of diversion and counterfeiting. In 2004, the state passed into law a requirement that by January 1, 2007, an e-pedigree "... accompany each distribution of a dangerous drug. . . ." Unlike Florida, California law specifies pedigrees as records in electronic form.

According to California Senator Liz Figueroa, author of the bill that was passed into law, "The bill is sponsored by the California [State] Board of Pharmacy to substantially decrease the threat of counterfeit drugs and drug diversion. Much of [the bill] draws from recently adopted laws in Nevada and Florida and from recent draft revisions to model laws published by the National Association of Boards of Pharmacy."

Several other states also have e-pedigree legislation pending including Indiana, New Jersey, and New Mexico. In January 2005, NABP compiled a summary of the legislative and regulatory activity regarding prescription drug pedigrees in these states:

Indiana

- Does not currently require pedigrees.
- SB 321 (pending bill) calls for January 1, 2007 implementation date for e-pedigrees.
- SB 321 defines pedigree as a document in written or electronic form that is approved by the Indiana Board of Pharmacy, which records each distribution of a legend drug from sale by manufacturer through acquisition and sale by each wholesale drug distributor.
- SB 321 requires e-pedigrees for all legend drugs.

New Jersey

- Does not currently require pedigrees.
- A 3177 (pending bill) calls for December 31, 2010 implementation date for e-pedigrees.
- A 3177 defines pedigree as a statement or record identifying each previous sale of the prescription drug, including each distribution to an ADR or to a retail pharmacy, starting with the last ADR, or the manufacturer if the prescription drug has not been purchased previously by an ADR or is a prescription drug on the specified list of susceptible products.
- Per A 3177, pedigrees will be required for all drugs unless the wholesale distributor is an ADR, in which case pedigrees will only be required for list products.

New Mexico

- Currently requires paper pedigrees, although the "source of drugs" is also acceptable and an alternate to a pedigree.
- Does not require e-pedigrees in current regulations.

NABP Model Rules

In consideration of the newly revised NABP Model Rules for the Licensure of Wholesale Distributors, NABP has continued to monitor state legislative and regulatory activity regarding pedigrees and wholesale distribution. The NABP Model Rules that was released in February 2004 specifies that the pedigree record all transactions involving the manufacturers and subsequent wholesale distributors of drugs. In the newly revised version of the NABP Model Rules, pedigrees are mandated to record all transactions from the manufacturer **to the pharmacy** and will record transactions involving **prescription (legend) drugs.**

As NABP assists boards of pharmacy with language for e-pedigree provisions contained in wholesale distributor legislation, it also educates boards on the Association's newly developed accreditation program for wholesale distributors. The Verified-Accredited Wholesale Distributors™ (VAWD™) program is an integral component in the elimination of prescription drug counterfeiters and operates in conjunction with NABP's Model Rules. VAWD was developed to help states determine that wholesaler distributors are legitimate, qualified for state licensure, and employing security and best practices for safely distributing prescription drugs from the manufacturer to the pharmacy to the patient. As part of the accreditation process, wholesale distributors must undergo on-site inspections and criminal background checks as well as screening through NABP's National Clearinghouse of Licensure, Certification, and Accreditation. VAWD is an especially useful tool for those boards with limited resources as these services are provided at no cost to the boards.

E-pedigree requirements, adoption of NABP's Model Rules for the Licensure of Wholesale Distributors, and VAWD accreditation are significant impediments to counterfeiting and diversion that create an environment in which unscrupulous wholesale distributors are unable to operate easily or profitably.

Summary of Current and Proposed E-Pedigree Components*

*As of January 14, 2005

	California SB 1307	Indiana SB 321	Florida	New Jersey A 3177	Nevada NAC 639.603, NRS 639.070	NABP Model Rules (February 2004)
Prescription drug name			●	●	●	
Amount of prescription drug	●	●	●	●	●	●
Dosage form	●	●	●	●		●
Dosage strength	●	●	●	●	●	●
Lot numbers	●	●	●	●	●	●
Control numbers				●		
Name and address of each owner of the prescription drug		●	●			●
Shipping information		●	●			●
Name and address of each person certifying delivery or receipt of the prescription drug	●	●	●			●
Certification that each recipient has authenticated the pedigree	●		●			●
Name, address, telephone number, and e-mail address (if available) of each wholesale distributor involved in the chain of the prescription drug's custody			●	●	●	●
Information that states the wholesale distributor has conducted due diligence of the wholesale distributor from which the wholesale distributor purchased, or may have purchased, the prescription drug		●				●
A certification from the designated representative of the wholesale distributor that the information contained therein is true and accurate under penalty of perjury	●	●	●			●
Source of the prescription drug, including the name and principal address of the seller	●				●	●
Sales invoice number	●					●
Expiration dates	●					●
Date of purchase	●				●	●
Name of the manufacturer of the finished dosage form					●	●
Be in writing and bear the title, "Statement Identifying Prior Sales of Prescription Drugs by Wholesalers Required by the Prescription Drug Marketing Act"					●	●

ATTACHMENT N

Acerity Corporation

RFID Anti-Counterfeiting, Anti-Diversion Solutions

Acerity Corporation Has a Good Solution

AuthentiTrak ™ and Trusted Source Inspector ™ Together:

- Curb Counterfeiting
- Curb Diversion
- Avoid Large and Complex Information Infrastructure
- Harmonizes the Various Participants in the Supply Chain
- Company Information Kept Within Corporate Boundary
- Support Cross-Country Transfer—Re-Importation

Benefits of the Process

- The RFID Tags Contain the Necessary Data for Supply Chain Management and for Product Authentication
- Company Data Kept within Corporate Boundary. Yet It Facilitates High Visibility, High Resolution Supply Chain Management within the Corporation
- Proactive Anti-Counterfeiting and Anti-Diversion—Suspected Items Are Stopped from Moving Down the Chain
- Does not Require Large I/T Infrastructure
- All Data Are Local and Therefore, it Allows Fast Response to the Execution of Tailored Business Rules

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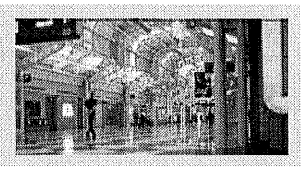
Acerity Corporation

AuthentiTrak™ :: Travel



AuthentiTrak™::Travel is designed and developed based on country governments' inputs and requirements addressing their needs in processing visitors and enhancing security resulting in a comprehensive solution facilitating the country government to:

- Identify visitors by using Radio Frequency Identification (RFID) on the travel document
- Track the visitor's entrance and exit of the country
- Make possible timely informed decision on travel visa issuance
- Facilitate effective security alerts and the use of "Black List"
- Identify overstays
- Keep easily retrievable records on visitors:
    - Connect, in a real-time basis, their Consulates, which issues visas
    - Port-of-entry, which process visitors' entries
    - Port-of-exit, which process visitors' exits
    - Immigration, which process visitors' extension of stay
    - National security, which has to provide instructions to other departments concerning the security of the border
    - With this tight connectedness and the identification of visitors the country government can significantly enhance its processing of travelers for better security and country image.

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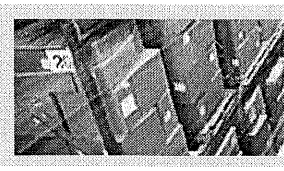
AuthentiTrak™ :: Supply Chain



The AuthentiTrak™::Supply Chain solution is for deployment in the whole supply chain as a proactive vehicle for combating counterfeits.

Acerity's supply chain solution:

- **Exposes counterfeits -** at any point in the supply chain if an item does not have a verifiable source or a source record which fails verification, the questionable nature of the item is exposed.

- **Intercepts counterfeits -** when an item is exposed as questionable it will not be accepted by any party downstream in the supply chain.

- **Deters counterfeiting -** authorized parties can request prove-of-source records from all the parties through whom the item passed and from the prove-of-source records AuthentiTrak™ can recreate the path of the item and identify the culprit.

- **Eliminates the issue of data custodian -** AuthentiTrak™'s "self sufficiency" in authenticity verification makes it possible to keep your data within your corporate boundary, eliminates the issue of data custodian and yet achieve reliable authentication. For some anti-counterfeit applications, for example, that in the supply chain for pharmaceutical products, as a participant in the supply chain you have to submit all your item flow transactions (where you obtained the item and where you shipped the item) to a data custodian. This has to be done because in those applications, in addition to the verification of the item's authenticity, the consistency of the source of the item against its flow paths have to be verified too to ensure that the item had not been infiltrated from questionable source.

- **AuthentiTrak™ effectively supports repackaging** - AuthentiTrak™ supports repackaging without compromising its abilities to authenticate and verify. For some industries the repackaging of products in the supply chain is inevitable.

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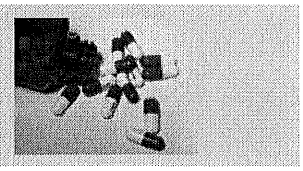
AuthentiTrak™ :: Covert



AuthentiTrak™::Covert is an advanced electronic covert authentication solution. Unlike the traditional approaches using chemical, optical or physical means, AuthentiTrak™::Covert is secure and cannot be compromised. It is based on Radio Frequency Identification (RFID) and proven cryptography techniques. The authenticity verification "self sufficiency" results in a cost effective solution that is easy to implement.

Constant changes are usually required in order to ensure that counterfeiters cannot keep up. With this covert solution, the constant changes are automatically performed and no process change is required.

This solution offers:

- Ease of use
- Has zero cost-of-change to ensure ongoing updates ahead of counterfeiters
- Ongoing automatic updates which are totally transparent to your operations
- Protection of your brand name and company image.

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Acerity Corporation

Company Overview

Acerity Corporation collaborates with customers to develop and deploy solutions to expose, intercept and deter counterfeits to:

- Protect Your Company Image
- Protect Consumers
- Reduce Losses and Fines
- Enhance Homeland Security (for government applications)

We implement our patent pending AuthentiTrak™ process for:

- Covert product authentication applications
- Proactive supply chain item authentication and verification
- Authentication and verification of documents, including travel documents, ID cards, etc.

The AuthentiTrak™ process is "self sufficient" where the checking of authenticity does not require database access for individual verification. With the use of proven cryptography techniques, similar to those for electronic credit card transactions, the AuthentiTrak™ process is secure. AuthentiTrak™'s strengths allow a broad spectrum of cost effective applications.

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Technology Overview

AuthentiTrak™

Acerity's security software deploys AuthentiTrak™ (patent pending), which is a "self sufficient" electronic authentication process. AuthentiTrak™ employs proven cryptography techniques in conjunction with Radio Frequency Identification (RFID) forming a multilayer secure process which provides numerous advantages and allows versatile and cost effective applications that other approaches do not have.

- **Self Sufficiency** - sufficient item and security data are stored in the RFID tag such that the RFID tag has sufficient information for identifying the item and for authenticity verification of the item. This capability allows cost effective solutions and avoids the need of company data going beyond the corporate boundary for applications (for example, pharmaceutical supply chain authentication application) which need to verify source against item flow path.
- **Versatile robust electronic approach** - compared to mechanical, chemical and optical approaches, Acerity's electronic authentication schema is secure. Encryption keys can be changed periodically, with zero cost-of-change, making it virtually impossible for the counterfeiters to keep up. You change your key rather than change your process. It is painless and transparent to your operations.
- **Significant cost avoidance in information infrastructure** - our competitors' electronic authentication solutions typically use approaches requiring database access on each verification of the item's authenticity. If you are the party authenticating the product, you have the huge burden of providing information services to others who have to verify the item. The magnitude of your burden relates to your item production rate and the number of verifications required throughout the life of each item. Also, the information services that you have to provide are mission critical to your clients and your distribution / sales channels. Using Acerity's solution you do not have that burden and yet the authentication process is robust and secure.
- **Cost effectively addressing the package reuse exposure** - it is expected that resourceful counterfeiters can gather and reuse authentic packages for fake products. With Acerity's solution deployed either as a covert authentication solution or as a supply chain authentication solution it is extremely difficult and economically unattractive for counterfeiters to reuse authentic packages.

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ATTACHMENT O

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

ENFORCEMENT COMMITTEE MEETING

Summary of Agenda Items Discussed – Not an Official Meeting
March 9, 2005

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

Staff: Patricia Harris, Executive Officer
Robert Ratcliff, Supervising Inspector
Judi Nurse, Supervising Inspector
Dennis Ming, Supervising Inspector
Joan Coyne, Supervising Inspector
Board of Pharmacy Inspectors
Dana Winterrowd, Staff Counsel

Call to Order

Board President and committee member Stan Goldenberg announced that due to the cancellation of flights to the Burbank airport, Committee Chair Bill Powers was be unable to attend the meeting and due to a previous commitment, committee member Dave Fong would not be in attendance either. Because the Enforcement Committee did not have a quorum, staff counsel advised that an official meeting of the Enforcement Committee could not be held. Therefore, President Goldenberg discussed the agenda items and began the discussion 9:35 a.m.

Importation of Prescription Drugs

President Goldenberg reported that the importation of prescription drugs is an ongoing issue that continues to be on the agendas of the Enforcement Committee and Board of Pharmacy meetings.

Articles were provided regarding legislation that was introduced in Washington that would allow various opportunities for prescription drug importation, anticipatory regulatory action by the Canadian Health Ministry that would impede Canadian importation to U.S. patients and Oregon's proposal to allow for importation. Also included was a letter from the Department of Health and Human Services to the Attorney General of Rhode Island regarding a recently enacted law in Rhode Island that authorizes the Rhode Island Board of Pharmacy to license Canadian pharmacies.

Concern was expressed that should the Canadian Health Ministry implement the proposed regulatory actions that would curtail the importation of prescriptions drugs from Canada, this

possibly could impact close to 2 million U.S. patients who may have difficulty in obtaining their prescription medications and choose other foreign sources.

Letter from Jeffrey A. Moss, Attorney for the Pharmacy Defense Fund Related to the Waiver of California Code of Regulations, title 16, sec. 1717(e) – Use of an Automated Dispensing Device

The Board of Pharmacy received a letter from Jeffrey Moss, an attorney for the Pharmacy Defense Fund. The letter expressed concerns regarding the board's issuance of a waiver pursuant to 1717(e) and the conditions for which the waiver was granted.

Supervising Inspector Dennis Ming reported that he inspected Longs Drug Store, #247 to determine the operational status of the Scriptcenter automated refill device installed at this location as a pilot program for dispensing certain select refill medications.

During the inspection, Supervisor Ming interviewed the pharmacist-in-charge (PIC) and representatives from Asteres Corporation. None of these individuals were contacted prior to the inspection.

Supervisor Ming confirmed that the Scriptcenter provided only selected refilled medications. During the course of the inspection, he asked the PIC to describe the operations of the Scriptcenter and what processes were in place to prevent dispensing drugs from the Scriptcenter that would require consultation. The PIC stated that to avoid inadvertent placement of "new" medications into the device, only those prescriptions with a prescription numerical suffix ending in .000 are processed into the device. It was explained that the Longs computer system (ADX) will not allow any medication without the correct suffix to be processed into the Scriptcenter. A bar code is produced and attached to the bag containing the medication. This bar code is scanned for identification and only then can the medication be dispensed from the device. The PIC further described that a pharmacist is responsible for conducting the final check of all medications for dispensing from the Scriptcenter to assure compliance that only refill medications are stocked in this system.

The PIC also provided copies of the Asteres Scriptcenter Training Instruction manual, the Scriptcenter Quick Reference Guide, and a copy of the Longs Drugs Scriptcenter In-Store Training manual.

It was Supervisor Ming's observation that the staff appeared to be well trained in the processing of prescriptions into the Scriptcenter, and that there were adequate safeguards in place to identify the correct drugs that could be dispensed from the device.

He explained that the PIC was asked to describe the process used to identify patients whose refilled medications are available in the Scriptcenter. The PIC stated that patients are provided a choice of obtaining their medications through the Scriptcenter or not. An enrollment form is stored on the Scriptcenter that patients can read and complete if they are interested in obtaining their routine refilled medications from the device. Patients are asked to provide a unique security

password and a login identification code for access to their medications from the Scriptcenter. There is a written acknowledgement on the application form that is signed by the patient who authorizes Longs to place their refilled prescriptions into the Scriptcenter and further advises the patient that not all of their prescriptions may be eligible for the service. The patient signs the completed form that is given to the pharmacist and the patient's confidential information is entered into the computer system. The patient keeps the bottom portion of the form, which contains their password and login identification code (which is not provided to the pharmacy). There is also an additional advisement at the bottom of the portion retained by the patient that states, *"Prescriptions that are oversized, unusually shaped, or that require refrigeration or consultation will not be available for pick-up in the Scriptcenter. These items will be available at the pharmacy counter."*

It was reported to Supervisor Ming that since the program's inception on December 2, 2004, Longs has enrolled approximately 600 patients and has dispensed over 1,000 refilled prescriptions from the Scriptcenter. There have been approximately 15 patients who have since dropped from the program. The reasons cited were varied and some were related to the inconvenience of utilizing their ATM or credit card twice in the store for purchases not related to the Scriptcenter. The PIC provided a copy of the in-store patient satisfaction survey questionnaire and a copy of the survey results. A review of the results showed that many of the patients found the Scriptcenter to be a convenience and were satisfied with the service.

Dr. Ming explained that he also conducted separate interviews with customers utilizing the Scriptcenter during the inspection. Statements from these patients were similar to the survey results in claiming convenience for obtaining the medications. One patient stated that a "not-so computer literate person" might have difficulty early on but did not feel it was a major issue. Patients felt that they had ample opportunity to talk to a pharmacist during and after hours if the need arose. There is a sign next to the ScriptCenter, which listed two telephone numbers for 24-hour pharmacies that could be called.

The Scripcenter is located at one end of the pharmacy cashier counter. The front of the device is accessible to the patients. The rear of the device where the drugs are loaded is in the back of the pharmacy cashier counter and directly accessible by the pharmacy staff during operational hours. Immediately behind the Scriptcenter is the will-call or pick-up shelf for medications not suitable for the Scriptcenter or for patient not enrolled in the program. During off hours, a retractable door descends to block off the prescription area; however, the Scriptcenter is then located outside of the secured area during off hours. Access to the rear of the cabinet is only done by pharmacy staff and requires computer access to unlock the cabinet. No keys are used.

The PIC demonstrated the process to access the Scriptcenter to load and unload the device with medication. The PIC stated only the pharmacy staff can access the device and it is computer controlled requiring the pharmacist or pharmacy technician to enter an individual specific log-in identification code and password. According to the PIC and consistent with Dr. Ming's observation, no one outside the pharmacy staff and only the licensed pharmacy staff have access codes into the device. The Scriptcenter is constructed of steel with steel rear doors that are unlocked only by the correct computer access codes. The doors cannot be pulled opened to gain

access. Once opened, the bin boxes containing the medications are accessible. The doors are manually closed and an audible click is heard when the doors are relocked and made secure. The Scriptcenter weighs 1300 pounds unloaded. There are two large bolts visible from the back of the device and under the rear doors, which attach the Scriptcenter to the floor for seismic safety purposes and to prevent intentional removal. There is an additional security feature located at the front of the Scriptcenter, which is a video unit that is activated each time an access code is entered onto the keyboard and creates a video record of the person accessing the device. Also, the keyboard screen on which the patient enters their access code and prescription number can only been seen by the user.

The pharmacy is open Monday thru Friday from 8am to 10pm, Saturday from 9am to 7pm and Sunday from 10am to 6pm. During these hours, the PIC stated that a pharmacist is always available to answer any questions regarding medications obtained from the Scriptcenter. A notification is provided to the patient at the time of enrollment that advises drugs requiring consultation would not be available in the Scriptcenter. The PIC also stated that a new access window is planned immediately adjacent to the Scriptcenter that will be used by patients who have difficulty obtaining their prescriptions or have questions regarding their Scriptcenter refilled medications. In the event that a refill medication requires patient consultation or discussion, a message would appear on the screen notifying the patient to contact the pharmacist in order to obtain their medication(s).

During after hours, there are two 24-hour Longs pharmacies nearby that will answer questions. There is a large information board next to the Scriptcenter that identified the two pharmacies and their telephone numbers. It was explained that Longs was planning to attach a telephone onto the Scriptcenter that will provide direct access to the other pharmacies during off hours. The intent of the Scriptcenter is to provide access to refill medications that patients must take on a chronic basis and are unchanged from refill to refill. Current pharmacy rules and regulations do not require consultation for these types of refilled medication; however pharmacy rules and regulations state that any changes in refill medication directions, strength, dosage etc. are considered "new" medications and require consultation. According to the PIC, none of these drugs are eligible for the Scriptcenter refill dispensing process.

Supervising Inspector Ming confirmed that refill medications and new prescriptions that require consultation are not placed in the Scriptcenter for automated dispensing. These prescriptions are filled and placed in the will-call/pick-up area and consultation is provided at the time the patient or the patient's representative asks for the prescription(s).

Dr. Ming concluded that Longs Drugs #247 is in compliance with the waiver provisions that authorizes its use of the Scriptcenter automated refill-dispensing device. It was his recommendation that the term "close proximity" used in granting the waiver for CCR 1717, be more defined to mean "within the immediate vicinity" of the licensed location. Locating the device within the pharmacy with the front in the public area and the back accessed only from the licensed area, or at the very least located at the pharmacy cashier counter as observed at the Longs pharmacy maintains the professional relationship between the patient and the pharmacist, and allows the staff to answer and resolve problems associated with obtaining the refilled

medications without leaving the pharmacy area unattended. In addition, patients should have the expectation that the device would be located in the pharmacy area and not in some remote location in another part of the business.

Request from the University of California San Diego (UCSD) for Waiver of California Code of Regulations section 1717(e) to Install and Use an Automated Dispensing Device

The Board of Pharmacy has received a request from UCSD for waiver of California Code of Regulations section 1717(e) to install and utilize a self-service dispensing unit at its hospital outpatient pharmacy.

At its October meeting, the Board of Pharmacy granted to Longs Drug Stores its request for a waiver of 1717(e) to install and utilize a self-service dispensing unit, such as the Asters ScriptCenter, at various Long Drug Stores in California. At its January meeting, the board granted a similar waiver to Safeway Inc. to install and utilize these same units at its Safeway and Vons pharmacies

The board granted the waivers pursuant to the following specified conditions:

- The automated dispensing device is used for refill prescriptions only.
- It is the patient's choice to use the automated dispensing device.
- The device is located in reasonable proximity to the licensed pharmacy premises.
- The device is secure from access and removal by unauthorized individuals.
- The pharmacy provides a means for the patient to obtain a consultation with a pharmacist if requested by the patient.
- The pharmacy is responsible for the prescriptions stored in the device.
- A pharmacist is not to use the device to dispense refilled prescriptions if the pharmacist determines that the patient requires counseling pursuant to CCR, title 16, sec. 1707.2(a)(2).

In conjunction with this waiver, the UCSD Skaggs School of Pharmacy and Pharmaceutical Sciences (SSPPS) is developing a formal study on the impact of this technology to pharmacy and patients. SSPPS plans to provide the information regarding the study to the board at its April meeting.

The waiver request will be presented to the Board of Pharmacy at its April meeting.

Centers for Medicare and Medicaid Services (CMS) Implementation of the Medicare Drug Improvement and Modernization Action (MMA) of 2003 – Proposed Electronic Prescribing Standards

On January 28, 2005, the Centers for Medicare and Medicaid Services (CMS) issued proposed regulations regarding electronic prescribing. The regulations propose to adopt standards for an electronic prescription drug program under Title 1 of the Medicare Prescription Drug, Improvement, and Modernization Act (MMA) of 2003. Of interest to the state boards is the area

in the regulations that addresses the federal preemption of state law. The MMA language that addresses the preemption is Section 1860D-4(e)(5).

In the proposed regulations, CMS has interpreted this section of the Act as preempting state law provisions that conflict with the federal electronic prescription program drug requirements that are adopted under part D. The deadline to submit comments to CMS on the proposed regulations is April 5, 2005.

Board counsel has advised the California law doesn't conflict with the federal electronic prescribing regulations.

The National Association of Boards of Pharmacy (NABP) is also requesting input as to whether or not the state boards will be implementing different requirements for the e-prescribing and transmission of prescriptions for controlled substances. To date, the U.S. Drug Enforcement Agency (DEA) has not released any final requirements on the electronic transmission or e-prescribing of controlled substances. NABP is asking states the following question:

> "Do you think that the security and privacy provisions for the electronic transmission or e-prescribing of non-controlled substances and C-III to C-V controlled substances prescriptions should be equivalent and more stringent requirements in place for C-II controlled substances prescriptions only?"

Health and Safety Code section 11164.5 specifies that a pharmacy or hospital may receive electronic data transmission prescriptions or computer entry prescriptions or orders as specified in Business and Professions Code section 4071.1, for Schedules II-V if authorized by federal law and in accordance with regulations promulgated by the DEA.

There was discussion that the DEA is studying the Public Key Infrastructure (PKI) for use for e-prescribing of schedule II drugs; however, the American Medical Association (AMA) is opposed to this system because it has its own system for electronic prescriptions.

Information on the Prescribing Authority for Naturopathic Doctors

On February 28, 2005, the board requested a legal opinion from staff counsel Dana Winterrowd regarding the prescribing authority for naturopathic doctors. An article appeared in the board's January 2005 newsletter regarding the authority of Naturopathic Doctors to prescribe; however, since the article appeared, the board has been working with the Bureau of Naturopathic Medicine to further clarify this authority. Due to the short timeframe for the request, counsel was unable provide the opinion for this meeting but will make an effort for the April Board meeting.

Implementation of SB 151 (Chapter 406, Statutes of 2003) – Requirements for Controlled Substance Prescriptions to Become Effective January 1, 2005

Supervising Inspector Robert Ratcliff reported that as of January 1, 2005, written prescriptions for all controlled substances must be on tamper-resistant security prescription forms that have

been printed by a board-approved printer and must contain specific elements. There is no specific format, size or color for the security prescription forms, so pharmacists need to be aware of the required elements.

If a pharmacist has questions concerning the validity of the prescription, the board is advising that the prescription should be treated like any other questionable prescription – call the prescriber to verify the prescription. If the form does not contain the proper features, it may indicate that a board-approved printer did not print it. Such prescriptions should be reported to the BNE at (916) 319-9062.

In summary the changes that took effect January 1, 2005 are:

- Triplicate prescription forms are no longer valid.
- All written controlled substance prescriptions must be on the new controlled substance prescription forms printed by an "approved" printer (oral and fax orders for Schedules III-V are still permitted).
- Pharmacies must report Schedule III controlled substance prescription information to the CURES system.
- Prescribers dispensing Schedule III controlled substances must report those prescriptions to the CURES system.
- The exemption for Schedule II prescriptions for the terminally ill remains in effect (H&S Code 11159.2). (This exemption doesn't apply to Schedule III prescriptions.)

To further aid in the implementation of the new controlled substance laws, the board prepared a series of articles that appeared in the January newsletter and on the board's Web site. Another series of questions has also been prepared that will be added to the board's Web site.

A question that is not on this recent updated series of questions but was asked at a recent SB 151 presentation is regarding prescriptions for Schedule III-V medications that are not on the new security forms. The board's direction to pharmacies is to treat these prescriptions as "oral" prescriptions and for the pharmacist to initial and date under Health and Safety Code 11164(b)(1). The pharmacist should always use his or her professional judgment when filling the prescription, contact the prescriber to verify if necessary and to advise the prescriber that for future written prescriptions, security forms are required.

Supervising Inspector Ratcliff emphasized that the direction board inspectors are giving to pharmacists is to take care of the patient. It is not the board's position that pharmacists be the "forms police." It is the responsibility of the prescriber to have the correct legal forms.

Implementation of SB 1307 (Chapter 857, Statutes of 2004) Relating to Wholesalers

Last year, the Board of Pharmacy sponsored SB 1307 (Figueroa). Governor Schwarzenegger signed the bill, which became effective January 1, 2005. The bill made various changes to the wholesaler requirements and distribution of dangerous drugs. Most of the changes strengthened and clarified the requirements for the distribution of dangerous drugs and dangerous devices in California.

The Enforcement Committee is monitoring the implementation of this legislation. One area of close oversight is the pedigree requirement. The bill requires an electronic pedigree by January 1, 2006 and gives the board the authority to extend the compliance date for wholesalers to January 1, 2008. The Legislature may extend the compliance date for pharmacies to January 1, 2009. The purpose of the pedigree is to maintain the integrity of the pharmaceutical supply chain in the United States.

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

At the April board meeting, Acerity Corporation will present its security software program, which is an electronic authentication process. The system employs a cryptography techniques in conjunction with RFID forming a multiplayer secure process, which provides numerous advantages and allows versatile applications. At the last enforcement committee meeting, there was a presentation by T3Ci. As stated with that presentation, it is not the intent of the Board of Pharmacy to support or endorse any specific technological solution for the electronic pedigree requirement.

At the invitation of the National Association of Boards of Pharmacy (NABP), California participated on its task force to develop recommendations for electronic pedigree requirements. The recommendations of the task force will be made public in early March. Again at the invitation of NABP, California has participated in two wholesale distributors regulatory meetings. The purpose of the these meetings is to work with the industry to established the prescription drug pedigree requirements so that the industry can identify its business solutions and technology standards to capture the pedigree data.

Implementation of SB 1159 (Vasconcellos)

Executive Officer Patricia Harris reported on the implementation of SB 1159. She noted that this agenda item was not noticed but is being provided for information purposes. With the recent signing and enactment of Senate Bill 1159 (SB 1159, Vasconcellos), local cities and counties can now legally authorize the establishment of the Disease Prevention Demonstration Project (DPDP), allowing pharmacies to sell syringes without requiring a doctor's prescription. The new legislation stipulates that the California Department of Health Services (DHS) must convene an uncompensated Evaluation Advisory Panel and, in coordination with this panel, design and implement a comprehensive evaluation that will assess the impact that SB 1159 has on HIV and HCV risk behaviors as well as the health and well-being of surrounding communities and stakeholders.

SB 1159 requires that the panel include the following:

- Infectious disease control specialists
- California State Board of Pharmacy representative(s)
- Representative(s) of independent pharmacies
- Representative(s) of chain pharmacies
- Law enforcement representatives
    - Executives, such as police chiefs and sheriffs
    - Rank and file officers
- Specialist(s) in hazardous waste management from DHS
- Waste management industry representative(s)
- Local health officers

SB 1159 requires that DHS evaluate the effects of allowing licensed pharmacists to furnish or sell a limited number of hypodermic needles or syringes without prescription, and provide a report to the Governor and the Legislature on or before January 15, 2010.

The report shall include, but need not be limited to, the effect of nonprescription hypodermic needle or syringe sale on all of the following: 1) hypodermic needle or syringe sharing practices among those who inject illegal drugs; 2) rates of disease infection caused by hypodermic needle or syringe sharing; 3) needle stick injuries to law enforcement officers and waste management employees; 4) drug crime or other crime in the vicinity of pharmacies; 5) safe or unsafe discard of used hypodermic needles or syringes; and 6) rates of injection of illegal drugs.

President Goldenberg and Vice-President Powers will be the Board of Pharmacy representatives.

Adjournment

President Goldenberg ended the discussion at 11:45 a.m.

ATTACHMENT P

California State Board of Pharmacy
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STATE AND CONSUMER SERVICES AGENCY
DEPARTMENT OF CONSUMER AFFAIRS
Arnold Schwarzenegger, Governor

Enforcement Team Meeting
March 9, 2005

2:00 p.m. – 3:00 p.m.

Present: President and Member Stan Goldenberg
Executive Staff
Supervising Inspectors
Inspectors

Announcements/Introductions
The meeting began at 2:00 p.m.

Quality Improvement Efforts
The supervising inspectors reported on the status of complaints/investigations and the compliance inspection program for pharmacies. It was noted that a routine inspection program for wholesalers was being implemented A wholesale self-assessment form and procedures were being developed.

Enforcement Committee Discussions
The Enforcement Team discussed the agenda items from the Enforcement Committee gathering.

Adjournment
The meeting was adjourned the meeting at 3:00 p.m.

ATTACHMENT Q

Board of Pharmacy Enforcement Statistics
Fiscal Year 2004/2005

Workload Statistics	July-Sept	Oct-Dec	Jan-Mar	Apr-June	Total 04/05
Complaints/Investigations					
Initiated	366	356	318		1040
Closed	584	532	402		1518
Pending (at the end of quarter)	629	537	540		540
Cases Assigned & Pending (by Team)					
Compliance Team	59	65	62		62
Drug Diversion/Fraud	57	72	74		74
Mediation Team	189	93	88		88
Probation/PRP	45	42	23		23
Enforcement	4	117	52		52
Application Investigations					
Initiated	41	33	38		112
Closed					
Approved	13	22	42		77
Denied	2	6	53		12
Total*	27	35	52		115
Pending (at the end of quarter)	54	65			52
Citation & Fine					
Issued	197	220	138		555
Abated	336	282	227		845
Total Fines Collected	$113,136.00	$119,406.00	$136,476.00		$369,018.00

* This figure includes withdrawn applications.

** Fines collected and reports in previous fiscal year.

Board of Pharmacy Enforcement Statistics
Fiscal Year 2004/2005

Workload Statistics	July-Sept	Oct-Dec	Jan-Mar	Apr-June	Total 04/05
Administrative Cases (by effective date of decision)					
Referred to AG's Office*	31	41	41		113
Pleadings Filed	22	27	24		73
Pending					
Pre-accusation	68	63	60		
Post Accusation	79	82	81		
Total	155	165	170		170
Closed**	19	28	33		80
Revocation					
Pharmacist	2	1	2		5
Pharmacy		1	2		3
Other	2	10	8		20
Revocation,stayed; suspension/probation					
Pharmacist	1		4		5
Pharmacy					
Other		1			1
Revocation,stayed; probation					
Pharmacist	5	4	5		14
Pharmacy		2	1		3
Other			1		1
Suspension, stayed; probation					
Pharmacist	1				1
Pharmacy					
Other					
Surrender/Voluntary Surrender					
Pharmacist	1	3	1		5
Pharmacy		1			1
Other	4	1	6		11
Public Reproval/Reprimand					
Pharmacist	1	1			2
Pharmacy					
Other					
Cost Recovery Requested	$49,126.50	$75,991.00	$138,531.00		$263,648.50
Cost Recovery Collected	$45,201.47	$55,390.86	$31,804.61		$132,396.94

* This figure includes Citation Appeals

** This figure includes cases withdrawn

Board of Pharmacy Enforcement Statistics
Fiscal Year 2004/2005

Workload Statistics	July-Sept	Oct-Dec	Jan-Mar	Apr-June	Total 04/05
Probation Statistics					
Licenses on Probation					
Pharmacist	105	106	108		108
Pharmacy	20	19	15		15
Other	23	23	24		24
Probation Office Conferences	7	8	13		28
Probation Site Inspections	23	41	46		110
Probationers Referred to AG for non-compliance	0	1	1		2

As part of probation monitoring, the board requires licensees to appear before the lead inspector at probation office conferences. These conferences are used as 1) an orientation to probation and the specific requirements of probation at the onset, 2) to address areas of non-compliance when other efforts such as letters have failed, and 3) when a licensee is scheduled to end probation.

Pharmacists Recovery Program (as of 03/31/05)

Program Statistics					
In lieu of discipline	0	1	0		1
In addition to probation	3	3	6		9
Closed, successful	0	3	7		10
Closed, non-compliant	3	4	3		10
Closed, other	1	0	0		1
Total Board mandated Participants	42	69	45		45
Total Self-Referred Participants*	30	4	18		18
Treatment Contracts Reviewed	38	35	45		118

Monthly the board meets with the clinical case manager to review treatment contracts for scheduled board mandated participants. During these monthly meetings, treatment contracts and participant compliance is reviewed by the PRP case manager, enforcement coordinator and lead inspector and appropriate changes are made at that time and approved by the executive officer. Additionally, non-compliance is also addressed on a needed basis e.g., all positive urines screens are reported to the board immediately and appropriate action is taken.

* By law, no other data is reported to the board other than the fact that the pharmacists and interns are enrolled in the program.

**Some PRP Participant Inspections are included in the Probation Site Inspections total.

As of March 31, 2005.

Citation and Fine Statistics
July 1, 2004 – April 1, 2004

689 citations have been issued this fiscal year

Total dollar amount of fines issued $ 325,800.00

Total dollar amount of fines collected $ 155,675.00*

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

Average number of days from date case is opened until citation is issued 177

Average number of days from date citation is issued to date citation is closed 63.8

Citation Breakdown by license type

Total issued	RPH with fine	RPH no fine	PHY with fine	PHY no fine	PIC with fine	PIC no fine	TCH with fine	TCH no fine
654	102	6	144	101	82	52	24	1

Miscellaneous Citation Breakdown by license type

Wholesalers	Exemptee's in charge	Clinics	Hypo permits	Hospital pharmacy	Unlicensed Premises	Unlicensed person
18	9	6	1	21	14	6

Board of Pharmacy Citation Statistics

Top Ten Violations for the third quarter of 2004/2005 by license type

Pharmacists	%	Pharmacies	%	Pharmacists in charge	%
1716 - Variation from prescription	45%	1716 - Variation from prescription	24%	1714(d) - Operational standards and security; pharmacist responsible for pharmacy security	25%
1716/1761 - Variation from Rx / Erroneous Rx	15%	1714(b) - Operational standards and security; pharmacy responsible for pharmacy security	24%	4125/1711 - Quality assurance program	10%
1717(b)(4)/4076(a)(4) Preprinted multiple check off Rx blanks/ container requirements for labeling - Name of the prescriber	4%	1715.6 – Reporting drug loss	12%	1716/1761 - Variation from prescription/Erroneous or uncertain prescriptions	6%
1714(d) - Operational standards and security; pharmacist responsible for pharmacy security	4%	1716/1761 - Variation from Rx / Erroneous Rx	10%	4051/11207/4036 - Conduct limited to a pharmacist; conduct authorized by pharmacist/Only pharmacist or Intern authorized to fill prescription/Pharmacist	6%
1707.2 – Duty to consult	2%	4125/1711 - Quality assurance program	5%	4127.1 – License to compound injectable sterile drug products required	6%
4125/1711 - Quality assurance program	2%	4116/1714(d) - Security of Dangerous Drugs and Devices in Pharmacy: Pharmacy responsibility for individuals on premises;	3%	1715 - Self-assessment of a pharmacy by the pharmacist in charge	4%
1715 - Self-assessment of a pharmacy by the pharmacist in charge	2%	4127.1(a) - License to compound injectable sterile drug products required	2%	4059 – Furnishing dangerous drugs or devices prohibited without prescription	4%
1716/4076(a)(4) - Variation from prescription/ container requirements for labeling - Name of the prescriber	2%	4115(e)-Pharmacy Technician license required	2%	4115(e) -4115(e)-Pharmacy Technician license required	4%
4051/11207/4036 - Conduct limited to a pharmacist; conduct authorized by pharmacist/Only pharmacist or Intern authorized to fill prescription/Pharmacist	2%	1708.2 – Discontinuance of business	2%	1305.11(a) - Unaccepted & defective order forms; No order form shall be filled if it is not complete, legible, or properly prepared, executed, or endorsed; or shows any alteration, erasure, or change of any description	2%
4116/1714(d) - Security of Dangerous Drugs and Devices in Pharmacy: Pharmacist responsibility for individuals on premises; Regulations/Operational standards and security	2%	1714(c) - Operational standards and security; the pharmacy must be maintained in a sanitary condition	2%	4114 – Intern pharmacist: activities permitted	2%

Contested Citations Office Conference

There were 16 office conferences held

Number of requests	355

Number scheduled	355

Number appeared	268

Number Postponed	73*

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

Total number of requests withdrawn	26
Failed to appear	3

Office Conference results

Total number of citations affirmed	162

Decision	Total citations	Total dollar amount reduced
Modified	64	$13,875.00
Dismissed	93	$5,875.00
Reduced to letter of admonishment	8	$2,125.00

ATTACHMENT R

Enforcement Committee

2004-2005

Third Quarter Report

January 1, 2005 – March 31, 2005

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

Outcome: **Improve consumer protection.**

Objective 1.1: **To achieve 100 percent closure on all cases within 6 months by June 30, 2005.**

Measures: **Percentage of cases closed or referred within 6 months.**

Tasks:

1. Mediate all consumer complaints within 90 days.
Quarter 1: based on 228 mediations/investigations sent to Supervising Inspectors for review.
Quarter 2: based on 156 sent for review
Quarter 3: based on 126 sent for review

Time Frame	Number				Percentage			
	Q1	*Q2*	*Q3*	*Q4*	*Q1*	*Q2*	*Q3*	*Q4*
0 to 90 days	34	12	34		68%	8%	27%	
91 to 180 days	13	26	12		26	17	10	
181 to 365 days	2	1	2		4	1	2	
366 to 730 days	1	0	1		2	0	0	
	2. Investigation all other cases within 120 days. **Quarter 1 & 2: same total stats as above**							
0 to 90 days	64	25	39		36%	16%	31%	
91 to 180 days	73	51	26		41	33	21	
181 to 365 days	32	36	10		18	23	8	
366 to 730 days	1	5	0		2	3	0	

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

Quarter 1: Based on 575 closed mediations/investigations
Quarter 2: Based on 495 closed mediations/investigations
Quarter 3: Based on 446 closed mediations/investigations

	Q1	*%*	*Q2*	*%*	*Q3*	*%*	*Q4*	*%*
0 to 90 days	177	31	149	30	150	32		
91 to 180 days	182	32	185	37	149	31		
181 to 365 days	148	26	109	22	122	22		
366 to 730 days	61	11	49	10	20	4		
731 + days	7	1	3	1	5	1		

4. Seek legislation to grant authority to the executive officer to issue a 30-day Cease and Decease Order to any boar-licensed facility when the operations of the facility poses an immediate threat to the public.

Quarter 1, 2 & 3: Nothing to report.

5. Integrate data obtained from computerized reports into drug diversion prevention programs and investigations (CURES, 1782 reports, DEA 106 loss reports).

CURES

First Quarter:

The Board has requested the addition of several critical date fields to the CURES system to ensure meaningful and accurate reports: 1) the date CURES was last updated by DOJ; 2) the date data was received at AAI from the pharmacy; and 3) the date data was transmitted from AAI to BNE. The date CURES was last updated is now available. Do to limitations in the current programming and since we are currently in the process of moving to a web based system, BNE has placed the other two date requests on hold until early 2005. No changes this quarter.

Second Quarter: *Screened transmitted CURES data for pharmacies for data non-compliance issues.*

Third Quarter

- *Staff uploads monthly CURES data files to the inspection program so that inspectors know how many prescriptions were filled, by drug, during the previous 3-month period before going in to do any pharmacy's inspection. Staff reviews data for accuracy and resolves data entry for issues. Staff runs ad hoc reports for additional*

information on a particular compound pharmacy at the request of the inspector if needed.

- *Staff researched CURES records that contained missing or incorrect pharmacy license numbers. The review resulted in bringing approximately 15 pharmacies into compliance.*
- *BNE implemented the new CURES web-based system mid-February 2005. The CURES enforcement analyst can run ad hoc queries to generate custom reports and schedule standard reports to run automatically all through a web browser. New Cognos Powerplay software appears to provide drag and drop functionality. BNE built a special error data cubes that staff can use to build ad hoc reports to assist in identifying pharmacies transmitting less than 97% accuracy for particular fields of data. For example, a pharmacy entering an invalid date of birth or NDC code. BNE has been very responsive when staff call for assistance; however, it will take some time for staff to rebuild many useful reports lost in the migration to the new database.*

5,208 pharmacies reported to CURES 3rd quarter.

CURES reports provided to supervising inspectors and/or inspectors to aid in an investigation or inspection:

- **Quarter 1:** *23*
- **Quarter 2:** *13*
- **Quarter 3:** *6*

CURES data used in complaint investigations:

- **Quarter 1:** *26*
- **Quarter 2:** *0*
- **Quarter 3:** *2*

CURES compliance issues found in inspections:

- **Quarter 1:** *14*
- **Quarter 2:** *8*
- **Quarter 3:** *21*

1782 Wholesaler Data Base: No changes first, second, or third quarter. Board has not been using 1782 reports for the last 3 to 4 years.

DEA 106 Theft/Loss :

- First Quarter: Approx. 39 investigations opened from DEA Loss reports.
- Second Quarter: Approx. 54 investigations....
- Third Quarter: Approx. 37 investigations...

Second Quarter: *Created the ability for the analyst to scan the DEA 106 form into a PDF file that is then accessible via an Access database tool.*

	6. Re-establish the CURES workgroup that includes other regulatory and law enforcement agencies to identify potential controlled substance violations and coordinate investigations. ▪ *The CURES Users Group is scheduled to meet every month to work on pharmacy noncompliance and data issues as well as to improve database functionality. Additionally, the boards and DOJ have used these meetings to discuss issues and share information related to the implementation of SB 151. Meetings were held on July 20th, September 21st, October 26th and November 30th. The August and December meetings were cancelled. Third quarter meetings are scheduled for January 11th, February 9th and March 16th. Fourth Quarter Meetings are scheduled for May 11 and June 8. The April meeting is canceled due to a conflict with SB734 hearings.* ▪ *First Quarter: Board met with BNE to discuss the board's needs for standard reports to be included on the new web-based CURES database scheduled for implementation by the end of this year. The board provided BNE with various samples of board-developed reports currently in use. In addition, staff highlighted numerous issues with BNE-developed standard reports available on the current system. Staff is currently working on updating business requirements and completing formal report development specifications documents.* ▪ *Second Quarter: Board staff met with BNE to discuss the board's needs for standard reports to be included on the new web-based CURES database. Implementation of the new web-based CURES system is planned for early 2005.* ▪ *Third Quarter: The CURES Users Group met the January 11th, February 9th and 10th, and March 9th this quarter. The April meeting is canceled due to a conflict with SB 734 hearings. The User Group meetings focused on SB 151 implementation issues and coordinating FAQ's on the prescribing boards' websites, as well the migration to the new web-based CURES system. BNE presented a powerpoint presentation and training session to the User Group at its February meeting to introduce the new web-based CURES system.* ▪ *Each quarter: An inspector and a supervising inspector continue to participate on the monthly diversion task force meetings regarding the importation of dangerous drugs, repackaging and distribution in the U.S.; monthly Oxycontin task force meetings in Ventura; FBI task force meetings; and diversion task force meetings in San Diego.*

	7. Secure sufficient staffing for a complaint mediation team and to support an 1-800 number for the public. Nothing to report first, second or third qtr.
	8. Improve public service of the Consumer Inquiry and Complaint Unit. **First Quarter:** ▪ *Board complaint staff provided information and brochures at the Asian Community Fair on July 15 in Sacramento and at the San Diego Better Business Bureau's Consumer Expo on August 7, 2004.* ▪ *Board staff provided consumer information at an adult day care program in Carmichael on September 28.* ▪ *In September the board staffed a booth at the Yreka Health Fair where about 450 people attended the event.* ▪ *The board staffed a booth at the Sixth Annual Los Angeles County Health Fair and Senior Exposition on October 7. Nearly 1,000 people attended* ▪ *Board has 21 consumer brochures available, including Health Notes.* ▪ *Board staff provided information about the board and discount programs for drugs at the Triple "R"* ▪ *Adult Day Program in Sacramento on September 28.* ▪
	Second Quarter: ▪ *October 16th – board staffed a booth at UCD Healthy Aging Event in Sacramento.* ▪ *November 16th – board staffed booth at Senior Health Fair in Paso Robles.* **Third Quarter:** ▪ *March 12, 2005: board staffed a UCD Healthy Aging Fair in Sacramento – "Focus on African American Health."* ▪ *5 health fair events are scheduled for April, May.* ▪ *In conjunction with UCSF, board developed and published three new consumer informational flyers addressing the issue of medications that have been recalled, generic medication and cutting drug costs. Board now has a total of 24 consumer brochures, including Health Notes available.*

	9. Automate processes to ensure better operations and integrate technology into the board's investigative and inspection activities. <u>Investigative Activities:</u> **First Quarter**: ▪ *A request to provide the board the capability to download its entire CAS enforcement database into and Access database has been submitted to the department's Office of Information Systems. This modification will enhance the board's reporting capabilities. If approved by OIS January 2005 is targeted for implementation.* ▪ *Developed new and improved reports for the automated audit program. This program is used to capture data from prescriptions.* ▪ *Security Printer database revisions and improvements this quarter include:* ✓ Various functionality revisions to ease data entry. ✓ Staff developed a new status report and statistical summary, which is set to automatically email an updated version to management weekly. ✓ Staff developed a worksheet style report that can be printed and included inside the file cover for easy reference within the file.
	Second Quarter: ▪ *CAS download capability request on hold as the department is evaluating tools to implement ad hoc reporting for Teale enforcement reports.* ▪ *Improved the audit program to include a set-up feature multiple pharmacy capability and database replication.* ▪ *Provided Blackberry devices to inspector staff.*
	Third Quarter: ▪ *Department OIS has been evaluating tools to implement ad hoc reporting for Teale CAS enforcement reports. OIS is in the process of selecting a vendor.*

	Inspection Activities – Automated inspection assignment status reports are sent to supervising inspectors weekly. Revisions and additions made to the automated inspection database include: **First Quarter:** ▪ *Modified import specification of Teale data into Access.* ▪ *Improved reports in assignment program.* ▪ *Improved functionality of Inspector Data program. Now prints nonlicensed staff titles and totals the number of staff employed and present. Inspection report prints license as well as LSC 12345/PHY 67890 when inspecting a LSC site. Improvements to be installed by the end of October.* ▪ *Added LSC license category to Inspector Activity to more accurately track inspector.* ▪ *Data Scrub Program - Each month staff extracts license data in various forms from one large chuck of data to meet the needs of several different internal and external requestors. Board staff finished the development of a data scrub program to automate this function.* **Second Quarter:** ♦ *Various improvements to the inspection program's functionality were implemented and deployed electronically to all inspectors. Inspectors were able to install the new enhancements with a click of a button to their laptops.* ♦ *Uploaded quarterly CURES data to inspection program so that inspectors can quickly identify whether or not a pharmacy is transmitting CURES data before going in for an inspection. Staff is currently working with DOJ to rectify a data loss issue for pharmacies that have no data during one or more of the 3 months queried. Currently, if a pharmacy has no data for one or two of the three months data queried the pharmacy currently shows they are not transmitting at all. Staff hopes to have the issue rectified early 2005.* ♦ *Improved inspector data functionality allows an inspector to select corrections issued on a written notice and also added a print preview on written notices.* ♦ *Improved inspection Word file program to automatically update each time the file is accessed by staff to speed download time for inspectors.* ♦ *Data Scrub program - staff identified and fixed some minor issues with the program.*

	Third Quarter: ♦ *Modified Assignment Program report to more accurately reflect submitted data. Single report shows submitted data from the Word database (Wordfile), Inspection Data (BOPTank) and Assignment History Tank.* ♦ *Added text highlighting to the assignment program to more easily identify and assign inspections that must be completed by June 30, 2005 to make strategic goal of inspecting all sites every 3-4 years. Similar highlighting added to inspector's laptops.* ♦ *Modified Inspector Data to automatically give pop-up warning if pharmacy does not have CURES data.* ♦ *Modified CURES Scrub Program to allow for importation of data files from a variable location and modified to be able to import up to 15 spreadsheets.* ♦ *Modified Evidence program – changes to Inventory Screen - remove duplicates and to show all entries - added comment field and normalized data to eliminate blank data fields - imported TEALE closure codes. Evidence Database – Staff added a destruction box number to the date inventory input worksheet to track the location of evidence that has been pulled and is waiting for destruction. Additionally, staff developed evidence pull list reports by region to aid in the evidence inventory and destruction process.* ♦ *Added index to Pharmacy Law PDF file* ♦ *Imported January Script into a PDF file with all Scripts for inspectors and staff.* ♦ *Modifed Inspector Data to tabulate staff statistics, to automatically enter outcomes, enabled all reports to print preview, to automatically generate Word Image file, and changed program flow for more efficient data entry.* ♦ *Installed all modifications to Inspector Program on Inspector laptops March 2005* ♦ *Security Printer Database – Staff added a new summary worksheet that documents every step of the review process for each application received to in the file when complete.* ♦ *Security printer application status reports are emailed monthly to the enforcement manager and executive officer.* ♦ ***65** security printers are currently approved to produce controlled substance prescription forms. 7 of the approved printers utilize the services of **several hundred** distributors that market their prescription products to prescribers.*
Objective 1.2 **Measure:**	**To achieve 100 percent closure on all administrative cases within one year by June 30, 2005.** **Percentage closure on administrative cases within one year.**

Tasks:

1. Pursue permanent funding to increase Attorney General expenditures for the prosecution of board administrative cases.

- *April 1st DAG costs increased from $112-$120 per hour to $132 per hour and Legal Assistants hourly costs increased from $53 to $91. Before this increase in fees, the board projected a deficit of $35,000. For 2003/04 the board will have to absorb the increased costs. For 2004/05 the board redirected $70,000 to the AG budget line item rather than pursuing an augment by a BCP.*
- *July 1 DAG costs increase to $139 per hour. Board receives supplemental funding of $216 thousand to purchase the same level of AG services at a higher hourly rate.*

2. Aggressively manage cases, draft accusations and stipulations and monitor AG billings and case costs.

- *Case management and review of pending cases is a continuous process.*

	Q1	Q2	Q3	Q4
Status memos sent to AG	26	19	15	
Disciplinary Cases Closed:				
0-365 days	8	8	10	
366 + days	13	17	22	
Accusations reviewed	27	28	33	
Accusations needing revision	10	7	6	
Accusations filed	22	27	24	
Stips/proposed decisions reviewed	18	20	26	
Cases reviewed for costs	12	12	19	

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

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

First Quarter

- *Administrative Case Management Database Program -*
  - ✓ *Changed calculations to reflect change in Legal Analyst and Deputy Attorney General Costs (changes effective April 2004 and July 2004).*
  - ✓ *Added a report to view cases that had status checks completed during a certain time frame.*

	✓ *Added a report to view Administrative Law Judge costs per case.* ✓ *Linked the database with the Activity Tracker database. Added reports and more fields to the cost form for easier access and viewing of inspector costs for each case.* **Second Quarter:** *No changes* **Third Quarter:** *Administrative Case Management DatabaseProgram – reviewed existing automated reports, revised and developed new reports for Enforcement Manager.* **5. Review and update disciplinary guidelines**. No changes first and second quarter. Third quarter: Guidelines targeted for review and submission at June Enforcement Committee meeting.
Objective 1.3: **Measure:**	**Inspect 100 percent of all licensed facilities once every 3 years by June 30, 2004.** **Percentage of licensed facilities inspected once every 3 years**
Tasks:	**1. Automate processes to ensure better operations and integrate technology into the board's investigative and inspection activities.** ▪ *For all quarters, see response to Objective 1.1, Task #9* **2. Inspect licensed premises to educate licensees proactively about legal requirements and practice standards to prevent serious violations that could harm the public.** ***Inspection Statistics Background:*** Total number of locations identified to inspect from those licensed at the time of the inspection program's July 1, 2001 inception date (does not include sites licensed after 7/1/01) to meet the board's goal of inspecting all sites every 3 to 4 years was approximately **5,570;** total number of inspections completed **5,445,** total number of inspections to be completed by July 2005 are **125**. **(Percentage completed toward goal: 97.75%)** Total number of locations identified to inspect (including sites licensed after 7/1/2001) was approximately **7,959**; total number of inspections completed **7,405**; total number of inspections to be completed are **554**. **(Percent of all site inspections completed 93.94%)**

Number				
Inspections Completed	*Q1* *657*	*Q2* *593*	*Q3* *824*	*Q4*
Type				
Sterile Compounding	*44*	*38*	*42*	
Status 3	3	6	6	
Routine resulting in complaint invest.	9	9	9	

2. Third Quarter - Implemented Wholesaler Inspection Program beginning March 1, 2005. A total of 490 sites identified for inspection by the Diversion Team.

Number			*Q3*	*Q4*
Wholesaler Inspections Completed			*44*	

3. Seek legislation to mandate that periodic inspections be done on all board-licensed facilities

Objective 1.4

Develop 4 communications in addition to the inspections program to educate board licensees by June 30, 2005.

Measure:

Number of communication venues (excluding inspection program)

Task

1. Develop the board's website as the primary board-to-licensee source of information.

- Public disclosure of disciplinary history on licensees is online.

First Quarter Web Additions/Revisions

- ✓ *Regulations updates.*
- ✓ *Added the option to join the Boards e-mail notification list.*
- ✓ *Posted Memo to Pharmacists on dispensing CII drugs without security or triplicate forms.*
- ✓ *Posted an audio recording of a presentation on SB 151*
- ✓ *Listed frequently asked questions on SB 151.*
- ✓ *Posted Board and Committee Meeting information - agenda, materials and minutes.*
- ✓ *Revised 2004 Pharmacy Lawbook*
- ✓ *Revised Key Facts about Emergency Contraception.*
- ✓ *Added Regrade Procedures for Pharmacist Examination.*
- ✓ *Added additional Security Printers and their distributors (total 25)*

Second Quarter Web Additions/Revisions

- ✓ *Website redesigned and changed over to the Governor's template*
- ✓ *Sent out subscriber alert notifications to the board's e-mail notification list.*
- ✓ *Posted board meeting dates for 2005*

- ✓ *Posted Board and committee information – agenda, materials & minutes*
- ✓ *Added an option to take the Board's survey*
- ✓ *Added non-resident wholesaler forms*
- ✓ *Updated Security Printer Information*
- ✓ *Added newly approved Security Printers*
- ✓ *Regulation updates*

Third Quarter Web Additions/Revisions

- ✓ *Revised security printer guidelines, and reorganized and revised security printer FAQs.*
- ✓ *Added new SB151 FAQ's. SB151 Prescribing and Dispensing web page scheduled for reorganization in April 2005.*
- ✓ *What to Look for on the New Tamper-Resistant Rx Forms, which describes Rx form security features, details preprinted prescriber requirements, details institution style forms for licensed health care facilities and limited exceptions for computer generated institution forms, and provides sample Rx forms.*
- ✓ *DHS Health Alert and Recall Information*
- ✓ *January 2005 The Script Newsletter*
- ✓ *Application Revisions*
- ✓ *Key Facts About Emergency Contraception in Armenian*
- ✓ *Additional approved security printers*
- ✓ *Updated version of the Pharmacy Laws and Regulations*
- ✓ *Index of new Pharmacy Laws and the effective dates*
- ✓ *Board meeting and committee materials*

2. Prepare two annual *The Scripts* to advise licensee of pharmacy law and interpretations.

- *March 2004 Script published*
- *January 2005 Script published*

3. Update pharmacy self-assessment annually.

- *October 2004 – revisions complete, being reviewed at October board meeting.*
- *Approved at October 2004 board meeting. Noticed for adoption at January 2005 board meeting.*
- *Board approved regulation change. New "draft" self-assessment posted on board's web-site.*

4. Develop board-sponsored continuing education programs for pharmacists in the area of pharmacy law and the expectations of the pharmacist-in-charge and coordinate presentations at local and annual professional association meetings throughout California.

First Quarter C/E presentations:

- ➢ *Board staff presented information to approximately 25 pharmacists regarding new controlled substances requirements at a leadership meeting of the Sacramento Valley Health System Society of Pharmacists (June 28).*

- *Board staff presented information to law enforcement agencies about CURES and drug diversion (May 27 and 28, not previously reported).*
- *Board staff presented information to audit staff of the Department of Health Services (June 30, not reported previously).*
- *Board staff presented information about compliance with California's sterile compounding requirements and radio pharmacy on July 8 to a group of about 10 pharmacists to a group in Southern California.*
- *Board staff presented information about the new prescribing requirements for controlled substances to physicians in San Luis Obispo on July 14, and to pharmacists and law enforcement staff on July 15.*
- *Board staff presented information about prescribing and dispensing controlled substances under the new California requirements to a group of over 40 physicians and other health care providers on August*
- *Board staff presented information about drug diversion investigations to invesors of the Department of Justice on August 26th.*
- *Board staff presented information regarding the new requirements for controlled drugs to investigators and staff pharmacists of the Department of Health Services on September 8, and to more than 50 pharmacists, physicians and other health care providers at a presentation hosted by the Pharmacy Foundation of California and Catholic Healthcare West.*
- *Board staff provided a major presentation at the CMA's annual pain conference in Sacramento on September 10 to more than 600 providers.*
- *President Goldenberg and Supervising Inspector Nurse presented information about new controlled substances requirements to the San Diego ASCP Chapter on September 13.*
- *Staff presented information about quality assurance programs and sterile compounding to the Sacramento Valley Society of Health Systems Pharmacists on September 17.*
- *Staff presented information about the board and new controlled substances requirements to the UCSF Medical Center on September 21.*
- *Board staff presented information about drug diversion investigations to investigators of the Department of Justice on September 28.*
- *Staff presented information about the new controlled substances requirements to a group of approximately 100 pharmacists, physicians and other health care providers at St Mary's Medical Center in Orange County on September 30.*
- *Board staff represented the board at the Circle of Advisors Meeting (regarding emergency contraception) on October 5.*

- *Supervising Inspector Ratcliff was a speaker at the California Primary Care Association's Tenth Anniversary*
- *Conference 0n October 7th*
- *Board Member Jones represented the board as speaker at the Indian Pharmacist Association on October 9, where approximately 500 individuals attended.*
- *In October board presented a telephone session on the new controlled substances requirements with health care providers in Redding.*
- *Board staff presented information about new controlled substances requirements to Santa Clara Medical Society.*
- *Supervising Nurse provided information about the new controlled substances requirements to the general public at a HICAP meeting in October.*

Second Quarter C/E Presentations

- *The board staffed a booth at the Yreka Health Fair, where 450 people attended.*
- *The board staffed a booth at the Sixth Annual Los Angeles County Health Fair and Senior Exposition on October 7—nearly 1,000 people attended.*
- *Supervising Inspector Ratcliff spoke at the California Primary Care Associations' Tenth Anniversary Conference on October 7.*
- *On October 15 board staff presented a telephone session on the new controlled substances requirements to 50 health care providers in Redding.*
- *On October 16 board staff hosted a booth at the Healthy Aging Summit in Sacramento where 700 people attended.*
- *Board staff presented information about new controlled substances requirements to the Santa Clara Medical Society.*
- *Supervising Inspector Nurse provided information about the board to a meeting of HICAP in October for training about when consumers who call HICAP should be routed to the board.*
- *Board staff provided consumer information at the Paso Robles Senior Center's Senior Health Fair to approximately 400 people on November 6.*
- *Board President Goldenberg speaker on importation at the CSHP's 2004 Seminar in Long Beach in November. More than 500 people attended.*
- *Supervising Inspector Robert Ratcliff gave the keynote address at CSHP's 2004 Seminar in Long Beach in November 2004*
- *Supervising Inspector Ming presented an "Update and What's New in Pharmacy Compounding" at the CSHP's 2004 Seminar in Long Beach in November 2004.*
- *Board staff presented information about the board and the new controlled substances requirements on November 18 to the Orange County Chapter of the CPhA, approximately 80 pharmacists attended.*

- *Board Member Jones and Supervising Inspector Ratcliff presented information on prescribing and dispensing controlled substances to 70 pharmacists at a Indian Pharmacist Association Meeting in Artesia on December 10.*
- *Supervising Inspector Nurse presented information to the Northern California Pain Initiative Executive Committee on December 14, 2004 via teleconference to approximately 50 prescribers.*
- *Supervising Inspector Ratcliff will present information on prescribing and dispensing controlled substances to approximately 60 pharmacists to the South Bay Pharmacy Association on January 6, 2005.*
- *The board will participate as a sponsor at a brown bag consultation event with pharmacists hosted by KCRA TV and Rite Aid in Sacramento, about 6,000 people are expected to attend this event on January 8 and 9, 2005.*
- *Supervising Inspector Ratcliff will present information about new controlled substances law to approximately 50 pharmacists at Vietnamese pharmacists on January 12.*
- *Supervising Inspector Ratcliff will present information on new pharmacy law to Phi Delta Chi at USC on January 20.*
- *The board will staff a booth at the Consumer Protection Day event in San Diego on January 29, 2005. Department Director Charlene Zettel will be the keynote speaker.*
- *Board Member Jones will present a section at the CPHA's Outlook 2005 Meeting in San Diego in February 2005.*
- *Supervising Inspector Ratcliff will present information to 4th year students at Western's School of Pharmacy on February 10.*
- *Supervising Inspector Ratcliff will present information on prescribing and dispensing controlled substances to approximately 60 pharmacists to the San Fernando Pharmacy Association on February 16, 2005.*
- *Supervising Inspector will present information to 1st year students at UCSF's School of Pharmacy on February 22.*

Third Quarter C/E Presentations:

- *Supervising Inspector Ratcliff presented information on new pharmacy law to 85 pharmacists and students at Phi Delta Chi at USC on January 20.*
- *The board staffed a booth at the Consumer Protection Day event in San Diego on January 29, 2005. Department Director Charlene Zettel was the keynote speaker at this event attended by approximately 1,500 individuals.*
- *The board staffed an information booth for two days at CPhA's 2005 Outlook on February 18-19. Over 500 pharmacists and students attended.*
- *Board President Goldenberg met with deans from the California schools of pharmacy, CSHP, and CPhA at the CPhA's Outlook 2005 Meeting.*
- *Board Member Jones presented information on new*

dispensing requirements for controlled drugs at the CPhA's Outlook 2005 Meeting in San Diego in February 2005 to over 200 pharmacists.

- *Supervising Inspector Ratcliff presented information on prescribing and dispensing controlled substances to approximately 90 pharmacists to the San Fernando Pharmacy Association on February 16, 2005.*
- *Supervising Inspector Ratcliff presented information to 100 1st year students at UCSF's School of Pharmacy on February 22.*
- *Supervising Inspector Ming and staff presented information on prescribing and dispensing controlled substances, and applying for the pharmacist licensure examination to 85 students at Western University on February 25.*
- *Executive Officer Harris presented information about the board to 1st year students at UCSF on March 1.*
- *The board staffed an information booth on March 12 at UCD's Healthy Aging Conference in Sacramento; over 1,000 people attended.*
- *Supervising Inspector Ming will present information about new prescribing and dispensing requirements for controlled drugs at the San Mateo County Pharmacists Association Meeting on March 17 to 480 pharmacist and pharmacy technicians.*
- *Board Member Schell presented information about pharmacy issues to a group of pharmacists in Buttee County on April 7, 2005.*
- *Board Member Schell will present information on automated technology in pharmacies to pharmacy students during April 2005's Legislative Day.*
- *The board will staff a consumer information booth on April 30 in San Diego at the Better Business Bureau's 2005 Smart Consumer Expo*

The board will staff a consumer information booth on May 7th in Sacramento at the 7th Annual Family Safety and Health Expo.

5. Hold quarterly Enforcement Committee Meetings

9/05: Meeting held. Discussed importation of prescription drugs, proposed legislative changes to pharmacy technician and pharmacist recovery program, waiver requests for prescription kiosks, automated dispensing devices and proposed regulations to authorize the use of kiosks and automated dispensing devices.

12/05: Meeting held. Discussed importation, new pharmacy laws, held presentation on electronic pedigree considered two waivers of 1717(e), and proposed statutory change to require mandatory reporting of impaired licensees.

3/05: Meeting held. Discussed importation, proposed electronic prescribing standards, waiver requests, information on prescribing authority for naturopathic doctors, implementation of SB 151& SB 1307.

Objective 1.5	**To monitor alternative enforcement programs for 100 percent compliance with program requirements by June 30, 2005.**
Measure:	**Percentage compliance with program requirements**
Tasks:	**1. Administer effective alternative enforcement programs to ensure public protection (Pharmacists Recovery Program, probation monitoring program, citation and fine program).**

Pharmacists Recovery Program	***Q1***	***Q2***	***Q3***	***Q4***
Total # of PRP Participants	42	69	63	
Number Referred to PRP	3	4	10	
Number Closed from PRP	4	7	10	

Probation Monitoring Program - # on probation	***Q1***	***Q2***	***Q3***	***Q4***
Pharmacists	105	106	108	
Pharmacies	20	19	15	
Other	23	23	24	

Citation and Fine	***Q1***	***Q2***	***Q3***	***Q4***
Citations Issued	197	220	138	
Fines Collected	$113,136	$119,406	$136,476	

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

- **First and second quarter:** *A citation and fine Access database is scheduled for development. Currently tracking of citation program activities is done on Enforcement CAS and Excel.*
- **Third Quarter:** *Citation and Fine program database in developed. Users have been reviewed to ensure the capture of all program activities.*

Objective 1.6	**Respond to 95 percent of all public information requests within 10 days by June 30, 2005.**
Measure:	**Percentage response to public information requests within 10 days.**
Tasks:	**1. Activate public inquiry screens to expand public information. Establish web look-up for disciplinary and administrative (citation) actions.**

- *Teale Public Disclosure Screen – completed disciplinary actions are entered int9o the database on a on-going basis During third quarter staff will begin review of adding filed accusations to public disclosure screens.*

- *Web Enforcement Look-Up – In production May 2004. No changes.*

2. Establish on-line address of record information on all board licensees-

- *Licensee address of record information became available on-line to public in December 2003. No changes.*

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

Type of Requests Received	***Q1***	***Q2***	***Q3***	***Q4***	
Public	31	32	**27**		
Licensees	35	16	23		
Other agencies	16	19	25		
License Verifications	227	208	198		
Time Frame Records Requests Responded To	***Q1***	***Q2***	***Q3***	***Q4***	
# & %					
Within 10 days	64 – 78%	49 – 73%	61-81%		
Over 10 days	18 – 22%	18 – 27%	14-19%		
Time Frame License Verifications Responded To	***Q1***	***Q2***	***Q3***	***Q4***	
# & %					
Within 10 days	146 – 64%	134 – 64%	158-80%		
Over 10 days	81 – 35%	74 - 36%	40-20%		

Objective 1.7 — **Initiate policy review of 25 emerging enforcement issues by June 30, 2005.**

Measure: — **The number of issues**

Tasks (Issues)

1. Reimportation of drugs from Canada.
   - Importation of Drugs - 2004: discussed at every Enforcement Committee meeting and board meeting. 1/05: discussed at board meeting. 3/05: discussed at Enforcement committee meeting.
2. Modification to the Quality Assurance Regulation regarding patient notification.
3. Proposals regarding wholesale transactions.
   - Sponsored legislation (SB 1307).
   - 1/05 – SB 1307 became effective.
   - 1/05 – participated in NABP Task Force to develop e-pedigree elements.
   - 1/05 – participated in NABP Wholesaler's Distributors Regulatory meeting ~~and participated in NABP Task Force to develop e-pedigree elements.~~ It participated in
   - 2/05 – implementation of SB 1307.
4. Clarification regarding prescription records by authorized officers of the law.
5. Review of Pharmacy Law regarding the delivery of medications after the

pharmacy is closed and a pharmacist is not present.
- Sponsored legislation SB 1913
- 1/05 – bill passed, SB 1913 effective

6. Off-site order entry of hospital medication orders (Bus. & Prof. Code Section 4071.1). Regulations adopted.
7. Prescriber dispensing.
8. Implementation of federal HIPAA requirements.
9. Prohibition of pharmacy-related signage.
10. Implementation of enforcement provisions from SB 361.
11. Implementation of SB 151 (elimination of the Triplicate).
    - 1/05 – new changes to controlled substance law took effect. Continued c/e presentations.
    - 2/05 – continued c/e presentations
    - 3/05 – discussed Q & A at Enforcement Committee meeting.
12. Dispensing non-dangerous drugs/devices pursuant to a prescriber's order for Medi-Cal reimbursement
13. Authorized activities in a pharmacy.
14. Review of Quality Assurance Program.
15. Limited distribution and shortage of medications.
16. Conversion of paper invoices to electronic billing.
17. Automated dispensing by pharmacies.
18. Public disclosure and record retention of substantiated complaints.
19. Evaluation of QA regulation
20. Biometric technology
    - Statutory change (SB 1913), regulation proposal to implement.
21. Update of pharmacy laws related to PRP.
    - 10/04 –board approved statutory changes.
    - 2/05 – Legislation introduced – SB 1111.
22. Update of pharmacy law related to pharmacy technicians.
    - 10/04 –board approved statutory changes.
    - 2/05 – Legislation introduced – SB 1111.
23. Clean-up of "Letter of Admonishment" provision.
    - 10/04 –board approved statutory changes.
    - 2/05 – Legislation introduced – SB 1111.
24. Use of "kiosks: for drop-off of prescriptions.
    - 10/05 – board approved waiver for kiosks and regulation change
25. Use of self-services dispensing units for pick-up of refill prescriptions.
    - 10/04 – board approved statutory changes
    - 1/05 – board approved second waiver
26. Mandatory reporting of impaired licensees.
    - 1/05 –board approved statutory change
    - 3/05 – SB 1111 introduced
27. Electronic Prescribing Standards for the implementation of the Medicare Drug Improvement and Modernization Act (MMA) of 2003.
    - 3/05 – Discussed at Enforcement Committee meeting – no action necessary.
28. Prescribing Authority for Naturopathic Doctors
    - 2/05 – Met with Bureau of Naturopathic Doctors and other interested parties regarding proposed legislative changes to address inconsistencies in pharmacy law.
    - 2/05 – Requested legal opinion from DCA.