



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 December 15, 2004

FOR ACTION

RECOMMENDATION 1

That the Board of Pharmacy consider the request from Safeway Inc. for a waiver of 1717(e) to install and use a self-service dispensing unit for refill prescriptions at its various Safeway and/or Vons Pharmacies.

Discussion

Safeway Inc. is requesting a waiver of 1717(e) to install and utilize a self-service dispensing unit, such as the Asters ScriptCenter, at its various Safeway and/or Vons pharmacies in California.

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.

At its October meeting, the Board of Pharmacy granted a similar waiver to Longs Drug Stores to use an automated dispensing device.

The board granted to Longs Drug Stores a waiver of the prohibition(s) stated by that section 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).

During the presentation to the Enforcement Committee, Ron Bingaman, R.Ph., Corporate Pharmacy Director for Safeway Inc. reported that Longs had placed an automated dispensing unit in one of its pharmacies. He stated that from November 30 to December 14th, Longs had 281 patients who had signed up to use the system, and of those 281 patients, 33 patients had actually used the system. Over all 52 prescriptions were dispensed and 10% of the 52 (or 5 prescriptions) were picked-up after hours. **(Attachment A)**

RECOMMENDATION 2

That the Board of Pharmacy approve the request from Advanced Pharmacy Solutions for waiver of CCR, title 16, sec. 1717(e) to allow the delivery of prescription medications to a licensed home health agency.

Discussion

Advanced Pharmacy Solutions requested a waiver of section 1717(e) so that they may deliver Synagis to licensed home health agencies for administration at a patient's residence. It was suggested that the board's counsel review the basic interpretation of 1717(e) in that the regulation does allow for the delivery to a licensed home health agency.

Concern was expressed that about the storage of this prescription medication at the home health agency prior to delivery to a patient specifically in some situations where the delivery may be throughout California. It was also asked as to what happens to the medication if it is not administered to the patient.

The Enforcement Committee recommended that the Board of Pharmacy support this waiver and suggested that Dr. Roache attend the January board meeting to answer any questions that the board may have. **(Attachment B)**

RECOMMENDATION 3

That the Board of Pharmacy support the proposed amendments to Business and Professions Code section 4104 to require mandatory reporting of impaired licensed individuals.

Discussion

Supervising Inspector Joan Coyne presented a request to amend B & P Code section 4104 that would mandate all pharmacies to report a licensed individual if the licensed individual is known to have engaged in the theft or diversion or self-use of prescription drugs belonging to the pharmacy. Current statute only requires that a pharmacy have in place procedures to protect the public when a licensed individual is known to be chemically, mentally or physically impaired to the extent it affects his or ability to practice pharmacy. The law does authorize the board to adopt regulation that would establish requirements for reporting to the board the conduct or incidents described in the law. Currently there is no regulation in place that requires a pharmacy to report impaired licensees to the board.

Supervising Inspector Coyne reported that as supervisor of the Pharmacist Recovery Program (PRP)/Probation team, she oversees the investigations on licensees that self-use of drugs and alcohol. Her team monitors probationers and recovery program participants. She reviewed recent cases involving impaired pharmacists.

She stated that her review indicated that a substantial number of incidents of theft and self-use of drugs, improper use of alcohol and obvious mental impairment by practicing pharmacists were never reported to the board. In many instances the discovery was made while the pharmacist was at work filling and dispensing prescriptions for patients. It was only after additional incidents with subsequent employers or an arrest was the impaired pharmacist or technician brought to the attention of the board.

Dr. Coyne explained that her research revealed that too many times, the pharmacy merely requested the resignation of the individual or terminated him/her from employment. And in some cases, the pharmacy would seek restitution for the stolen drugs in cash or a signed promissory note, followed by termination that allowed the pharmacist or technician to practice elsewhere. Usually the board didn't become aware of an impaired licensee until a serious prescription error was made or, a patient, co-worker or conscientious employer at a new work location reported the impaired licensee. It was also discovered through subsequent board investigations that many individuals had lost previous jobs because of chemical, mental or physical impairment affected their practice. She added that her review showed 22 cases where subsequent investigations would probably not have materialized had a prior employing pharmacy been required to report an employee whose practice was affected.

She concluded her presentation by stating that an impaired pharmacist or technician is a threat to the health and safety of the public. Early discovery of an impaired individual will not only protect the public but will also allow intervention and hopefully rehabilitation of that individual.

The committee recommended that the board approved the proposed requirement to mandate reporting of impaired licensees. Based on the comments, Deputy Attorney General Joshua Room revised the proposal. **(Attachment C)**

RECOMMENDATION 4

That the Board of Pharmacy support the changes as proposed by the Department of Justice to the Health and Safety Code related to the new security prescription forms and the proposal from board staff that the Board of Pharmacy no longer approve security printers.

Discussion

Over the last year, the Board of Pharmacy has been implementing the changes to the prescribing and dispensing requirements for Schedule II controlled substances. The board has been working very hard educating pharmacists and prescribers on the new requirements and has been coordinating efforts with the Bureau of Narcotics Enforcement (BNE), the Medical Board of California, other prescribing boards and the professional associations. Since January 2004 (and before), the board has provided over 30 presentations on SB 151 that have included telephone conference calls that have involved large number of individuals.

Starting 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. **(Attachment D)**

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, the board has prepared a series of articles that will appear in the January newsletter and on the board’s Web site.

Meanwhile, the Department of Justice (DOJ) is proposing some amendments and additional provisions to make technical changes to effectuate the administration of the CURES program.

The proposed amendments are as follows:

- DOJ would be the originating agency for fingerprint processing (instead of the Board of Pharmacy).
- DOJ would collect a fee for processing criminal background checks.
- The applicant class that that must submit criminal background checks would be clarified.
- The Board of Pharmacy and DOJ would be authorized to make any examination of the books and records of any applicant or visit and inspect the business.
- The Superior Court would be authorized to order a prescriber not to order or obtain or use any additional prescription forms during a pending criminal action based on the request of the law enforcement agency bringing the criminal action.
- The approved security printers would be required to print security prescriptions forms with a vendor identification code issued by DOJ.
- The security prescription form would be required to have a check box by the name of each prescriber to be checked to identify the prescriber issuing the prescription when there are multiple prescribers on one security prescription form.

DOJ is requesting that the Board of Pharmacy support these proposed changes. Staff is recommending that the board support them and in addition is proposing additional amendments. It is staff's recommendation that the Board of Pharmacy no longer approve security printers. The board absorbed this workload initially to assist with the transition from the triplicate prescription form to the new tamper-resistant forms printed by "approved" printers. It is no longer necessary that both the Board of Pharmacy and DOJ approve the printer. It should be the sole responsibility of DOJ. (**Attachment E**)

NO ACTION

Importation of Prescription Drugs

Background information is included on the activities related to this issue since the last board meeting. The Enforcement Committee was provided a copy of SB 19 that was introduced by Senator Ortiz on December 6, 2004. The purpose of the bill is to establish the California Rx Program, to be administered by the Department of Health Services. The bill would authorize the department to negotiate drug rebate agreements with drug manufacturers to provide for program drug discounts. The bill would authorize any licensed pharmacy or drug manufacturer to provide services under this program. The bill also establishes eligibility criteria and application procedures for California residents to participate in the program.

The bill would also require the Department of Consumer Affairs to implement, as part of the California Rx Program, a Prescription Drug Resource Center Web site to educate California consumers about options for lowering their prescription drug costs. The Web site shall include information about public and private drug coverage and drug discount programs that are available to California seniors and other consumers and tips for cutting costs on medications, including guidance concerning generic drugs.

In addition, the Web site shall include information about ordering prescription drugs from Canada and other countries. The Web site is to include a list of pharmacies that the Board of Pharmacy has determined meet pharmacy management practices required of pharmacies licensed to operate in California and the United States and a list of medications that can be ordered through the Web site from licensed pharmacies in Canada and other countries.

The department may either provide a direct link for consumers to pharmacies in Canada and other countries or provide a link for consumers to other Web sites if the Board of Pharmacy determines that the pharmacies listed in those other Web sites meet pharmacy management requirements that apply to California licensed pharmacies.

Also the committee was provided with a press release issued by the federal FDA regarding action it took against a company for the importation of prescription drugs into the U.S and other articles are being provided. **(Attachment F)**

On December 21, 2004, the United States Department of Health and Human Services (HHS) released its report of the Task Force on Drug Importation. Pursuant to the Medicare Prescription Drug Improvement and Modernization Act of 2003, which was signed by President Bush in December 2003, the secretary of HHS was directed to conduct a study that would examine whether and under what circumstances drug importation could be conducted safely. In compliance with this mandate, the secretary of HHS formed the Task Force on Drug Importation, which assisted HHS with this study. The study was sent to all board members. A copy of the executive summary is attached. **(Attachment G)**

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 will be monitoring the implementation of this legislation. One area of close oversight will be 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 be the method used to track a drug's pedigree. The manufacturer would tag the drug with a small chip and antenna. When the tag is in close proximity of a reader, it would receive a low-powered radio signal and interact with a reader exchanging identification data and other information. Once the reader receives data, it would be sent to a computer for processing.

McKesson reported that 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. **(Attachment H)**

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.

T3Ci, is an application software company that provides drug counterfeit, diversion detection and electronic drug pedigree for the pharmaceutical market. They demonstrated their technology solution for the electronic pedigree. 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. **(Attachment I)**

Cardinal Health requested that the Board of Pharmacy consider an exemption from the registration and licensure process for out-of-state distributors that solely provide intra-company transactions of dangerous drugs and dangerous devices into California. It is their position that such an exemption is warranted because it is practical while retaining the safeguards that the board is trying to achieve. It is their position that this approach is practical because it reduces the unneeded paperwork, which would be required in licensing all out-of-state entities. It is also their position that it is not necessary to license such related out-of-state wholesalers.

They argue that the Board of Pharmacy has jurisdiction over the transaction and affected parties at issue. The in-state wholesaler, which receives the shipment from the related out-of-state wholesaler, is licensed with the board. The board has the ability to bring an enforcement action against the in-state wholesaler for any transgressions, which may result from an inappropriate shipment into California by the related out-of-state wholesaler. This would include any action that the board may take against the in-state entity's corporate parent. Third, all transactions would be traceable and readily accounted for given the relationships of the entities involved.

It was presented that these intra-company transactions for which Cardinal was requesting an exemption would only take place when there was a temporary shortage of a drug and the in-state licensed wholesaler was unable to fill the order. Staff counsel commented that the Board of Pharmacy doesn't have the authority to provide an exemption to the licensure requirement. Such an exemption would require a statutory change. Cardinal stated that it was their position that under the proposed change that takes effective January 1, 2005, an inter-company transfer would not constitute a transaction at wholesale. Counsel advised Cardinal submit their request and legal analysis in writing for board review and consideration. **(Attachment J)**

Pharmacist-in-Charge Certification Program at the College of Pharmacy, Western University of Health Sciences

Jesse Martinez, Executive Director of External Affairs and Development and Sam Shimomura, Associate Dean Professional and Student Affairs at the College of Pharmacy, Western University of Health Sciences presented an overview of a course of study in the skills required to become a pharmacist-in-charge (PIC) in California. It will be a 12-week advanced elective course in their curriculum this year. Both the community pharmacy practitioner track and the community pharmacy management track with an emphasis in independent pharmacy ownership will include training in the requirements to serve as a PIC.

In addition, Western plans to develop a 15-hour "certificate" course designed to prepare a licensed pharmacist in the knowledge, skills and requirements to serve in a PIC position. They

plan to offer the “certificate” program to all interested licensed pharmacists in convenient sites in southern and northern California starting in the second quarter of 2005.

The vision for the PIC “certificate” CE program is a format that includes an experiential component with workshop discussions and lectures presented by experts with “real world” experience. The faculty will include attorneys, pharmacy managers, industrial security representatives, medical waste disposal experts and faculty from the WesternU College of Pharmacy. They also asked for participation from the Board of Pharmacy. They requested that board member or inspector with expertise in community and hospital outpatient pharmacy self-assessment process be a part of the training program. The final format that would include a board representative is open at this time. It was explained that the core content of the PIC certificate program would be in the areas of compliance with the board’s self-assessment form.

The enforcement committee agreed that the PIC certificate program was an excellent idea and expressed a willingness to participate in the development of such a program. One concern was the commitment of board resources to actively participate in the training program. However, Supervising Inspector Robert Ratcliff agreed to work with WesternU College of Pharmacy to determine how best the board could support their efforts. **(Attachment K)**

New Statutory Changes Effective January 1, 2005

The Enforcement Committee was provided with an overview of the new statutory changes that became effective January 1, 2005. These changes will be in the board’s January newsletter. Comments were made clarifying some of the changes. **(Attachment L)**

Enforcement Committee Meeting Summary of December 15, 2004 (Attachment M)

Enforcement Team Meeting Summary of December 15, 2004 (Attachment N)

Report on Enforcement Actions (Attachment O)

Report on Committee Strategic Objectives for 2004/2005 (Attachment P)

ATTACHMENT A



RECEIVED BY CALIFORNIA
BOARD OF PHARMACY

2004 NOV -3 AM 10:44 October 31, 2004

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:

Safeway Inc. is requesting a waiver to install and utilize self service prescription dispensing units, such as the Asteres ScriptCenter, at various Safeway and/or Vons pharmacies located within the state of California.

The Asteres ScriptCenter, that would be featured as the unit for our pilot 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 toward the front of the store to evaluate patient acceptance and usage especially for those patients that are ambulatory impaired. These units may be accessed by a patient during pharmacy hours or during those times when the main store is open but the pharmacy is closed, to improve patient therapeutic compliance.

Prescriptions would be filled, then checked by a pharmacist using the same safeguards currently in place. The filled prescriptions would be placed into the unit under the supervision of a pharmacist. As medications are placed into the unit, security measures are used to ensure accurate dispensing. The manufacturer of the Asteres Unit has previously provided 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 a patient may receive his/her prescription, but also allows the Board to waive this section for good cause. Accordingly, Safeway Inc is requesting a waiver for California Code of Regulations, Section 1717(e) to install and utilize self service dispensing units at its pharmacies throughout the state. 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 address above listed or directly by phone (925) 469-7747 with any questions or comments.

Sincerely,

Ron Bingaman, R.Ph.
Corporate Pharmacy Director
Safeway Inc.

Cc: Dave Fong, Corporate Vice Pres. Pharmacy
File



Board of Pharmacy Waiver Request (CCR 1717e) - Safeway



Agenda

- Description of focused use of remote Rx refill dispensing
- Benefits
- Description and specifications of proposed remote Rx refill dispenser

Remote Rx Refill Dispensing – Focused Use

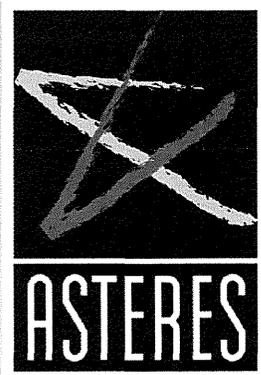


- Facilitates:
 - Busy lifestyle
 - More convenient access to Rx refills
- May only be used:
 - Upon patient request - "opt in"
 - Only for Rx refills when the pharmacist determines no consultation or other intervention is required
 - When Patients are comfortable using with ATM type units

Benefits

- Enhances availability of Rx refills that improves patient medication compliance
- Shifts routine Rx refill pick up away from pharmacy register resulting in better access for patients who wish to talk with their pharmacist
- Provides value add services to help keep patients using their local pharmacy and not shift to mail order services

Asteres ScriptCenter™



A secure, self-service prescription refill dispensing unit to be used by Safeway



ScriptCenter Functions

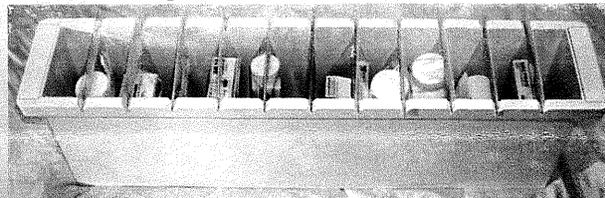


- Automates the storage and purchase of finished prescription refills that do not require any pharmacist consultation or intervention
- Allows pharmacy patients to pick up and pay for finished prescriptions
- Provides patients access to their prescription refills when store is open but the pharmacy closed

ScriptCenter Procedures

Fill → Load → Pay

- Fill prescriptions using established work flow with final check by the pharmacist
- Patient requests refilled prescription be available via ScriptCenter dispensing unit
- Place checked prescription refills in dispensing bags
- Link bar-coded bags to prescriptions
- Load bags into trays
- Load trays into ScriptCenter
- Customers purchase from ScriptCenter



How do pharmacy patients access their Rx refills from ScriptCenter?

ScriptCenter Welcome Alan Smith Quit

Select purchases and then press Check Out... Shopping Cart

Item	Price
Alan Smith \$5.00 Lisinopril 10mg Tab #30 1 Add to Cart	
Alan Smith \$10.00 Metformin 500mg Tab#60 2 Remove from Cart	
Betty Smith \$10.00 Furosemide 40mg Tab#30 3 Remove from Cart	
2 Metformin 500mg Tab#60 \$10.00	
3 Furosemide 40mg Tab#30 \$10.00	

Currently view 3 items available



- Login
- Select prescriptions
- Sign and acknowledge
- Pay
- Remove from bin
- Take receipt



Security Features

- One prescription per bag
- Bar code assures patient/RX match
- Electronic signature and photo log
- Equipped with floor bolts & door locks
- Privacy screen for confidentiality



Pharmacy Patient Satisfaction

- Easy to use
- Shorter lines
- More flexibility
- Private transaction environment
- Added convenience



Initial Pharmacy Patient Feedback:



Nov. 4-21, 2003

Retail drug store - San Diego, CA

- 450 surveys collected
- 99% - easy to use
- 92% - likely to use
- 31% - requested email notification



Memorandum

To: Enforcement Committee

Date: December 6, 2004

From: Patricia F. Harris 
Executive Officer

Subject: **Request from Safeway Inc. for
Waiver of California Code of
Regulations section 1717(e) to Install
and Use An Automated Dispensing
Device**

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.

The board granted to Longs Drug Stores a waiver of the prohibition(s) stated by that section 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).

The Board of Pharmacy has received a second request for waiver of California Code of Regulations section 1717(e) to install and utilize a self-service dispensing unit. This waiver request is from Safeway Inc. to use the dispensing units at its various Safeway and /or Vons Pharmacies in California.



California State Board of Pharmacy

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

December 6, 2004

Michael Cantrell, RPh, Esq.
Vice President Professional Services
Longs Drug Stores
P.O. Box 5222
Walnut Creek, CA 94596

Dear Mr. Cantrell:

Pursuant to its authority to do so granted by California Code of Regulations, title 16, section 1717, subdivision (e), the Board of Pharmacy hereby grants Longs Drug Stores a waiver of the prohibition(s) stated by that section 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).

This waiver is temporary and given without guarantee or promise of continuance or renewal. This waiver may be rescinded at any time by the board, with or without cause, with or without notice, and without regard to any reliance or injury claimed by Longs Drug Stores. No rights shall accrue to Longs Drug Stores by way of this temporary waiver.

Please complete the information on the following page and return it to my attention.

Sincerely,

A handwritten signature in cursive script that reads "P. F. Harris".

Patricia F. Harris
Executive Officer

Michael Cantrell, RPh, Esq.

Page Two

November 24, 2004

I, _____ (Name and Title), am authorized to execute this waiver acceptance on behalf of Longs Drug Stores. By my signature hereon, I acknowledge on behalf of Longs Drug Stores that the waiver is temporary, is given without guarantee or promise of continuance or renewal, may be rescinded at any time with or without cause or notice and without regard to any reliance or injury by Longs Drug Stores, and causes no rights to accrue to Longs Drug Stores.

Signature

Date:

ATTACHMENT B

State of California

Department of Consumer Affairs

Memorandum

To: Enforcement Committee

Date: December 6, 2004

From: Patricia F. Harris 
Executive Officer

Subject: Request for Waiver of 1717(e)

Advanced Pharmacy Solutions is requesting a waiver of California Code of Regulations section 1717(e) so that they may deliver Synagis to a licensed home health agency for administration at the patient's residence.

ADVANCED

Pharmacy Solutions

Critical Home Care Specialists

October 25, 2005
Patricia Harris
Executive Secretary
California State Board of Pharmacy

Dear Patti,

VIA FAX AND OVERNIGHT UPS EMERGENCY WAIVER REQUEST

Attached please find the new DHS Policy Statement regarding the Synagis Injection program for Medi-Cal beneficiaries to begin on November 1, 2004.

I specifically call your attention the third paragraph, section "b" whereby prescriptions filled pursuant to B&P Code 4051 may be delivered, under arrangement with a licensed home health care, directly to the HHA (licensed Home Health Agency) for administration by the HHA at the patient's place of residence.

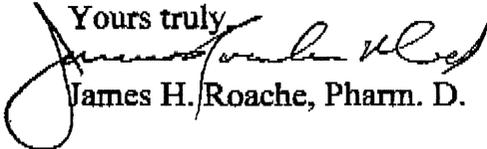
I have reviewed this new DHS policy with Dennis Ming and we have both come to the conclusion that a waiver from the Board of Pharmacy under the California Code of Regulations 1717e would be required.

Background: Synagis is a heat labile, life sustaining injection for the prevention of RSV (respiratory syncival virus) in certain compromised infants. It requires a professional nurse to reconstitute the medication within a few hours of the administration time and as such, we propose to deliver patient specific prescriptions directly to the licensed HHA as authorized in the DHS Policy Statement. We currently have 465+ fragile infants that we intend to begin filling their prescriptions as soon as DHS and EDS solve their TAR and claiming issues. We expect this to be accomplished within the next 48 hours.

It is not feasible to deliver refrigerated containers directly to patients because of cost constraints and reliability of the caregiver to be present when the package arrives. **Therefore we are urgently requesting this emergency waiver as I do not feel DHS Medical Policymakers took 1717e into consideration during their recent emergency enactment of this new policy statement.**

Time is of the essence. Please contact me as quickly as possible to discuss how we can begin providing these prescriptions within the legal limits of the law.

Yours truly



James H. Roache, Pharm. D.

State of California—Health and Human Services Agency
Department of Health Services



California
 Department of
 Health Services

SANDRA SHEWRY
 DIRECTOR

ARNOLD SCHWARZENEGGER
 Governor

POLICY STATEMENT
PRIOR AUTHORIZATION AND BILLING INSTRUCTIONS FOR SYNAGIS

To ensure continued timely access to palivizumab (Synagis®) during the upcoming flu season.

The Department will allow certain Medi-Cal fee-for-service providers to bill on form HCFA 1500 for Synagis® 50mg using code X7441, and Synagis® 100mg using code X7439, for dates of service beginning October 1, 2004. Physician, clinic, and home health agency (HHA) providers will not be allowed to bill using these X codes. Physician and clinic providers will continue to bill for Synagis® on form HCFA 1500 using 90378. HHA providers will continue to bill for Synagis® on form HCFA 1500 using Z6918.

Providers that meet the following criteria may bill for Synagis on form HCFA 1500 using codes X7441 and X7439:

- a) The provider operates an ambulatory infusion suite whereby the pharmacist is administering Synagis pursuant to the provisions of Business and Professions Code Section 4052(a)(5)(A) or,
- b) The provider, under an arrangement with a licensed HHA, dispenses a Synagis prescription in accordance to the provisions of Business and Professions (B&P) Code Section 4051 either directly to the caregiver or the HHA for administration by the HHA at the patient's place of residence, provided that the HHA is not separately billing Medi-Cal for a skilled nursing visit under Z6900.

Providers that dispense Synagis in accordance to the provisions of B&P Code Section 4051 directly to a HHA, physician's office or clinic for administration, whereby the HHA, physician's office or clinic separately bills Medi-Cal for the administration of Synagis will bill Medi-Cal through CAL-POS on-line system, CMC or paper using the drug's NDC.

All claims will require an approved TAR, which must be submitted to the Los Angeles Medi-Cal Field Office on fax line 1-866-816-4377.

All claims for Synagis using X7441 or X7439 will be paid at the rate of AWP minus 5% plus a one-time administration fee of \$4.49.

All claims for Synagis using the product NDC will be paid at AWP minus 17% plus the dispensing fee of \$7.25.

ATTACHMENT C

Proposed Amendment to B & P Code sec. 4104

This version was discussed during the Enforcement Committee meeting on December 15th.

4104. (a) Pharmacies shall ~~report to the board the identity of~~ have in place procedures for taking action to protect the public when a licensed individual employed by or with the pharmacy ~~if the licensed individual is known to be chemically, mentally, or physically impaired to the extent it affects his or her ability to practice the profession or occupation authorized by his or her license.~~
(b) Pharmacies shall ~~report to the board the identity of~~ have in place procedures for taking action to protect the public when a licensed individual employed by or with the pharmacy ~~if the licensed individual is known to have engaged in the theft or diversion or self-use of prescription drugs belonging to the pharmacy within 30 days of admission or termination of employment.~~
~~(c) The board may, by regulation, establish requirements for reporting to the board conduct or incidents described in subdivision (a) or (b).~~

DAG Room modified the proposed amendments to B & P Code sec. 4104 based on the discussion at the Enforcement Committee meeting on December 15th.

4104. Impairment or Theft by Licensed Individuals; Policies and Procedures; Duty to Report

(a) Pharmacies Every pharmacy shall have in place written policies and procedures for taking action to protect the public when a licensed individual employed by or with the pharmacy is discovered or known to be chemically, mentally, or physically impaired to the extent it affects his or her ability to practice the profession or occupation authorized by his or license, or is discovered or known to have engaged in the theft, diversion, or self-use of dangerous drugs.

(b) Pharmacies Every pharmacy shall ~~have in place procedures for taking action to protect the public when a licensed individual employed by or with the pharmacy is known to have engaged in the theft or diversion or self-use of prescription drugs belonging to the pharmacy~~ written policies and procedures for detecting chemical, mental, or physical impairment, as well as theft, diversion, or self-use of dangerous drugs, among licensed individuals employed by or with the pharmacy.

~~(c) The board may, by regulation, establish requirements for reporting to the board conduct or incidents described in subdivision (a) or (b).~~

(c) Every pharmacy shall report to the board, within 30 days of the receipt or development of such information, the following with regard to any licensed individual employed by or with the pharmacy:

(1) Any admission by a licensed individual of chemical, mental, or physical impairment affecting his or her ability to practice;

(2) Any admission by a licensed individual of theft, diversion, or self-use of dangerous drugs;

(3) Any video or documentary evidence demonstrating chemical, mental or physical impairment of a licensed individual to the extent it affects his or her ability to practice;

(4) Any video or documentary evidence demonstrating theft, diversion, or self-use of dangerous drugs by a licensed individual;

(5) Any termination based on chemical, mental, or physical impairment of a licensed individual to the extent it affects his or her ability to practice;

(6) Any termination of a licensed individual based on theft, diversion, or self-use of dangerous drugs;

(7) Any information supporting a reasonable suspicion that a licensed individual is chemically, mentally, or physically impaired to the extent it affects his or her ability to practice; or

(8) Any information supporting a reasonable suspicion that a licensed individual has engaged in theft, diversion, or self-use of dangerous drugs.

(d) Anyone participating in good faith in the making of a report authorized or required by this section shall have immunity from any liability, civil or criminal, that might otherwise arise from the making of such a report. Any such participant shall have the same immunity with respect to participation in any administrative or judicial proceeding resulting from the report.

ATTACHMENT D

11167. Notwithstanding subdivision (a) of Section 11164, in an emergency where failure to issue a prescription may result in loss of life or intense suffering, an order for a controlled substance may be dispensed on an oral order, an electronic data transmission order, or a written order not made on a controlled substance form as specified in Section 11162.1, subject to all of the following requirements:

(a) The order contains all information required by subdivision (a) of Section 11164.

(b) Any written order is signed and dated by the prescriber in ink, and the pharmacy reduces any oral or electronic data transmission order to hard copy form prior to dispensing the controlled substance.

(c) The prescriber provides a written prescription on a controlled substance prescription form that meets the requirements of Section 11162.1, by the seventh day following the transmission of the initial order; a postmark by the seventh day following transmission of the initial order shall constitute compliance.

(d) If the prescriber fails to comply with subdivision (c), the pharmacy shall so notify the Bureau of Narcotic Enforcement in writing within 144 hours of the prescriber's failure to do so and shall make and retain a hard copy, readily retrievable record of the prescription, including the date and method of notification of the Bureau of Narcotic Enforcement.

(e) This section shall become operative on January 1, 2005.

SB 151 Requirements for Prescribing and Dispensing Controlled Substances

Senate Bill 151 has brought changes in the controlled substance prescribing and dispensing requirements. A major change is the elimination of the triplicate forms used for prescribing Schedule II controlled substances and use of easier to order tamper-resistant prescription forms that are purchased from designated security printing companies.

The Board has a number of educational materials on its Web site to aid pharmacists, prescribers and patients in understanding the new requirements, which will be in effect January 1, 2005.

To help you in finding answers to prescribing questions regarding these changes, an annotated index for the contents of the key prescribing laws (Health & Safety Code) is offered below. This index provides a quick overview of where in law particular provisions can be found. The exact text of SB 151 can be found at the Board's Web site, www.pharmacy.ca.gov, and a question and answer segment is also at that site.

Tamper-resistant prescription forms

Health & Safety Code Sections

11029.5 Defines "security printer"

A person approved to produce controlled substance prescription forms pursuant to Section 11161.5.

11161.5 Applying to become an approved security printer

Contains the requirements for: applying for approval by the Department of Justice and the Board of Pharmacy to print tamper-resistant prescription forms, delivery of forms to the prescriber, and record-keeping requirements for printers.

11162.1 Requirements for tamper-resistant prescription forms

Describes all the features required for tamper-resistant forms and information to be entered on the forms by the prescriber. Included is a requirement that the form contains either (A) a statement printed on the bottom of the prescription blank that the "Prescription is void if more than one controlled substance prescription is written per blank" or (B) contain a space for the prescriber to specify the number of drugs prescribed on the prescription and a statement printed on the bottom of the prescription blank that the "Prescription is void if the number of drugs prescribed is not noted."

Details tamper-resistant prescription form requirements for the designated prescriber of a *licensed health care facility*.

Prescribing Schedules II – V controlled substances

11159.2 Exception to triplicate prescription requirements; terminally ill patient

Includes retention of requirements for a Schedule II prescription written on a regular plain prescription form for a “terminally ill” patient—must still include notation “11159.2 exemption.”

11164 Requirements for writing and dispensing Schedule II-V prescriptions

Includes all entries required on a controlled substance prescription. Directions for handling a Schedule II prescription that contains errors or uncertainties are found in Title 16 of the California Code of Regulations section 1761(a).

11164.1 Controlled substance prescriptions written by out-of-state prescribers

Allows filling such prescriptions when delivered to out-of-state patients and requires the reporting of Schedules II and III prescriptions to the Department of Justice

Business & Professions Code Sections

4170 Dispensing by the prescriber: requirements and restrictions

Includes definition of “prescriber” and details labeling and packaging requirements

Oral and faxed prescriptions

Health & Safety Code Sections

11164 Faxing of prescriptions for Schedule III-V controlled substances

Permits Schedule III-V control substances to be dispensed upon an oral or electronically transmitted prescription. Note: Faxing a prescription written on the tamper-resistant forms will produce the word “VOID” across the face of the prescription, so prescribers are encouraged to use a regular form when faxing.

11167 Faxing of Schedule II controlled substance prescriptions allowed in an emergency

Describes the emergency circumstances that allow the faxing of a Schedule II controlled substance prescription. This section lists all the requirements for a

pharmacist who receives an oral, electronic data transmission, or a written order not made on a tamper-resistant prescription form.

11167.5 Faxing of Schedule II controlled substance prescriptions for specified inpatients, residents, and home hospice patients

Contains pharmacists' procedures upon receipt of an oral or faxed Schedule II prescription for a patient of a licensed skill nursing facility, a licensed intermediate care facility, a licensed home health agency, or a licensed hospice

See Article 1 (commencing with Section 1250) of Chapter 2 of Division 2 of the Health & Safety Code for definitions of "*licensed health care facility*."

Controlled Substance Utilization, Review, and Evaluation System (CURES)

Health & Safety Code Sections

11164.1 Schedule III added to CURES data collection

Beginning January 1, 2005, all Schedule II and III prescriptions must be reported to the CURES data collection vendor, Atlantic Associates (see below).

11165 CURES

Fully describes the purpose of and procedures for pharmacies to report Schedules II and III prescriptions to the CURES data collection vendor. Questions regarding the reporting procedures should be directed to Atlantic Associates at 1-888-492-7341.

Dispensing physicians with questions regarding CURES should contact the Bureau of Narcotic Enforcement (BNE) at (916) 227-4051.

11165.1 Obtaining patient's medical history from CURES data

Allows prescribers to request patient's history from the Department of Justice

To request a patient history of controlled substance prescriptions from the CURES, pharmacists or physicians can download a Patient Activity Report (PAR) request form by visiting the Board of Pharmacy Web site, www.pharmacy.ca.gov/pharmacy/secure/pharmacy_forms_request.htm. Complete the appropriate PAR form and fax it to the BNE at (916) 227-5079.

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 printed by a Board-approved printing company. To prevent fraud or diversion, these forms must contain specific security features (Health & Safety Code Section 11162.1 et seq.). There is no one specific format, size or color for the security prescription forms, so pharmacists need to be aware of the required features.

Security Features

The law requires that the list or description of the required security features must be printed on the security prescription form. The list/description may be printed **anywhere on the form** (e.g., in warning bands along the edges of the form's face or listed on the back of the form). The description should tell what and where the features are on the form and how to test them.

Examples of what a new security form might look like are on the following pages. These are examples only—actual form designs and security feature application will vary significantly from form to form and from printer to printer. However, all forms are required to have specific security features and preprinted prescriber information.

More specific information about the security features required on these forms, as well as other new requirements for prescribing and dispensing controlled substances can be found on the Board's Web site at www.pharmacy.ca.gov.

Important Note: If you have questions concerning the validity of the prescription, treat it 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 it was not printed by a Board-approved printer. Such prescriptions should be reported to the Bureau of Narcotic Enforcement at (916) 319-9062.

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 printed by a Board-approved printer and must contain specific elements (Health & Safety Code Section 11162.1 et seq.). There is no one specific format, size or color for the security prescription forms, so pharmacists need to be aware of the required elements. 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 the 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.

The specific security feature components are:

1. **Latent Repetitive Void Pattern**—the word “void” appears all over the front of a 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 of the words, “California Security Prescription,” must be seen on the back of the security form. The watermark is often very light but can be seen by holding the form at an angle.
3. **Chemical Void**—any area 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**—a feature (e.g., a symbol or text) printed in this ink 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 or Microprinting**—the opaque writing disappears if the prescription is lightened or microprinted text so small that it cannot be detected without a magnifier, and which becomes a solid line when copied.
6. **Quantity Check-off Boxes**—six boxes with specific drug quantity amounts listed with each box. The prescriber checks off the box that matches the number of tablets or capsules prescribed. This feature is important to prevent alteration of the quantity ordered after the prescription is written. The law requires specific quantity boxes to be listed:

1-24

25-49

50-74

75-100

151 and over

7. **Unit Designation** —there must be a space for designating the 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** – security forms must have one of two statements at the bottom on the face of the prescription that delineates a single drug prescription versus a multiple drug prescription:
 - “Prescription is void if more than one controlled substance prescription is written per blank; or
 - “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.

Other required components on the security forms include:

- **Preprinted Prescriber Information** —the security prescription forms must include the name, category of licensure, license number, and federal controlled substance registration number of the prescriber, already preprinted on the form. There is an exception:
 - **Forms for Institutional Use**—there are special provisions that may be used only by a health care facility licensed by the Department of Health Services (DHS) pursuant to Health & Safety Code 1250. The facility 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. The facility must maintain the records for three years. The designated prescriber’s name, category of licensure, license number, and federal controlled substance registration number is preprinted on the form. The form must also include the facility’s name, address, category of licensure, and DHS license number. A blank area is provided for the actual prescriber to print 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.
- **“Do Not Substitute” Check-off Box** - this statement must appear on the form, and if checked off, indicates the prescriber’s order not to substitute another drug for the prescribed one. The prescriber must also personally initial the check box.
- **Form Batch Numbers**—requires that every batch of forms have a unique lot number printed on the forms and that each form within that batch is numbered sequentially, beginning with numeral one.

If you have questions concerning the validity of the prescription, treat the prescription 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 it was not printed by a Board–approved printer. Such prescriptions should be reported to BNE at (916) 319-9062.

INSTITUTION OR FACILITY SECURITY PRESCRIPTION FORM SAMPLE

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.

VOID APPEARS WHEN COPIED		REVERSE RX		MICROPRINT SIGNATURE LINE		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: <input type="checkbox"/> M <input type="checkbox"/> F			
1)					Quantity: <input type="checkbox"/> 1-24 <input type="checkbox"/> 25-49 <input type="checkbox"/> 50-74 <input type="checkbox"/> 75-100 <input type="checkbox"/> 101-150 <input type="checkbox"/> 151 - over Unit _____ Refills: 0 - 1- -2- -3- -4- -5 <input type="checkbox"/> Do Not Substitute Initials _____		
2)	SAMPLE ONLY – ACTUAL FORMS WILL VARY SIGNIFICANTLY				Quantity: <input type="checkbox"/> 1-24 <input type="checkbox"/> 25-49 <input type="checkbox"/> 50-74 <input type="checkbox"/> 75-100 <input type="checkbox"/> 101-150 <input type="checkbox"/> 151 - over Unit _____ Refills: 0 - 1- -2- -3- -4- -5 <input type="checkbox"/> Do Not Substitute Initials _____		
3)					Quantity: <input type="checkbox"/> 1-24 <input type="checkbox"/> 25-49 <input type="checkbox"/> 50-74 <input type="checkbox"/> 75-100 <input type="checkbox"/> 101-150 <input type="checkbox"/> 151 - over Unit _____ Refills: 0 - 1- -2- -3- -4- -5 <input type="checkbox"/> Do Not Substitute Initials _____		
X	Prescription is void if the number of drugs is not noted: _____						Date _____
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** –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.
- **Microprint signature line** – seen only with a magnifier, which becomes a solid line when copied.
- **Statement** allows multiple prescriptions on one form. Prescribers must note the number of drugs prescribed.

Alternatively, prescribers may order a form designed to write only single drug prescriptions. See the previous form sample using a single drug prescription format.

SAMPLE BACKSIDE OF SECURITY PRESCRIPTION FORMS

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.

● **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)

**SAMPLE ONLY – ACTUAL FORM
DESIGNS WILL VARY**

SINGLE PRESCRIBER OR GROUP PRACTICE SECURITY PRESCRIPTION FORM SAMPLE

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 Rx

SAMPLE ONLY – ACTUAL FORM
DESIGNS MAY VARY SIGNIFICANTLY

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

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.

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

ATTACHMENT E

**DEPARTMENT OF JUSTICE - LEGISLATIVE PROPOSAL
2005**

LEG UNIT DRAFT NUMBER: 22

I. DIVISION AND BUREAU/SECTION SUBMITTING THE PROPOSAL

Bureau of Narcotic Enforcement, Controlled Substance Utilization, Review and Evaluation System (CURES)

II. TITLE

Proposed technical changes to Pain Treatment and Diversion Act of 2003, Health and Safety Code §, 11159.2 et seq.)

III. SUMMARY

The proposed amendments and additional provisions make technical changes to effectuate the administration of the CURES Program.

IV. BACKGROUND

A. Existing Law

Pursuant to SB 151 (Chapter 406, Statutes of 2003) implementing the “Pain Treatment and Diversion Act of 2003,” the Controlled Substances Utilization Review and Utilization Review and Evaluation System (CURES) became permanent. (See Health and Safety Code §, 11159.2 et seq.) CURES is administered by the DOJ, Bureau of Narcotic Enforcement (BNE). SB 151 made several notable changes, among those the official “triplicate” prescription form issued by BNE was discontinued for Schedule II controlled substances and a new secure forgery resistant prescription form was adopted for Schedule II through IV drugs. CURES was also authorized to initiate the collection of Schedule III drug information, necessitating changes in the CURES technology and data collection procedures. Among other things, BNE, in conjunction with the Board of Pharmacy, was mandated new duties in the approval of vendors of the new security prescription forms. Among the new duties, CURES must obtain criminal background checks on applicants seeking to become vendors of the secure prescription form. This has included vendors from out of state and Canada. New requirements were also imposed on prescribers in the information provided to CURES. The proposals below address needed clean up and technical changes to facilitate the effective operation of CURES and the program duties of BNE.

SB 151 was not submitted by DOJ but directly impacted a DOJ program. Since these are operational changes that favor DOJ, DOJ should assume responsibility for addressing these changes.

B. Problem

1. Health and Safety Code, § 11161.5 (Approval of security printers)

Number One:

The Act would be amended to specify that DOJ, and not the Board of Pharmacy (BOP), will control the manner in which fingerprints are provided. Under SB 151, the BOP was designated as the agency that first receives applications from vendors seeking approval to print the new security prescription forms. In doing so, the Board was identified as the agency to control obtaining fingerprints. Hence, the BOP is required to obtain fingerprints for DOJ to clear. This has led to delaying the approval process when the application is finally received by DOJ. Additionally, operational needs are presently not being met, specifically with approving out-of-country vendors with the BOP as the lead agency in the fingerprinting process. Full records are also not made available to DOJ under the present statutory scheme.

Currently, the BOP processes the vendor applications. The application includes a live scan form to be taken with the applicant to the place they have their fingerprints live scanned at DOJ or sent to DOJ. At this time, the live scan form contains the originating agency number (ORI) and mail code for the Board of Pharmacy. This means that when the fingerprints are processed by DOJ, DOJ must treat this as an application for the BOP and provide the clearance or rapp sheet information directly back to them as the submitting agency under the guidelines of applicant processing. The BOP then forwards this information to CURES at DOJ, as part of the completed application package. This manner of dissemination is not the norm. Additionally, as the requesting agency, it is the BOP that currently receives all subsequent arrest information for current approved vendors and it is up to the BOP to pass this information on to CURES. This leaves a critical information gap when the DOJ, as CURES, assumes its role in the applicant approval process.

Another problem with this process is that the information the BOP receives from DOJ is limited to arrests with dispositions. If there is an entry on the rapp sheet that does not have a disposition, the arrest information must be removed before dissemination to the BOP. If DOJ were the processing agency DOJ would receive the arrest information as the submitting agency with the authority to receive and review such information.

Accordingly, with the amendment, the live scan form can be changed to reflect DOJ as the submitting agency with DOJ's ORI and mail code, thereby allowing the response to go directly to DOJ as well as all subsequent arrest information. The above proposed processes are consistent with existing criminal background policy and practice.

Number Two:

The Act would be amended to allow DOJ to collect a fee for processing criminal background

checks when a vendor applies to become an approved security printer of prescription forms. Each applicant shall pay at the time of filing an application for a permit a fee determined by the department which shall not exceed the application processing costs of the department. This is consistent with DOJ policy of a fee for services and similar legislation governing, for example controlled substance transactions under the “precursor” statutes. See Health and Safety Code §, 11106 (h). The impact will be on those vendors that apply after the enactment of this legislation. The far majority of vendors will already have been approved before this amendment. The fee, however, is an important cost recovery item.

Number Three:

The Act would be amended to specify and define the applicant class that must submit criminal background checks. The statute presently refers only to the “applicant” but does not specify who the applicant class is. BNE has already discovered that it must have the authority to require backgrounds of individuals that will directly handle the secure prescription forms. Specifying the applicant class also will comply with DOJ policy and to allow for consistency as found in related precursor statutes where the applicant class is specified. See Health and Safety Code §, 11106 (d)(2). The impact will fall more on BNE and DOJ since BNE will request more criminal background checks. Nonetheless, BNE must have the specified authority for a more expansive class to facilitate background checks and avoid legal challenge.

Number Four:

The Act would be amended to authorize the BOP and the DOJ (BNE) to make any examination of the books and records of any applicant or visit and inspect the business. This authority is necessary given the approval authority already provided and is needed to comply with DOJ policy for auditing and enforcement as found in related precursor statutes. See Health and Safety Code §, 11106 (c). The impact will fall more on BNE since it will be authorized to conduct examinations as resources permit.

2. Health and Safety Code, § Section 11161 (Judicial Enforcement)

The Act would be amended to authorize the Superior Court to order a prescriber not to order or obtain or use any additional prescription forms during a pending criminal action. The law enforcement agency bringing the action will be directed to notify the DOJ of such orders. This amendment addresses an important omission in the enforcement scheme. The amendments also bring the statute current since triplicate prescription blanks will no longer be in use. This will impact prescribers in a criminal proceeding but is a technical change to authorize the court to prevent a prescriber from getting new prescription forms, thus evading a more limited order to turn existing forms in to the court.

3. Health and Safety Code, § Section 11162.1 (Prescription From Features)

Number one:

The Act would be amended to require approved security printers to print security prescription forms with a vendor identification code issued by the DOJ. The Act omitted any identifier on the new security prescription forms that would identify the security printer who issued the form. Hence, there is no manner to confirm that a form was issued by an approved security printer and no way to trace back a form to a specific printer. This will address important fraud concerns. The impact will be on vendors but the costs to add an identifier should be negligible.

Number two:

The Act would be amended to require a check box by the name of each prescriber on a security prescription form to be checked to identify the prescriber issuing the prescription when there are multiple prescribers on one security prescription form. Pharmacists have identified problems in identifying the prescriber based solely on the signature of the prescriber. The check box will serve the purpose of identifying the prescriber. The impact will be on prescribers but it will be negligible.

4. Health and Safety Code sec. 11190 (Direct Dispensing)

The Act would be amended to require a prescriber who directly dispenses controlled substances to submit the information to the DOJ in a format set by the department. The amendment would leave the format open to adjust for changing technology. The format will be specified by regulation. Presently, prescribers are authorized to submit the information in either hard copy or electronic form. This change is necessary to meet the submission needs of the CURES program. The impact will be solely on prescribers who directly dispense controlled substances as opposed to prescribers that write a prescription and the prescription is filled by a pharmacist.

V. PROPOSALS

None of these proposals have ever been introduced in the Legislature. There is no need for urgency legislation. These proposals are projected to address the present problems affecting the administration of the CURES program under BNE.

A. Suggested Legislation

1. Health and Safety Code, § 11161.5 (Approval of security printers)

Proposed Amended Statute:

Section 11161.5

(b)

(5)(A)

(B) The ~~applicant~~ *Board of Pharmacy* shall ~~also~~ *provide the applicant with the means and*

direction to provide fingerprints and related information, in a manner specified by the Board of Pharmacy Department of Justice, for the purpose of completing state, and federal or foreign criminal background checks.

(C) The Department of Justice shall require an applicant to have their fingerprint images and related information captured for submission to the Department of Justice, for the purpose of obtaining information as to the existence and nature of a record of state, federal or foreign level convictions and state, federal or foreign level arrests for which the Department of Justice establishes that the applicant was released on bail or on his or her own recognizance pending trial. Requests for federal level criminal offender record information, received by the Department of Justice, pursuant to this section, shall be forwarded to the Federal Bureau of Investigation, by the Department of Justice.

(D) The Department of Justice shall respond to the Office of the Attorney General with information pursuant to section 11105 (l) of the Penal Code.

(E) The Office of the Attorney General shall request subsequent arrest notification, from the Department of Justice, as provided under Section 11105.2 of the Penal Code, for all applicants described in subdivision (b).

(F) Each applicant shall pay at the time of submitting fingerprints and related information to the Department of Justice a fee determined by the Department of Justice to be sufficient to cover all processing or investigative costs generated from or associated with completing state, federal or foreign criminal background checks.

.

(d) The Board of Pharmacy or the Department of Justice may deny a security private application on any of the following grounds:

(1) The applicant, *any individual owner, partner, corporate officers, manager, agent, representative, employee or subcontractor for the applicant, who has direct access, management or control of controlled substance prescription forms, has been convicted of a crime.* [Remainder as is.]

.

(5) The Board of Pharmacy or Department of Justice determines that the applicant failed to demonstrate adequate security procedures relating to the production and adequate security procedures relating to the production and distribution of controlled substance prescription forms. *Applicants shall authorize the Board of Pharmacy and the Department of Justice, as a condition of approval, to make any examination of the books and records of any applicant or visit and inspect the business hours, as deemed necessary to enforce this section.*

2. Health and Safety Code, § Section 11161 (Judicial Enforcement)

Proposed Amended Statute:

Health and Safety Code, § Section 11161

(a) When a practitioner is named in a warrant of arrest or is charged in an accusatory pleading with a felony violation . . . , the court in which the accusatory pleading is filed or the magistrate who issued the warrant of arrest shall, . . . issue an order which requires the practitioner to surrender to the clerk of the court all ~~triplicate prescription blanks or~~ controlled substance prescription forms in the practitioner’s possession at a time set in the order *and which prohibits the practitioner from obtaining, ordering or using any additional prescription forms. The law enforcement agency obtaining the order shall notify the Department of Justice of this order.*

(b) The order provided by Evidence presented at the hearing shall be limited to the warrant of arrest with supporting affidavits, the motion to require the defendant to surrender *and prohibit obtaining, ordering or using all* ~~triplicate prescription blanks or~~ controlled substance prescription forms with supporting [remainder as is]

3. Health and Safety Code, § Section 11162.1 (Prescription Form Features)

Proposed Amended Statute:

Health and Safety Code, § Section 11162.1

(a) The prescription forms for controlled substances shall be printed with the following features:

.

(11) An identifying number assigned to the approved security printer as issued to the approved security printer by the Department of Justice.

.

(3) Forms ordered pursuant to this subdivision that list multiple prescribers on one prescription form shall have a check box by the name of each designated prescriber and each designated prescriber who signs the prescription form shall identify themselves as the prescriber by checking the box by their name.

~~(3)~~ (4)

(4) (5)

4. Health and Safety Code sec. 11190 (Direct Dispensing)

Proposed Amended Statute:

Health and Safety Code, § Section 11190

(G) (2): Each prescriber that dispenses controlled substances shall provide the Department of Justice the information required by this subdivision on a monthly basis in ~~either hard copy or electronic form~~ *a format set by the Department of Justice.*

B. Alternative Solutions

Regulations will be promulgated that will address program administration issues as a supplement to the present statutory scheme.

Regulations, however, will not resolve the statutory shortcomings that the amendments address.

C. Public Policy

These amendments address program administration issues. The CURES program is now permanent. It is in the interest of all parties that work with the CURES program to have the program effectively administered.

ATTACHMENT F

USA TODAY
December 29, 2004

Canada may stop over-the-border drug sales

By Julie Appleby, USA TODAY

A tough new stance by Canada's health minister on Internet drug sales has increased the odds that Americans will soon be stopped from buying Canada's lower-cost medicines, say pharmacists on both sides of the importation fight.

In recent weeks, Canadian health minister Ujjal Dosanjh has spoken out against the cross-border drug trade, saying he might prevent Canadian doctors from co-signing prescriptions for American patients they have not examined. Dosanjh considers the practice unethical without an exam.

Canadian law requires that prescriptions bear the signatures of Canadian doctors, so such a move could cut off many of the estimated 2 million Americans who buy drugs from Canada, often over the Internet.

"We're hanging by a thread," says Dave MacKay of the Canadian International Pharmacy Association, which represents pharmacies that do business in the USA. "There's a very real chance that by the middle of January, drugs will not flow from Canada anymore."

Tension over the debate has been growing in Canada and the USA. Some Canadian pharmacists oppose the Internet sales, and others have built a lucrative business because of it.

Lothar Dueck of the Coalition for Manitoba Pharmacy, an opponent of drug sales to the USA, says the growing trade has led to increased drug prices in Canada. He also says the matter is part of ongoing trade disputes between the two countries.

"The U.S. doesn't want our wheat, wood, beef or pigs. Why do they want our drugs?" Dueck asks.

The issue may arise when the Canadian Cabinet meets again on Jan. 11. Ken Polk, director of communications for the health minister, says some of the changes being considered may not need Parliament's approval.

Polk said Prime Minister Paul Martin told reporters this month that the health minister "is articulating the position of the government of Canada."

Dosanjh's ideas have not received much coverage in the USA, but he has been widely quoted in Canadian media. Dosanjh fears that U.S. demand might cause shortages for Canadians.

"I want to make sure that we don't have ... 250 million Americans buying drugs in Canada," Dosanjh said in an interview Dec. 12 on a CTV television show in Canada. "We cannot be the drugstore for the United States."



U.S. Food and Drug Administration



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FDA News

FOR IMMEDIATE RELEASE
P04-108
December 1, 2004

Media Inquiries: 301-827-6242
Consumer Inquiries: 888-INFO-F

FDA Takes Action Against Company for Illegal Importation of Unapproved, Potentially Unsafe Drugs

The U.S. Attorney's Office, Southern District of New York, has on behalf of the Food and Drug Administration (FDA), filed a civil complaint against Canada Care Drugs, Inc. (Canada Care), Claire Ruggiero, and Christine Ruggiero for the illegal importation of prescription drugs into the U.S.

Canada Care was previously affiliated with Rx Depot, Inc., a company that was engaged in the illegal importation of prescription drugs until November 6, 2003, when the United States District Court for the Northern District of Oklahoma entered an order of preliminary injunction against the company and its affiliates to stop their illegal activity.

"By continuing to illegally import unapproved drugs, Canada Care is putting at risk the health of patients who are expecting to improve their health," said Dr. Lester M. Crawford, Acting FDA Commissioner.

According to the complaint filed in the Southern District of New York on Monday, following the preliminary injunction order against Rx Depot and its affiliates, which was made permanent with the entering of a consent decree on August 20, 2004, Canada Care severed its relationship with Rx Depot, but continued illegal activity in violation of the Food, Drug and Cosmetic Act (FDCA).

As is alleged in the complaint, FDA's investigation of Canada Care's illegal importation operations has revealed several products that pose a risk to the public health. In February and August 2004, FDA made two undercover purchases of the FDA-approved drugs Sporanox and Neurontin through Canada Care.

Instead of Neurontin, FDA received unapproved drugs called APO-Gabapentin and Novo-Gabapentin. The unapproved drugs purchased through the defendants pose a public health threat because, as alleged in the complaint, FDA cannot assure the safety and efficacy of unapproved drugs. Because unapproved drugs are not subject to the FDA's oversight, the FDA has no knowledge how unapproved drugs are made, what patient information is included with the drug, or what the side effects of the drugs are, and as a result they are more likely to be contaminated, counterfeit, inherently ineffective, or contain different amounts of the active ingredients from similar drugs that have been reviewed and approved by the FDA.

In addition, as alleged in the complaint, the manner in which the Sporanox shipment was sent by the foreign pharmacy posed a potentially serious health threat to the patients who received it. Patients should take it in treatment "pulses" of one week, and then wait three weeks before resuming another pulse treatment. Between treatments, patients should consult their doctors to determine whether the treatment should be terminated either

because it is no longer necessary or because they are experiencing liver or heart side effects. Because the foreign pharmacy sent three packages of Sporanox at one time, patients receiving the drugs could have taken all 84 tablets without consulting their doctor in between "pulse" treatments - an action that could have exposed them to serious and even fatal side effects.

The complaint was filed in the United States District Court in the Southern District of New York and seeks to enjoin Canada Care from directly or indirectly importing or causing the importation of U.S.-manufactured and unapproved, foreign-manufactured prescription drugs into the U.S. in violation of the FDCA. The government will also seek preliminary injunctive relief and monetary relief in the form of restitution, disgorgement, or both.

####

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Introduced by Senator OrtizDecember 6, 2004

An act to add Division 113 (commencing with Section 130600) to the Health and Safety Code, relating to prescription drugs, and making an appropriation therefor.

LEGISLATIVE COUNSEL'S DIGEST

SB 19, as introduced, Ortiz. California Rx Program.

Under existing law, the State Department of Health Services administers the Medi-Cal program, and is authorized, among other things, to enter in to contracts with certain drug manufacturers. Under existing law, the department is entitled to drug rebates in accordance with certain conditions, and drug manufactures are required to calculate and pay interest on late or unpaid rebates.

This bill would establish the California Rx Program, to be administered by the department. The bill would authorize the department to negotiate drug rebate agreements with drug manufacturers to provide for program drug discounts. The bill would authorize any licensed pharmacy or drug manufacturer to provide services under the program. The bill would establish eligibility criteria and application procedures for California residents to participate in the program.

The bill would establish the California Rx Program Fund, as a continuously appropriated fund, into which all payments directly received under the program would be deposited.

The bill would appropriate \$3,000,000 from the State Treasury to the department to fund staff and contract costs for the program.

The Pharmacy Law is administered by the California State Board of Pharmacy in the Department of Consumer Affairs.

This bill would require the Department of Consumer Affairs to implement, as a part of the California Rx Program that would be established under the bill, a Prescription Drug Resource Center Web site to educate California consumers about options for lowering prescription drug costs.

Vote: $\frac{2}{3}$. Appropriation: yes. Fiscal committee: yes. State-mandated local program: no.

The people of the State of California do enact as follows:

1 SECTION 1. Division 113 (commencing with Section
2 130600) is added to the Health and Safety Code, to read:

3

4 DIVISION 113. CALIFORNIA RX PROGRAM

5

6 CHAPTER 1. GENERAL PROVISIONS

7

8 130600. (a) This division shall be known, and may be cited,
9 as the California Rx Program.

10 (b) For the purposes of this division, the following definitions
11 shall apply:

12 (1) "Department" means the State Department of Health
13 Services.

14 (2) "Fund" means the California Rx Program Fund.

15 (3) "Prescription drug" means any drug that bears the legend:
16 "Caution: federal law prohibits dispensing without prescription,"
17 "Rx only," or words of similar import.

18 (4) "Private discount drug program" means a prescription drug
19 discount card or manufacturer patient assistance program that
20 provides discounted or free drugs to eligible individuals. For
21 purposes of this division, a private discount drug program is not
22 considered an insurance or a third-party payer program.

23 (5) "Program" means the California Rx Program.

24 (6) "Recipient" means a resident that has completed an
25 application and has been determined to be eligible for the
26 program.

27 (7) "Resident" means a California resident pursuant to Section
28 17014 of the Revenue and Taxation Code.

29 130602. (a) There is hereby established the California Rx
30 Program.

1 (b) Any California resident may enroll in the program if
2 determined eligible pursuant to Section 130605.

3
4 CHAPTER 2. ELIGIBILITY AND APPLICATION
5 PROCEDURES
6

7 130605. (a) To be eligible for the program, an individual
8 shall meet all of the following requirements at the time of
9 application and reapplication for the program:

10 (1) Be a resident.

11 (2) Have family income, as reported pursuant to Section
12 130606, that does not exceed 400 percent of the federal poverty
13 guidelines, as revised annually by the United States Department
14 of Health and Human Services in accordance with Section 673(2)
15 of the Omnibus Budget Reconciliation Act of 1981 (42 U.S.C.
16 Sec. 9902), as amended, or be a resident whose family incurs
17 unreimbursed expenses for prescription drugs equal to or greater
18 than 5 percent of family income, or be a resident whose family
19 incurs unreimbursed medical expenses equal to or greater than 15
20 percent of family income.

21 (3) Not have or be eligible for outpatient prescription drug
22 coverage paid for in whole or in part by any of the following:

23 (A) The Medi-Cal program.

24 (B) The children's health insurance program.

25 (C) Another health plan or pharmacy assistance program that
26 uses state or federal funds to pay part or all of the cost of the
27 individual's outpatient prescription drugs. Notwithstanding any
28 other provision of this division to the contrary, an individual
29 enrolled in Medicare may participate in this program, to the
30 extent allowed by federal law, for prescription drugs not covered
31 by Medicare.

32 (b) Application and a simple annual reapplication for the
33 program shall be made pursuant to subdivision (d) of Section
34 130606. An applicant may apply or reapply on behalf of the
35 applicant and the applicant's spouse and children. The guardian
36 or custodian of an applicant may apply or reapply on behalf of
37 the applicant.

38 130606. (a) The department shall develop an application
39 form for the determination of a resident's eligibility for the
40 program.

1 (b) The application, at a minimum, shall do all of the
2 following:

3 (1) Specify the information that an applicant or the applicant's
4 representative must include in the application about the applicant.

5 (2) Require that the applicant attest that the information the
6 applicant provides in the application is accurate to the best
7 knowledge and belief of the applicant.

8 (3) Specify that the application fee is due upon application
9 submission. The application fee shall be ten dollars (\$10) for the
10 initial enrollment. The initial application may be made at
11 participating pharmacies or through a private third-party vendor.

12 (c) In assessing the income requirement for program
13 eligibility, the department shall use the income information
14 reported on the application and not require additional
15 documentation.

16 (d) Application and annual reapplication may be made at any
17 pharmacy participating in the program. The pharmacy
18 completing the application shall keep the application fee as
19 reimbursement for its cost of processing the application. If it is
20 determined the applicant is already enrolled in the program, the
21 pharmacy shall return the fee to the applicant and inform the
22 applicant of his or her current status as a recipient.

23 (e) The department may provide for a secure electronic
24 application process that can be used by pharmacies to enroll
25 applicants in the program.

26 (f) During normal hours, the department shall make a
27 determination of eligibility within four hours of receipt of the
28 application. The department shall mail the recipient an
29 identification card no later than four days after eligibility has
30 been determined.

31 (g) For applications submitted through a pharmacy, the
32 department may issue a recipient identification number for
33 eligible applicants to the pharmacy for immediate access to the
34 program.

35 130607. (a) The department shall execute agreements with
36 private discount drug programs to provide a simple point of entry
37 for eligibility determination and claims processing for drugs
38 available in those private discount drug programs.

1 (b) (1) An applicant may be required to provide additional
2 information to determine the applicant's eligibility for other
3 discount card and patient assistance programs.

4 (2) An applicant shall not be, under any circumstances,
5 required to participate in, or to disclose information that would
6 determine the applicant's eligibility to participate in, these
7 private discount drug programs in order to participate in the
8 program provided for in this division.

9 (c) For those drugs available pursuant to subdivision (a), the
10 department shall develop a system that provides a recipient with
11 the best prescription drug discounts that are available to them
12 through the program or through private discount drug programs.

13 (d) The recipient identification card issued pursuant to
14 subdivision (f) of Section 130606 shall serve as a single point of
15 entry for drugs available pursuant to subdivision (a) and shall
16 meet all legal requirements for a health benefit card.

17
18 CHAPTER 3. ADMINISTRATION AND SCOPE
19

20 130615. The department shall conduct outreach programs to
21 inform residents about this program. No outreach material shall
22 contain the name or likeness of a drug or the likeness of an
23 elected state official.

24 130616. (a) Any pharmacy licensed pursuant to Chapter 9
25 (commencing with Section 4000) of Division 2 of the Business
26 and Professions Code may participate in the program provided
27 for under this division.

28 (b) Any drug manufacturer may participate in the program
29 provided for under this division.

30 130617. (a) The amount a recipient pays for a drug within the
31 program shall be equal to the participating provider's usual and
32 customary charge or the pharmacy contract rate pursuant to
33 subdivision (c), less a program discount for the specific drug or
34 an average discount for a group of drugs or all drugs covered by
35 the program.

36 (b) In determining program discounts on individual drugs, the
37 department shall take into account the rebates provided by the
38 drug's manufacturer and the state's share of the discount.

- 1 (c) The department may contract with participating
2 pharmacies for a rate other than the pharmacies' usual and
3 customary rate.
- 4 (d) The department shall provide a claims processing system
5 that complies with all of the following requirements:
- 6 (1) Provides for the price that meets the requirements of
7 subdivision (b).
- 8 (2) Provides the pharmacy with the dollar amount of the
9 discount to be returned to the pharmacy.
- 10 (3) Provides a single point of entry for access to private
11 discount drug programs pursuant to Section 130607.
- 12 (4) Provides drug utilization review warnings to pharmacies
13 consistent with the drug utilization review standards outlined in
14 Section 1927 of the federal Social Security Act (42 U.S.C. Sec.
15 1396r-8(g)).
- 16 (e) The department shall pay a participating pharmacy the
17 discount provided to recipients pursuant to subdivision (b) by a
18 date that is not later than two weeks after the claim is received by
19 the department.
- 20 130618. (a) The department shall negotiate drug rebate
21 agreements with drug manufacturers to provide for program drug
22 discounts.
- 23 (b) The drug rebate agreements shall do all of the following:
- 24 (1) Specify which of the manufacturer's drugs are included in
25 the agreement.
- 26 (2) Permit the department to remove a drug from the
27 agreement in the event of a dispute over the drug's utilization.
- 28 (3) Require the manufacturer to make a rebate payment to the
29 department for each drug specified under paragraph (1)
30 dispensed to a recipient.
- 31 (4) Require the rebate payment for a drug to be equal to the
32 amount determined by multiplying the applicable per unit rebate
33 by the number of units dispensed.
- 34 (5) Define a unit, for purposes of the agreement, in compliance
35 with the standards set by the National Council of Prescription
36 Drug Programs.
- 37 (6) Require the manufacturer to make the rebate payments to
38 the department on at least a quarterly basis.
- 39 (7) Require the manufacturer to provide, upon the request of
40 the department, documentation that the department can use to

1 validate that the per unit rebate provided complies with
2 paragraph (4).

3 (8) Permit a drug manufacturer to audit claims for the drugs
4 the manufacturer provides under the program. Claims
5 information made available to a manufacturer pursuant to this
6 paragraph shall comply with all federal and state privacy statutes
7 to protect a recipient's individual health information.

8 (9) Develop a program to prevent the occurrence of fraud in
9 the program.

10 (10) Develop a mechanism for recipients to report problems or
11 complaints regarding the program.

12 (c) If the department receives a determination that the
13 California Rx Program is a state pharmaceutical assistance
14 program for purposes of federal law pursuant to Section 130621,
15 the department shall seek to contract for drug rebates that result
16 in a net price equal to the lowest price paid for the drug by the
17 federal government.

18 (d) To obtain the most favorable discounts, the department
19 may limit the number of drugs available within the program,
20 including through development of a formulary or preferred drug
21 list.

22 (e) No less than 95 percent of the drug rebates negotiated
23 pursuant to this section shall go to reducing the cost to
24 participants in the program of purchasing drugs. The Legislature
25 shall annually appropriate an amount to cover the state's share of
26 the discount provided by this section.

27 (f) The department may collect prospective rebates from drug
28 manufacturers for payment to pharmacies pursuant to subdivision
29 (e) of Section 130617. The amount of the prospective rebate shall
30 be contained in drug rebate agreements executed pursuant to this
31 section.

32 (g) The names of manufacturers and labelers who do and do
33 not enter into rebate agreements pursuant to this division are
34 public information. The department shall release the information
35 to health care providers and the public. The department may
36 impose prior authorization requirements in the Medi-Cal
37 program, as permitted by law, on the drugs of any manufacturer
38 or labeler that either does not agree to provide rebates pursuant to
39 this section or does not agree to provide rebates that result in
40 drug prices that are equal to the lowest price paid for its drugs by

1 the federal government. A prior authorization requirement
2 imposed pursuant to this subdivision shall be consistent with the
3 goals of the California Rx Program and the requirements of Title
4 XIX of the federal Social Security Act (42 U.S.C. Sec. 1396 et
5 seq).

6 130619. (a) The department shall deposit all payments the
7 department directly receives pursuant to Section 130618 and any
8 other provision of this division into the California Rx Program
9 Fund, which is hereby established in the State Treasury.

10 (b) Notwithstanding Section 13340 of the Government Code,
11 the fund is hereby appropriated to the department without regard
12 to fiscal years for the purpose of providing payment to
13 participating pharmacies pursuant to Section 130617 and for
14 defraying the costs of administering this division.
15 Notwithstanding any other law, no money in the fund is available
16 for expenditure for any other purpose or for loaning or
17 transferring to any other fund, including the General Fund.

18 130620. (a) The department may hire any staff needed for the
19 implementation and oversight of the program established under
20 this division.

21 (b) The department may contract with one or more public or
22 private entities, such as pharmacy benefit management
23 companies, to implement or administer the program completely
24 or in part.

25 (c) (1) Drug rebate contracts negotiated by a third-party
26 vendor shall be subject to review by the department.

27 (2) The department shall not enter into a contract, and may
28 cancel a contract, negotiated by a third-party vendor pursuant to
29 paragraph (1) that it finds not to be in the best interest of the state
30 or the recipients of the program.

31 (3) The third-party vendor may directly collect rebates from
32 manufacturers in order to facilitate payment to pharmacies
33 pursuant to subdivision (f) of Section 136017.

34 (4) The department shall develop a system to prevent
35 diversion of funds collected by the third-party vendor.

36 (d) Any entity with whom the department is contracting
37 pursuant to subdivision (b) shall issue a monthly report to the
38 department that, at a minimum, provides all of the following:

39 (1) Drug utilization information.

40 (2) Amounts paid to pharmacies.

1 (3) Amounts of rebates collected from manufacturers.

2 (4) The information provided in paragraphs (1), (2), and (3), at
3 the national drug code level.

4 (5) A summary of the problems or complaints reported
5 regarding the program.

6 (e) Payment of fees to entities contracting pursuant to
7 subdivision (b) shall be from the fund.

8 (f) (1) The department shall require any pharmacy benefits
9 manager that it contracts with to pass on to the department any
10 revenues, rebates, or discounts that it receives from
11 pharmaceutical manufacturers and labelers or other entities in
12 connection with prescription drug benefits specific to the
13 program.

14 (2) The department shall prohibit the disclosure or sale of
15 enrollee utilization data by the pharmacy benefits manager to any
16 person or entity other than the department.

17 130621. The department shall seek and obtain confirmation
18 from the federal Centers for Medicare and Medicaid that the
19 program established pursuant to this division complies with the
20 requirements for a state pharmaceutical assistance program
21 pursuant to Section 1927 of the federal Social Security Act (42
22 U.S.C. Sec. 1396r-8) and that discounts provided under the
23 program are exempt from the Medicaid best price.

24 130622. Notwithstanding Chapter 3.5 (commencing with
25 Section 11340) of Part 1 of Division 3 of the Government Code,
26 the director may implement this article, in whole or in part, by
27 means of a provider bulletin, or other similar instructions,
28 without taking regulatory action.

29

30

31 CHAPTER 4. PRESCRIPTION DRUG RESOURCE CENTER

32

33 130630. (a) The Department of Consumer Affairs shall
34 implement a Prescription Drug Resource Center Web site to
35 educate California consumers about options for lowering their
36 prescription drug costs.

37 (b) The Web site shall include information about public and
38 private drug coverage and drug discount programs that are
39 available to California seniors and other consumers and tips for

1 cutting costs on medications, including guidance concerning
2 generic drugs.

3 (c) (1) The Web site shall also include information about
4 ordering prescription drugs from Canada and other countries.

5 (2) Subject to paragraph (3), this information shall include a
6 list of pharmacies that the California State Board of Pharmacy
7 has determined meet pharmacy management practices required of
8 pharmacies licensed to operate in California and United States
9 and a list of medications that can be ordered through the Web site
10 from licensed pharmacies in Canada and other countries.

11 (3) For purposes of paragraph (2), the department may either
12 provide a direct link for consumers to pharmacies in Canada and
13 other countries or provide a link for consumers to other Web sites
14 if the California State Board of Pharmacy determines that the
15 pharmacies listed in those other Web sites meet pharmacy
16 management requirements that apply to California licensed
17 pharmacies.

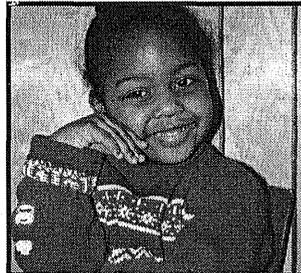
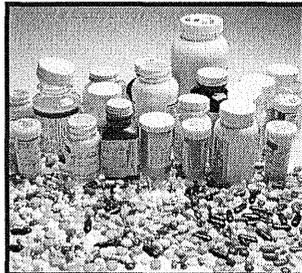
18 SEC. 2. The sum of three million dollars (\$3,000,000) is
19 hereby appropriated from the State Treasury to the State
20 Department of Health Services, to fund staff and contract costs
21 for the California Rx Program established pursuant to Division
22 113 (commencing with Section 130600) of the Health and Safety
23 Code.

O

ATTACHMENT G



HHS TASK FORCE ON DRUG IMPORTATION



Report on Prescription Drug Importation

HHS TASK FORCE ON DRUG IMPORTATION



Report on Prescription Drug Importation

Department of Health and Human Services

December 2004

HHS TASK FORCE ON DRUG IMPORTATION

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TABLE OF CONTENTS

LIST OF ABBREVIATIONS	IV
LIST OF FIGURES	V
EXECUTIVE SUMMARY	VII
BACKGROUND	1
CHAPTER 1 Scope, Volume, and Safety of Unapproved Drugs.....	7
CHAPTER 2 Limits on Resources and Authorities	23
CHAPTER 3 Impact on the Pharmaceutical Distribution System.....	35
CHAPTER 4 Role of New Technologies	45
CHAPTER 5 Agency Resources Associated with Drug Importation Activities.....	51
CHAPTER 6 Role of Foreign Health Agencies.....	59
CHAPTER 7 Effects of Importation on Prices and Consumer Savings	65
CHAPTER 8 Impact of Importation on Research and Development and Consumer Welfare	81
CHAPTER 9 Impact on Intellectual Property Rights	91
CHAPTER 10 Liability Issues Related to Importation	99
APPENDIX	111

EXECUTIVE SUMMARY

OVERVIEW

Introduction

In 2003, Congress passed the Medicare Prescription Drug, Improvement and Modernization Act of 2003, Pub. L. 108-173 (Medicare Modernization Act or MMA), which for the first time provided a prescription drug benefit for seniors and people with disabilities. The MMA also contained provisions that would permit the importation of prescription drugs into the U.S. if the Secretary of the Department of Health and Human Services (HHS) certifies that drugs imported from Canada pose no additional risk to public health and safety and that such imports would provide significant cost savings to American consumers. The MMA also requires the Secretary to conduct a study on the importation of drugs. The conference agreement for MMA included eleven issues for consideration. The Surgeon General of the U.S. Public Health Service, Dr. Richard H. Carmona, was charged with leading a task force of senior executives across the Federal government to conduct the analysis required by the MMA. The Task Force met with key constituencies numerous times throughout 2004 in public forums, received testimony from over one hundred presenters from around the world with all types of backgrounds, and received over one hundred written comments providing insight into these issues. This report is a summary of what the Task Force reviewed from the testimony and written comments for the specific questions posed in the MMA conference agreement and their findings based on this evaluation.

Background

In the early years of the twentieth century, pharmaceuticals in the U.S. were characterized by a large number of ineffective, often dangerous, compounds, the principal ingredient of which was often

alcohol. The invention of penicillin in the 1930s marked the beginning of the modern era of drug development, when scientists were able to create powerful new chemicals that were safe and effective in killing bacteria. Since then, the world's investment in research and development (R&D) has produced many more safe and effective treatments to reduce pain and inflammation, regulate the cardiovascular system, impede the growth of cancer cells, and provide a host of other effective therapies for disease. The resulting discovery of new medications has enabled doctors to offer comfort for the sick and to prescribe from an extensive array of drugs to treat most human afflictions.

As this innovation began in the 1930s, Congress recognized the need for a strong oversight body to ensure that drugs were properly tested before being given to patients. The manufacturing of drugs needed equally rigorous oversight to ensure that drugs were made in a safe and consistent way. The Federal Food, Drug, and Cosmetic (FD&C) Act of 1938 and its 1962 amendments provided that oversight, by requiring that the U.S. Food and Drug Administration (FDA) approve each new drug as safe and effective before marketing and authorizing FDA to oversee the production of drugs, whether manufactured in a U.S. facility or imported from abroad.

By the 1980s, Congress recognized that some entities not subject to U.S. law were importing counterfeit drugs as well as improperly handled and stored drugs. For example, at that time, counterfeit birth control pills found their way into the U.S. drug distribution system. These types of activities posed significant risks to American consumers. Therefore, in 1987, Congress passed the Prescription Drug Marketing Act (PDMA), which, among other things, strengthened oversight of domestic wholesalers and added the "American goods returned" provision to the FD&C Act, which prohibits anyone

except a drug's manufacturer from importing into the U.S. a prescription drug that was originally manufactured in the U.S. and then sent abroad.

We recognize that there are different categories of "imported drugs" that potentially have different levels of associated risk. Currently, the only types of legally imported drugs are: 1) those that are manufactured in foreign FDA-inspected facilities and adhere to FDA-approval standards, or 2) those that are U.S.-approved and manufactured in the U.S., sent abroad, then imported back into the U.S. by the manufacturer under proper controls and in compliance with the FD&C Act. This latter category includes products that are truly re-imported. In both cases, the manufacturing process is subject to direct FDA oversight and the drug distribution system is "closed," and the manufacturer complies with FDA and other regulations to assure that the drug delivered to the pharmacy is of high quality.

Another category of imported drugs are those that are manufactured in a foreign facility that also manufactures the U.S.-approved version. In such a case, FDA would have inspected the U.S.-approved manufacturing process, but not the unapproved production lines; in this case, the foreign version may differ in certain respects from the U.S.-approved version. Although there may be significant similarities between the two versions, because of the potential differences and the fact that only the U.S.-approved drugs have been shown to meet U.S. standards enforced by FDA, the foreign version cannot necessarily be considered equivalent to the U.S.-approved version.

A final category of imported drugs are unapproved drugs that are produced in foreign facilities that FDA has not inspected and, therefore, has no knowledge of, or experience with, the facility. Consequently, the safety and effectiveness of these drugs and the safety and security of their distribution systems are unknown. These drugs pose the greatest level of concern because they are not regulated within the U.S. drug safety system and little is known to U.S. regulators about the specifications to which they are made, the processes used to ensure their safety, and the integrity of their distribution. As the report describes,

there is ample evidence that these are the types of drugs that consumers have received when they order prescription drugs from some international sources over the internet.

When a drug is imported into the U.S., FDA inspectors are required to confirm that the drug meets the necessary approval requirements. Such review of imported drugs is limited by the amount of resources available, given the substantial amount of legal and illegal prescription drugs that are imported daily. If there is a question of whether the drug can legally be imported and, thus, raises safety questions, FDA has the authority to detain the product and gives the importer several days to demonstrate the drug's acceptability (or, failing that, the drug is either refused admission and returned to its foreign source, if known, or destroyed.)

The conclusion of Congress reflected in current law is that the safety and effectiveness of imported drugs can only be assured for drugs legally imported into the U.S., as described above. In these cases, the chain of custody is known for a U.S.-approved drug manufactured in an FDA-inspected facility using FDA-approved methods as it travels through the U.S. distribution system. Much of the current public debate about the safety of broader importation comes down to issues regarding the additional oversight authorities, resources, and foreign government support that would be needed to assure the safety and effectiveness of other types of drugs, principally foreign drug purchases from international internet operations that are not subject to FDA's regulatory oversight.

Since the FD&C Act's passage in 1938, American citizens returning from overseas with foreign drugs have been advised that most of these drugs are not legal, but, as a matter of enforcement discretion, FDA has generally allowed those citizens to bring in small quantities for their personal use and advised them to consult with their physician. FDA created this enforcement discretion policy to allow American residents who became ill in another country to continue the treatment prescribed by a foreign healthcare practitioner until they could receive medical attention back home. That policy was not controversial until the latter part of the 1990's, when some citizens

began traveling regularly to other countries to fill their prescriptions, and especially when more Americans began ordering drugs via internet pharmacies located in other countries.

The Task Force understands what motivates more and more Americans to import drugs. Access to affordable prescription drugs, many of which are needed to treat life-threatening and serious conditions, is a daily concern and challenge for many Americans. As there has been a significant increase in drug utilization and in list prices for drugs in the U.S. over the last few years, spending by American consumers on prescription drugs has risen significantly. Over 40 percent of Americans take at least one prescription drug and, in an effort to lower their prescription drug bill, a relatively small but increasing number have turned to importing drugs.

Consequently, the Task Force believes that access to drugs that are safe and effective, as well as affordable, is a critical policy goal, and that all approaches to achieving this challenging goal should be explored thoroughly. Drugs that are affordable, but not safe and effective, could be more harmful to patients than not having the drugs at all. The difficult balance between the need for affordable prescription drugs and concerns over potential safety hazards that many imported drugs may pose is reflected in the public debate and controversies regarding drug importation policy in the U.S. The Task Force report presents a comprehensive overview of the evidence related to this balance, as well as a number of other critical issues, as requested by Congress, on the subject of prescription drug importation.

THE REPORT IN BRIEF

Chapter 1 –Scope, volume, and safety of unapproved drugs

The number of unapproved prescription drug products entering the U.S. is now very large. Nearly five million shipments, comprising about 12 million prescription drug products with a value of approximately \$700 million, entered the U.S. from Canada alone in 2003, via internet sales and travel to Canada by

American consumers. This report estimates that an equivalent amount of prescription drugs are currently coming in from the rest of the world, mostly through the mail and courier services.

Imported drugs are arriving from all corners of the world, including developed and emerging countries. Their scope is broad and includes tablets, capsules, inhalants, injectables, biologics, generics, brand name drugs, and controlled substances. Some of the arriving products appear to have been made in the U.S.; however, many are not. The majority of these currently imported drugs are unapproved by FDA and do not appear to conform in many aspects to the properly approved and manufactured products available in American pharmacies.

Numerous comments submitted to the Task Force described the current practice of internet purchases by American consumers who seek lower-priced drugs. Many state-licensed internet pharmacies provide a legitimate means for consumers to access safe and effective medicines, but others raise significant safety concerns.

Most of these drugs are purchased by individual consumers via internet, phone, or fax, from entities that focus on providing drugs to Americans and other long-distance purchasers. These entities generally are cross-border foreign pharmacies that may not primarily serve the citizens of the country in which they are located, and their methods for providing drug products may not be subject to the same oversight that foreign governments provide for drugs and pharmacies serving their own citizens. When consumers order prescription drugs over the internet from international sources, they generally receive drugs that do not have regulatory assurances of equivalence to U.S. products or of safety and security in the distribution process.

Some sellers of imported drugs are “rogue” internet pharmacies that pretend to be legitimate and operate behind facades. Many of the drugs sold over the internet claim to be interchangeable with the approved U.S. drug, but are not. Imported drugs include those that pose special concerns, such as drugs that require special handling, drugs with high

abuse potential, drugs that should be sterile, counterfeit drugs, improperly packaged drugs shipped loose in sandwich bags and envelopes, and drugs from countries that have differing and sometimes more limited regulatory authority to assure the safety of pharmaceuticals manufactured and exported from those countries. In sum, this report finds that American consumers currently purchasing drugs from overseas are generally doing so at significant risk.

Chapter 2 – Limits on resources and authorities

The Federal law governing drug safety in the U.S. establishes the standards by which FDA determines whether a prescription drug is “safe and effective” for sale in the U.S. These standards govern the way in which prescription drugs are manufactured, packaged, labeled, held, and shipped. Many of the prescription drugs that are imported into the U.S. now by individual citizens, via mail and courier services, fail to comply with some or all of these Federal standards. To ensure that imported prescription drugs are as safe as those that are legally sold in the U.S., an importation program for U.S.-approved drugs would have to ensure that the imported drugs meet the current (or equivalent) Federal standards. This report determines that it would be extraordinarily difficult to ensure that drugs personally imported by individual consumers could meet the necessary standards for a certification of safety to be made, especially if consumers continue to import prescription drugs in the same or increased numbers. Meanwhile, a commercial importation program could be feasible but would require new legal authorities, substantial additional resources and significant restrictions on the type of drugs that could be imported, which could increase the costs of imported drugs.

Chapter 3 – Impact on the pharmaceutical distribution system

The drug distribution network for legal prescription drugs in the U.S. is a “closed” system that involves several players (e.g., manufacturers, wholesalers, pharmacies) who move drug products from the point of manufacture to the end user, and provides the American public with multiple levels of protection

against receiving unsafe, ineffective, or poor quality medications. This system evolved as a result of legislative requirements that drugs be treated as potentially dangerous consumer goods that require professional oversight to protect the public health. The result has been a level of safety for drug products that is widely recognized as the world’s “gold standard.” Legalized importation of drugs in such a way that creates an opening in the “closed” system will likely result in some increase in risk, as the evidence shows that weaknesses in the oversight of drug regulation and the distribution system have been exploited. For example, doing so would increase the opportunity for counterfeit and other substandard drugs to enter and be dispersed into the U.S. drug distribution system.

Chapter 4 – Role of new technologies

There are a number of anti-counterfeiting technologies that show potential for effectively assuring the authenticity of drugs and, thus, for combating the counterfeiting of drugs. Some examples include holograms, color shifting inks, and watermarks currently employed for U.S. currency. So-called “track and trace” technologies, such as radio-frequency identification (RFID) and sophisticated bar coding, can provide effective monitoring of a drug’s movement from the point of manufacture and through the U.S. distribution chain. Although these new and emerging technologies are promising, until they are fully adopted internationally they cannot be adequately relied upon to secure the safety, efficacy, and integrity of the global market to safely import prescription drugs into the U.S.

Chapter 5 – Agency resources associated with drug importation activities

FDA currently has about 3,800 employees assigned to field activities (e.g., inspections) involved in protecting the many thousands of products that make up the Nation’s food, drug, biologic, medical device, and veterinary drug supply. Of the 3,800 field staff, 450 are involved in investigative import activities. Only a limited number of FDA inspectors are available to staff the 14 international mail facilities in the U.S., where they historically have had to inspect a small number

of large commercial pharmaceutical imports. FDA managers have repeatedly noted that the large number of personal drug shipments coming into the international mail and courier facilities is overwhelming the available staff.

This report finds that despite significant efforts, including joint efforts with CBP and import alerts/bulletins, FDA currently does not have sufficient resources to ensure adequate inspection of current levels and categories of personal shipments of prescription drugs entering the U.S. With respect to commercial shipments, based on the information presented to the Task Force, FDA would need a meaningful investment, among other things, in new information technology and personnel, as well as appropriate standards to ensure adequate inspection of commercial quantities of drug products, if importation were legalized.

Chapter 6 – Role of foreign health agencies

Just as the U.S. is responsible for the safety and effectiveness of drugs made available to its citizens, foreign governments give priority to ensuring the safety of drugs used by their citizens. Foreign governments have little incentive and limited resources to ensure the safety of drugs exported from their countries, particularly when those drugs are transshipped or are not intended for import. No country expressed any interest or willingness to ensure the safety and effectiveness of drugs exported from their country in any expansion of legal U.S. importation. Although we specifically solicited them, few comments were submitted by foreign governments, and none outlined a specific strategy for new steps to collaborate with the U.S. government on the effective oversight of importation, suggesting that they are not willing or do not have the means to ensure the safety of exported products and that the primary safety responsibilities would have to remain with the U.S.

Chapter 7 – Effects of importation on prices and consumer savings

Consumers seek to import prescription drugs from other countries in part because they believe they can save money if they purchase their drugs from outside

the U.S. In many instances, U.S. consumers have been able to purchase from abroad foreign versions of U.S.-approved brand name drugs at lower prices. However, based on an analysis of actual data on drug prices and volumes, this report finds that total savings to consumers from legalized importation under a commercial system would be a small percentage relative to total drug spending in the U.S. (about one to two percent). These savings are much smaller than some specific international comparisons of retail prices for certain drugs might suggest. Under any safe, legalized commercial importation program, when the scope is limited, intermediaries would likely capture a large part of the price differences. (This is based on evidence from European countries where some form of importation is legal.)

This report also finds that generic drugs are often cheaper in the U.S. compared to international prices for similar drugs. Other, independent studies have reached similar conclusions. The prices foreigners pay for generic drugs are on average 50 percent greater than the prices Americans pay for generic drugs. Furthermore, there is evidence that greater use of U.S.-approved generic drugs by Americans could reduce drug spending by billions of dollars annually. In addition, to the extent that prescription drugs are eligible for importation from the same company at a lower price than in the U.S., potential quantity constraints imposed by manufacturers or foreign governments would limit the eligible supply and the benefits to U.S. consumers.

Chapter 8 – Impact of importation on research and development and consumer welfare

One of the most frequently debated issues surrounding drug importation is whether the legalization of importation would reduce research and development (R&D), including spending on discovery, development, and launching of new drugs. Based on both an empirical analysis of drug data and a review of previous studies, this report finds that, by shifting sales to countries with price controls for new drugs, importation would reduce overall U.S. pharmaceutical industry revenues. Since revenues would fall without a reduction in the cost to produce new medicines, prof-

its would likely fall, as well as spending on R&D. Consequently, legalized importation would likely adversely affect incentives for R&D, thereby slowing the flow of new drugs. This report also finds that since annual R&D spending would drop, importation could result in between four to eighteen fewer new drugs being introduced per decade at a substantial cost to society. Furthermore, if there were a likely reduction in innovative new drugs, then the foregone consumer benefits associated with loss or delay in new therapies may significantly offset any anticipated savings from legalized importation, depending on uncertainties.

Chapter 9 – Impact on intellectual property rights

Intellectual property rights have evolved over many years to strike a balance between, on the one hand, providing incentives for innovation through grants of exclusive rights over new ideas or products and, on the other hand, ensuring that knowledge and products are widely disseminated and accessible to provide the maximum benefit to society now and in the future. As with most new ideas and products, inventors of pharmaceuticals may obtain patents and other intellectual property protections for their products that provide certain exclusive rights. The challenge policymakers face is to ensure that intellectual property protection for pharmaceuticals provides adequate economic incentives to develop new drugs while facilitating access to affordable medicines.

An exhaustive legal analysis of the implications of allowing importation of patented pharmaceuticals to which intellectual property protections apply would require further study. However, it is clear that importation could impact the intellectual property rights of developers of pharmaceutical products and could be subject to challenge under domestic law, including possibly the U.S. Constitution, and international intellectual property rules.

Chapter 10 – Liability issues related to importation

This report identifies the liability issues raised if importation is legalized for entities within the phar-

maceutical distribution system. This report notes that allowing prescription drug importation would have uncertain effects on the litigation exposure of manufacturers, distributors, doctors, and pharmacists. To deal with these likely increased risks, entities in the pharmaceutical distribution chain may take additional costly defensive actions. Perhaps the largest source of additional liability and/or litigation risk under a drug importation system would be an increase in the number of injuries and poor disease outcomes if imported drugs are, as a class, less safe and effective.

KEY FINDINGS

This report details the diverse opinions expressed, the data collected, and Task Force findings based on the information presented. Some of the key findings of the Task Force are:

- 1) **The current system of drug regulation in the U.S. has been very effective in protecting public safety, but is facing new threats. It should be modified only with great care to ensure continued high standards of safety and effectiveness of the U.S. drug supply.** Americans have the benefit of one of the safest drug supplies in the world and generally have first access to the newest breakthrough drug treatments. Any legislation to permit the importation of foreign drugs should only be done in a way that provides the statutory authority and substantial resources needed to effectively regulate imported drugs and, most importantly, protect the public health by providing the same level of safety assurances available for drugs sold in the U.S.
- 2) **There are significant risks associated with the way individuals are currently importing drugs.** While some means of drug importation (e.g., traveling to Canada for certain brand name drugs available in both countries) may be relatively safe in specific instances, this is not the only way “importation” into the U.S. is occurring today. Many transactions are occurring via poorly-regulated and occasionally bogus internet operations that have been documented in some cases to provide consumers with inferior products that are not the same as the U.S.-approved ver-

sions. Also, treatment failures, which are not obvious adverse events, are a real concern with substandard drug products.

3) 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.

While wholesalers and pharmacists purchase, transport, and dispense imported drugs within our regulatory framework, American consumers making individual purchases from foreign sources outside our regulatory system, in particular those making long-distance purchases from internet sites or by fax or phone, face safety hazards that would be extraordinarily difficult to effectively address and prevent.

4) 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 rightly expects that, under any legal importation program, the imported drugs will be safe and effective. To accomplish this, additional safety protections would need to be added that would increase the costs of the program in an additive way as more safety measures are put in place. Substantial resources would also be needed to ensure adequate inspection of imported drug products. In addition to other factors that are likely to reduce potential consumer savings, these increased regulatory and program costs will also impact potential savings to consumers. Furthermore, intermediaries will likely capture at least half of any savings between the U.S. and price-controlled countries and potential quantity constraints imposed by foreign governments and manufacturers will likely further limit the supply of these drugs to U.S. consumers.

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

Generic drugs account for most prescription drugs used in the U.S. and are usually less expensive in the U.S. than

abroad. Shopping around for price comparisons, asking a doctor or pharmacist for a generic alternative to a prescribed brand name drug, or using a Medicare or other prescription drug discount card is a proven method to save American consumers money on domestic prescription drugs while retaining the protections of a comprehensive safety regime.

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

This report estimates that R&D incentives will be lowered by legalized importation, resulting in roughly between four and eighteen fewer new drugs introduced per decade.

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

A host of legal and constitutional challenges are probable, and the effects on enforcement of intellectual property rights and on agreements with foreign countries are likely to be problematic. These effects could create additional disincentives to develop breakthrough medicines and further limit any potential savings that might have been realized.

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

Consumers harmed by imported drugs may not have legal recourse against foreign pharmacies, distributors, or other suppliers. Entities in the pharmaceutical supply chain may take actions to protect themselves from liability that could ultimately raise the cost of drugs.

BACKGROUND

I. WHY ARE WE ISSUING THIS REPORT?

A. Medicare Modernization Act (MMA)

1. Statutory Language

The Medicare Prescription Drug, Improvement and Modernization Act of 2003¹ (Medicare Modernization Act, or MMA) was signed into law on December 8, 2003. MMA primarily provides a new prescription drug benefit enabling Medicare beneficiaries to receive coverage for drugs not administered in a hospital setting. However, MMA also includes provisions aimed at providing lower cost drugs to consumers.

Title XI, Subtitle C of MMA amends 21 U.S.C. 384 (importation of covered products) in the Federal Food, Drug, and Cosmetic (FD&C) Act. Under section 384, the Secretary of the Department of Health and Human Services (HHS) is directed to promulgate regulations that would allow pharmacies and wholesalers to import certain FDA-approved prescription drug products from Canada. The section also requires the Secretary to promulgate regulations to grant individuals a waiver to import certain FDA-approved prescription drugs from Canada under certain circumstances and permits the Secretary to grant individuals, by regulation or on a case-by-case basis, a waiver to import other drugs under such conditions as the Secretary determines appropriate. By allowing individuals to import such drugs, the MMA expands the scope of section 384, as originally established by the Medicine Equity and Drug Safety Act of 2000² (MEDS Act) because the MEDS Act authorized only pharmacists and wholesalers to import drugs. Nevertheless, as with the MEDS Act, Congress conditioned the implementation of the MMA's importation program on an initial certification by the Secretary. Section 384 provides that drug importation shall become effective only if the Secretary of the HHS is able to certify that implementing the program will:

- pose no additional risk to public health and safety, and
- result in a significant reduction in the cost of drugs to the American consumer.

Regardless of whether the Secretary certifies safety and savings, however, MMA also requires the Secretary to submit a study to Congress within one year on the importation of drugs. This study is the subject of this report.

2. MMA Conference Agreement

The MMA requires the Secretary of HHS, in consultation with appropriate government agencies, to provide a comprehensive study that identifies problems with implementation of existing law and examines a range of issues associated with the importation of drugs. The conference agreement³ specifies eleven separate issues that Congress requested the Secretary address in the study:

- Identification of the limitations, including limitations in resources and, if applicable, in current law authorities that may inhibit the Secretary's ability to certify the safety of pharmaceutical products imported into the U.S.
- Assessment of the pharmaceutical distribution chain and the need for, and feasibility of, modifications, in order to assure the safety of products that may be imported into the U.S.
- Analysis of whether anti-counterfeiting technologies could improve the safety of products in the domestic market as well as those products that could be imported from foreign nations. This analysis shall identify the types of technologies, if available, and assess the limitations of these technologies to the distribution chain.*
- Estimate of costs borne by entities within the pharmaceutical distribution chain to utilize any new technologies identified.*

- Assess the scope, volume, and safety of unapproved drugs, including controlled substances, entering the U.S. via mail shipment. This assessment should include the percentage of drugs commercially available in other countries that conform in all respects to FDA requirements, and the limitations of visual inspection, sampling, and other testing methods to determine its quality.
- The extent to which foreign health agencies are willing and/or able to ensure the safety of drugs being exported from their country into the U.S., including drugs that are transshipped through their countries.
- Assessment of the potential short and long-term impacts on drug prices and prices for consumers and other system costs associated with importation of pharmaceuticals from Canada and other countries into the U.S.
- Assessment of the impact on the research and development of drugs—and the associated impact on consumers and patients—if importation were permitted.
- Estimation of agency resources, including additional field personnel, needed to adequately inspect the current amount of pharmaceutical products entering into the country. This estimate shall detail the number of field personnel needed in order to appropriately secure all ports of entry on a daily basis.
- Identification of liability protections, if any, that should be in place, if importation is permitted, for entities within the pharmaceutical distribution chain.
- Identify the ways in which importation could violate U.S. and international intellectual property rights and describe the additional legal protections and agency resources that would be needed to assure the effective enforcement of these rights.

* For purposes of this report, we combined the issues of anti-counterfeiting and new technologies to better communicate the intricate relationship between the two.

B. The Task Force's Charge

On February 26, 2004, HHS Secretary Tommy G.

Thompson announced the creation of a task force⁴ to advise him on how to address the questions posed by Congress in the MMA conference report.

Surgeon General Richard H. Carmona serves as chairman of the Task Force. The other Task Force members are: Jayson P. Ahern (Assistant Commissioner for Field Operations, Customs and Border Protection); Alex M. Azar II (General Counsel, HHS); Josefina Carbonell (Assistant Secretary for Aging, HHS); Lester M. Crawford (Acting Commissioner, Food and Drug Administration); Elizabeth M. Duke (Administrator, Health Resources Services Administration); Tracey Hardin (Attorney, Department of Justice); Mark B. McClellan (Administrator, Centers for Medicare & Medicaid Services); Michael J. O'Grady (Assistant Secretary for Planning and Evaluation, HHS); William Raub (Deputy Assistant Secretary for Public Health Emergency Preparedness, HHS); Thomas M. Reilly (Public Health Branch Chief, Office of Management and Budget); Amit K. Sachdev (Deputy Commissioner for Policy, Food and Drug Administration); and Elizabeth A. Willis (Chief of Drug Operations Section, Drug Enforcement Administration).

C. How did we address the issues?

As part of our fact-finding and information collection process to address the issues, we made great efforts to gather input, ideas, and expertise from the public to give us guidance.

1. Listening Sessions and Public Meeting

We held five listening sessions and a public meeting, bringing together a wide variety of stakeholders to present testimony and provide information relating to the questions posed in the MMA conference report. The public meeting was held on April 14, 2004 and everyone who wanted to speak was given an opportunity to be heard. We heard from over 100 individuals, including: consumer representatives; pharmaceutical industry representatives; international regulatory and industry representatives; academicians; health care purchasers; professional medical groups; government and elected officials; and members of the public. All of the listening sessions were open to the media.

2. Website

Immediately following the first listening session, HHS developed a website (<http://www.hhs.gov/import-taskforce/>) dedicated to Task Force activities. The website contains information about each stakeholder listening session, including: the agenda, the text of the speaker presentations, and a complete transcript of each meeting. In addition, the website provides a link for the public to submit and view comments.

3. Docket

We established a public docket to solicit and receive information and comments.⁵ We announced the creation of the docket in the Federal Register.⁶ To stimulate and focus the discussion, the Federal Register notice listed the broad questions that Congress posed in the MMA conference agreement and also asked more specific questions to seek additional input to assist us in preparing this report. We requested that all comments be submitted by June 1, 2004; however, we also considered comments submitted after this date. We received and considered more than 100 written comments to the docket before drafting this report.

4. Other Sources of Information

We supplemented the information presented during the listening sessions and submitted to the docket with information from other sources to be certain that we adequately addressed the questions posed by Congress. We obtained information relating to the volume of imported drugs and drug prices from IMS Health, a global data collection and analysis firm. For some issues, where the comments did not provide sufficient data or other information, we received information from the U.S. Customs and Border Protection (CBP), the U.S. Food and Drug Administration (FDA), and the Department of Justice (DOJ). Additionally, in June 2004, a group of Task Force members toured the international mail facility at John F. Kennedy (JFK) airport to observe how imported drugs are processed daily by CBP and FDA personnel. During this visit, we saw how drugs are processed by this facility and the types of drugs that are being imported.

D. What is in this report?

This report contains our findings based on all of the information presented to us and expert views solicited from appropriate government agencies. The report is divided into chapters according to the issues posed by Congress in the MMA conference agreement.

1. Definitions

The terms "imported," "importation," "re-imported," and "re-importation," are commonly used throughout this report. For purposes of this report, imported drugs are drugs manufactured for sale inside and outside of the U.S., then brought into this country for use by U.S. consumers. Unless otherwise specified, the term "importation" includes a) *personal importation* (internet sales, foot traffic across the border, mail order) where the drugs are purchased by those who consume them, and b) *commercial importation* where the drugs are purchased by pharmacies and wholesalers for resale to the ultimate consumer.

"Re-imported" drugs refer to FDA-approved prescription drugs that were made in the U.S., sent abroad, and then brought back into the U.S. Currently, only the original manufacturer can legally re-import a prescription drug and only if the manufacturer ensures that the drug is authentic, properly handled, and relabeled for sale in the U.S., if necessary.

2. Types of Imported Drugs

We recognize that there are different categories of imported drugs that potentially have different levels of associated risk. Currently, the only types of legally imported drugs are: 1) those that are manufactured in foreign FDA-inspected facilities and adhere to FDA-approval standards, or 2) those that are U.S.-approved and manufactured in the U.S., sent abroad, then re-imported back into the U.S. by the manufacturer under proper controls and in compliance with the FD&C Act. This latter category includes products that are truly re-imported.

Another category of imported drugs are those that are manufactured in a foreign facility that also man-

ufactures the U.S.-approved version (in such a case FDA would have inspected the U.S.-approved manufacturing process, but not the unapproved production lines); however, the foreign version may be slightly different than the U.S.-approved version. Although there may be significant similarities between the two versions, because of the potential differences and the fact that FDA determined the U.S.-approved drugs meet U.S. standards, the foreign version cannot necessarily be considered equivalent to the U.S.-approved version.

A final category of imported drugs are unapproved drugs that are produced in foreign facilities that FDA has not inspected and, therefore, has no knowledge of, or experience with, the facility. Consequently, the safety and effectiveness of these drugs are unknown. These drugs pose the greatest level of concern because they are not regulated within the U.S. drug safety system and there is little known about the specifications to which they are made, the processes used to ensure their safety, and the integrity of their distribution. These are the types of drugs that consumers may receive when they order prescription drugs over the internet.

E. Brief History of U.S. Importation

1. The Current U.S. System

The FD&C Act limits the types of drugs that may be imported into the U.S. The current drug distribution system is relatively “closed,” which helps ensure that the domestic drug supply is safe and effective.

New drugs marketed in the U.S., regardless of whether they are manufactured in the U.S. or a foreign country, must be the subject of a New Drug Application (NDA) approved by FDA based on demonstrated safety and efficacy. The drug must be produced in plants that are inspected by FDA and are operated in accordance with the current Good Manufacturing Practice (cGMP) regulations.⁷ Also, the drug’s labeling must bear certain information required by the FD&C Act. Only a drug’s manufacturer can re-import into the U.S. a U.S.-made prescription drug that was sent abroad, but the law clearly allows

legal, FDA-approved drugs to be made abroad. In fact, many drugs now sold in the U.S. were made in foreign, FDA-inspected facilities to standards approved by FDA. When such drugs or active ingredients are offered for import into the U.S., FDA inspectors evaluate them as they would any other drug—they attempt to assess whether the drug is FDA-approved, whether it is properly labeled, and whether it otherwise complies with the FD&C Act.

Under sections 381 and 331, unapproved, misbranded, and adulterated drugs cannot be legally imported into the U.S. This includes unapproved “foreign versions” of FDA-approved medications. In addition, under the “American goods returned” provision, it is illegal for any person other than the original manufacturer of a drug to re-import into the U.S. a prescription drug that was originally manufactured in the U.S. and then exported to another country.⁸ This provision was included in the Prescription Drug Marketing Act of 1987 (PDMA)⁹ to ensure that prescription drug products purchased by consumers would be safe and effective and to avoid an unacceptable risk that counterfeit, adulterated, misbranded, subpotent, or expired drugs were being sold to American consumers. Congress determined that legislation was necessary because there were insufficient safeguards in the prescription drug distribution system to prevent the introduction and retail sale of substandard, ineffective, or counterfeit drugs and that a wholesale drug diversion submarket had developed that prevented effective control over, or even routine knowledge of, the true sources of drugs. Congress limited access to reimported drugs because of these safety concerns.

Thus, in order to comply with the FD&C Act, any entity that intends to import prescription drugs into the U.S. must ensure that each drug is FDA-approved, meets all the U.S. manufacturing and labeling requirements, and that the importation does not violate section 381.

FDA drug approvals are manufacturer-specific, product-specific, and include 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.¹⁰ Drugs sold to

wholesale or retail establishments outside the U.S. may comply with the foreign country's specifications, but may not be manufactured pursuant to an FDA approval at all.

Even if a manufacturer has FDA approval for a drug, the version produced for foreign markets may not meet all of the requirements of the FDA approval, and thus it may be considered to be unapproved in the U.S.¹¹ Moreover, the version 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.¹²

Under FDA's regulations, the shipment and storage of prescription drugs must be properly documented and, when necessary, inspected.¹³ One concern FDA has expressed is that, when a foreign manufacturer makes an FDA-approved drug in a foreign plant and then distributes it into foreign commerce, FDA has no assurance that the drug was properly stored or handled while abroad.

It is also important to note that the Controlled Substances Act (CSA), Title 21 U.S.C., Chapter 13, Subchapter II, specifically prohibits controlled substances to be imported except by DEA registrants. Any individual who imports controlled substances without being registered with DEA and without DEA authorization, is in violation of the CSA and is subject to prosecution.

2. Personal Importation Policy

Importing unapproved prescription drugs is illegal. However, FDA's long-standing policy on importing prescription drugs for personal use recognizes that there are circumstances in which FDA may exercise its enforcement discretion and not take action against illegal importation. The personal importation policy was first adopted in 1954; it was last modified in 1988 in response to concerns that certain AIDS treatments were not available in the U.S. Under the policy, FDA exercises its enforcement discretion to not stop individuals with serious conditions, such as a rare form of cancer, from bringing into the U.S. treatments that are legally available in foreign countries

but are not approved in the U.S.

The current policy is not a law or a regulation, but serves as guidance for FDA field personnel. The importation of certain unapproved prescription medication for personal use may be allowed in some circumstances if all of the following factors apply:¹⁴

- If the intended use is for a serious condition for which effective treatment may not be available domestically;
- If the product is not considered to represent an unreasonable risk;
- If the individual seeking to import the drug affirms in writing that it is for the patient's own use and provides the name and address of the U.S.-licensed doctor responsible for his or her treatment with the drug or provides evidence that the drug is for continuation of a treatment begun in a foreign country;
- If the product is for personal use and is a three-month supply or less and not for resale. (Larger amounts would lend themselves to commercialization); and
- If there is no known commercialization or promotion to U.S. residents by those involved in distribution of the product.¹⁵

The majority of drugs coming into this country via personal importation today do not technically meet all of these factors. Nonetheless, given the high demand and limits on available resources it is difficult to effectively police this practice.

3. The Medicare Prescription Drug, Improvement and Modernization Act of 2003 (MMA)

MMA provides authority for pharmacists and wholesalers to import drugs from Canada, subject to certain conditions. These specific conditions include:

- Requirements that importers and foreign sellers keep certain information and records;
- Qualified laboratory drug testing;
- Registration of Canadian sellers; and
- Use of approved labeling.

Once effective, MMA directs the Secretary to promulgate regulations to grant individuals a waiver to per-

mit importation of a 90-day supply of any FDA-approved prescription drug imported from Canada from a licensed pharmacy for personal use, if the drug is accompanied by a valid prescription, in a final finished dosage that was manufactured in a registered establishment, and imported under such other conditions as the Secretary determines necessary to ensure public safety.

Section 1121 of MMA provides that the drug importation program described above shall become effective only if the Secretary of HHS first certifies that implementing the program will pose no additional risk to public health and safety and will result in a significant reduction in the cost of drugs to the American consumer.

In 2000, Congress enacted legislation similar to the MMA as part of the Fiscal Year 2001 Appropriations Bill for the Department of Agriculture and Related Agencies, also known as the MEDS Act.¹⁶ The MEDS Act, if implemented, would have allowed pharmacists or wholesalers in the U.S. to import FDA-approved prescription drugs that were manufactured in the U.S. in FDA-inspected facilities and exported to 26 specific foreign countries listed in the FD&C Act. On December 26, 2000, then-HHS Secretary Donna Shalala stated in a letter to President Clinton that she was unable to certify the safety and cost savings required by the MEDS Act.¹⁷ Similarly, in a letter to Senator Jim Jeffords dated July 21, 2001, Secretary Thompson also declined to make the certification necessary to implement the MEDS Act due to safety concerns.¹⁸

Importation," March 16, 2004. Accessed at www.hhs.gov/news/press/2004pres/20040316.html on 11/4/04.

- 5 U.S. Food and Drug Administration Docket 2004N-0115. Accessed at www.fda.gov/ohrms/dockets/dockets/04n0115/04n0115.htm on 11/4/04.
- 6 69 Fed.Reg. 12810 (Mar. 18, 2004).
- 7 21 C.F.R. Part 211.
- 8 21 U.S.C. § 381(d)(1).
- 9 Pub. L. 100-293.
- 10 21 C.F.R. § 314.50.
- 11 21 U.S.C. § 355.
- 12 21 C.F.R. § 201.15(c).
- 13 21 C.F.R. § 205.50.
- 14 FDA, Regulatory Procedures Manual, Subchapter, "Import Operations/Actions: Coverage of Personal Importations," March 2004.
- 15 Pub. L. 108-173.
- 16 Pub. L. 106-387.
- 17 U.S. Department of Health and Human Services, Letter from Secretary Donna E. Shalala to President William J. Clinton, December 26, 2000.
- 18 U.S. Department of Health and Human Services, Letter from Secretary Tommy G. Thompson to Senator James Jeffords, July 9, 2001. Accessed at www.fda.gov/oc/po/thompson/medsact.html on 11/4/04.

1 Pub. L. 108-173.

2 Pub. L. 106-387.

3 U.S. House of Representatives, Conference Report on H.R. 1, Medicare Prescription Drug And Modernization Act of 2003, H. Rept. 108-391, November 20, 2003. Accessed at <http://thomas.loc.gov/cgi-bin/query/R?r108:FLD001:H11878> on 11/4/04.

4 U.S. Department of Health and Human Services, "HHS Announces Task Force on Drug Importation," February 26, 2004. Accessed at <http://www.hhs.gov/news/press/2004pres/20040226.html> on 11/4/04; U.S. Department of Health and Human Services, "HHS Names Members to Task Force on Drug

ATTACHMENT H



Electronic Pedigrees: To Assure the Security of the Pharmaceutical Supply Chain

McKesson has long been an industry leader in developing and implementing cutting-edge technology to enhance the security of the pharmaceutical supply chain. We were the first pharmaceutical wholesaler to fully automate our warehouses and distribution networks with radio frequency and scanning technology. Today, we are again taking the lead as we work with pharmaceutical manufacturers and a major retailer to test radio frequency identification (RFID) technology that will track pharmaceutical products from the manufacturer to the wholesaler to the pharmacy and facilitate the creation of electronic or e-pedigrees. This technology represents the next step in our continuous efforts to further secure the integrity of the pharmaceutical supply chain.

Government Support for Electronic Solutions

Federal and state governments are seeking solutions to address growing concerns about counterfeit pharmaceutical products. McKesson applauds the FDA's support for RFID technology that will enable the industry to create e-pedigrees to further assure the safety and security of the nation's drug supply. To achieve this goal, manufacturers need to place RFID tags on their products, while wholesalers and pharmacies must install the infrastructure to read the tags. The additional costs that will be incurred to implement this technology will be offset by a more secure distribution system that facilitates accurate and faster recalls, enhances operational efficiencies and improves inventory management for manufacturers, distributors, retailers and healthcare institutions.

On November 15, the FDA published compliance guidelines for the implementation of RFID feasibility studies and pilot programs. In conjunction with this FDA effort to accelerate adoption of RFID technology, Pfizer, Purdue Pharma, and GlaxoSmithKline announced their plans to place RFID tags on specific products. McKesson will continue to work closely with the FDA and state governments as well as with broad industry groups to advance RFID technology.

Cross-Industry Efforts

Through our leadership and proactive involvement with EPCglobal and Jumpstart, McKesson is on the leading edge of a cross-industry effort to develop standards and implement electronic track and trace technology to create e-pedigrees.

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. In early 2003, the healthcare and life sciences industry identified a similar technological need for pharmaceutical product EPCs. 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 the 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 recommended time frame for implementation of electronic track and trace technology by late 2007.

A coalition of manufacturers, wholesalers and retailers worked with Accenture to launch Jumpstart in 2003 to enhance the security and safety of the pharmaceutical distribution chain. Jumpstart has been actively involved in the utilization of RFID technology for tracking individual bottles of pharmaceutical tablets. Jumpstart recently completed the first phase of its feasibility study, during which McKesson installed RFID scanners in select warehouses to capture data from numerous test shipments, and track them to their ultimate destinations. The test successfully demonstrated the value of RFID in counterfeit detection, recall management and returns processing.

McKesson Position

We are committed to innovative solutions that will make the nation's pharmaceutical supply chain, already the best in the world, even stronger and more secure.

- 1) We support e-pedigrees for all drugs and biologics from the case to unit-of-sale level. E-pedigrees will complement the advanced technology already in place in our highly automated and virtually paperless distribution system. By making it significantly more difficult for counterfeiters or other rogue operators to insert illegitimate or contaminated product into the supply chain, e-pedigrees would negate the need for an ineffective, potentially fraudulent and costly paper pedigree trail.
- 2) We advocate ongoing communication and collaboration with federal and state agencies as McKesson and our supply chain partners finalize industry standards for the implementation of RFID technology and EPCs, and promote the widespread deployment of electronic track and trace technology.
- 3) Provided that states do not mandate the use of unworkable paper pedigrees that will divert attention and resources from time-critical investments in electronic technology, we anticipate that manufacturers and distributors will have systems in place by the end of 2007 to electronically track and trace pharmaceutical products throughout the supply chain.
- 4) To the extent that our retail partners may need additional time and resources to phase-in this technology, we urge policymakers to give them appropriate flexibility.
- 5) McKesson strongly advocates more stringent and uniform wholesaler licensing standards, tougher penalties for those who counterfeit or knowingly distribute counterfeit products, and more state resources for enhanced oversight of wholesalers. To protect those products that are most likely to be counterfeited, we endorse the establishment of a national list of pharmaceutical products which must be purchased by the wholesaler directly from manufacturers.

For the past 170 years, McKesson has led the industry in the delivery of medicines and healthcare products to pharmacies, hospitals and other healthcare entities. Today, a Fortune 16 corporation, McKesson delivers vital pharmaceuticals, medical supplies and health information technology solutions that touch the lives of more than 100 million patients in every healthcare setting. We purchase pharmaceutical products from more than 450 manufacturers and supply more than 75,000 customer sites. McKesson seeks to protect the integrity of the pharmaceutical supply chain while ensuring the delivery of safe medicines to patients. Our leadership in furthering the implementation of electronic track and trace technology supports this overarching and important role.

Memorandum

To: Enforcement Committee

Date: December 7, 2004

From: Patricia F. Harris 
Executive OfficerSubject: SB 1307 (Figueroa)
Chapter 857, Statutes of 2004

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

Electronic Pedigree for Dangerous Drugs (New)

B&PC 4034—requires an electronic “pedigree” by January 1, 2007. Said pedigree will 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.

The application of the pedigree requirement in pharmacies will be subject to review during the Board’s sunset review in 2008.

Embargoed Dangerous Drugs or Devices (New)

B&PC 4084 and 4085—allows Board inspectors to embargo dangerous drugs or devices that are suspected of being adulterated or counterfeit by affixing a tag or other marking to the drug. If a Board inspector determines that an embargoed dangerous drug or device is not adulterated or counterfeit, the inspector may remove the tag or marking. It is unlawful for any person to remove, sell, or dispose of an embargoed dangerous drug or device without the Board’s permission.

Furnishing Dangerous Drugs to Specified Entities and Violation Penalty (New)

B&PC 4126.5—permits pharmacies to furnish dangerous drugs only to:

- A wholesaler owned or under common control by the wholesaler from whom the dangerous drug was acquired;
- The pharmaceutical manufacturer from whom the dangerous drug was acquired;

- A licensed wholesaler acting as a reverse distributor;
- Another pharmacy or wholesaler to alleviate a temporary shortage of a dangerous drug that could result in the denial of health care. A pharmacy furnishing dangerous drugs pursuant to this paragraph may only furnish a quantity sufficient to alleviate the temporary shortage.
- A patient or to another pharmacy pursuant to a prescription or as otherwise authorized by law;
- A health care provider that is not a pharmacy but that is authorized to purchase dangerous drugs; and
- Another pharmacy under common control.

Violation of this section by either a pharmacy whose primary or sole business is filling prescriptions for patients of long-term care facilities or a person engaged in a prohibited transaction with such a pharmacy may result in a fine of \$5,000 per violation.

Surety Bond for Wholesalers (New)

B&PC 4162—requires applicants for the issuance or renewal of a wholesaler license to submit a surety bond of \$100,000 or other equivalent means of security to the Board. The purpose of the bond is to secure payment of any administrative fine imposed by the Board and any cost recovery ordered. If the applicant’s annual gross income for the previous tax year is less than \$10,000,000, a surety bond for \$25,000 will be accepted. Additionally, a surety bond of \$100,000 may be required for any licensee who has been disciplined by any state or federal agency or has been issued an administrative fine pursuant to the Pharmacy Law. A single surety bond or equivalent means of security acceptable to the board will satisfy this requirement for all licensed sites under common control. This section becomes effective January 1, 2006.

Pedigree Required (New)

B&PC 4163— presently allow manufacturers and wholesalers to acquire or furnish dangerous drugs or devices only from or to those authorized by law to possess or furnish those dangerous drugs or devices. This section is in effect until January 1, 2007, when it will be repealed unless a later enacted statute is enacted before that date. If this section is repealed, the new section will prohibit a wholesaler or pharmacy from selling, trading, or transferring a dangerous drug at wholesale without a pedigree. Additionally, a wholesaler or pharmacy may not acquire a dangerous drug without receiving a pedigree. This section becomes operative on January 1, 2007.

Extension May be Allowed for Implementing Pedigree Requirement for Wholesalers (New)

B&PC 4163.5—authorizes the Board to extend the time allowed for implementing electronic technologies to track the distribution of dangerous drugs within the state if the Board determines that manufacturers or wholesalers cannot meet the requirement by January 1, 2007. The pedigree requirement compliance date may then be extended until January 1, 2008.

Extension May be Allowed for Implementing Pedigree Requirement for Pharmacies (New)

B&PC 4163.6—authorizes the Legislature to extend the time allowed for pharmacies to implement electronic tracking the distribution of dangerous drugs within the state if the Legislature determines that it is not economically and technically feasible for pharmacies to comply with the requirement by January 1, 2007. The date for compliance with the requirement may be extended to January 1, 2009.

Wholesaler Tracking System of Individual Sales of Dangerous Drugs (Amended)

B&PC 4164—effective January 1, 2006, will require licensed wholesalers to develop and maintain a system for tracking individual sales of dangerous drugs at preferential or contract prices to pharmacies that primarily or solely dispense prescription drugs to patients of long-term care facilities.

No Business License for any Wholesaler Not Licensed by the Board (New)

B&PC 4168—prohibits a county or municipality from issuing a business license to a wholesaler who does not have a current wholesaler license issued by the Board.

Wholesaler Sales Requirements (New)

B&PC 4169—prohibits the following:

- The purchase, trade, sale, or transfer of dangerous drugs or devices at wholesale to a person or entity that is not licensed with the Board as a wholesaler or pharmacy;

- The purchase, trade, sale, or transfer of dangerous drugs that the person knew or should have known were adulterated or misbranded;
- The purchase, trade, sale, or transfer of dangerous drugs or devices after the beyond use date on the label; and
- The failure to maintain records of the acquisition or disposition of dangerous drugs or devices for at least three years.

Violation of this section may result in a fine for each violation.

Excessive Furnishing of Dangerous Drugs by a Wholesaler to a Pharmacy (Amended)

B&PC 4301—defines acts of unprofessional conduct and authorizes the Board to take action against a wholesaler who clearly excessively furnishes dangerous drugs to a pharmacy that primarily or solely dispenses prescription drugs to patients of long-term facilities.

The Enforcement Committee will be monitoring the implementation of this legislation. One area of close oversight will be 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 be the method used to track a drug's pedigree. The manufacturer would tag the drug with a small chip and antenna. When the tag is in close proximity of a reader, it would receive a low-powered radio signal and interact with a reader exchanging identification data and other information. Once the reader receives data, it would be sent to a computer for processing.

Attached is recent background material regarding the RFID process. Additionally T3Ci, which is an application software company that provides drug counterfeit, diversion detection and electronic drug pedigree for the pharmaceutical market, will demonstrate their technology solution for informational purposes only. As stated in their letter, they are involved in 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.



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News Release

FOR IMMEDIATE RELEASE

November 18, 2004

For more information contact:

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NABP's NDAC Assembles for Inaugural Meeting and Soon After Develops Formal Recommendations

The National Association of Boards of Pharmacy[®]'s (NABP[®]) National Drug Advisory Coalition (NDAC) convened its inaugural meeting in early September and then concluded with formal recommendations in early October 2004. The NDAC was commissioned by NABP to develop criteria for determining which prescription drugs should be included on NABP's "National Specified List of Susceptible Products" because of counterfeiting or susceptibility to counterfeiting as well as to evaluate and revise NABP's "National Specified List of Susceptible Products" as needed. In this capacity, the Coalition will serve as an advisory resource to the NABP Executive Committee, which will review the Coalition's final recommendations.

On February 20, 2004, NABP released the updated Model Rules for the Licensure of Wholesale Distributors. The updated Model Rules, part of the *Model State Pharmacy Act and Model Rules of the National Association of Boards of Pharmacy*, were provided to assist state boards of pharmacy in maintaining the integrity of the United States medication distribution system through the regulation of wholesale distributors. In addition to stricter licensing requirements such as criminal background checks and due diligence procedures prior to wholesale distribution transactions, the Model Rules mandate specific pedigree requirements for products that are particularly prone to adulteration, counterfeiting, or diversion. These products, as defined in the

(— more —)

**NABP's NDAC Assembles for Inaugural Meeting and
Soon After Develops Formal Recommendations**

Page 2

updated Model Rules, are designated as the "National Specified List of Susceptible Products." NABP hopes that states will adopt NABP's "National Specified List of Susceptible Products" as wholesale distributor regulations are revised.

The NDAC, appointed by the NABP Executive Committee, consists of representation from the state boards of pharmacy, American Medical Association, American Society of Health-System Pharmacists, Healthcare Distribution Management Association, National Association of Chain Drug Stores, Pharmaceutical Distributors Association, Pharmaceutical Research and Manufacturers of America, and United States Pharmacopeia. Ex-officio members, who serve as resources for the Coalition, include Food and Drug Administration, an independent counterfeit expert, and representation from the wholesale distribution and pharmaceutical manufacturing industries.

Following presentations on the NABP Model Rules for the Licensure of Wholesale Distributors (Charisse Johnson, NABP), Florida Prescription Drug Protection Act (Jerry Hill, bureau chief of Pharmaceutical Services, Florida Department of Health), and an Overview of Counterfeiting (Lewis Kontnik, Lew Kontnik Associates), the Coalition discussed the development of criteria for determining prescription drug products to be included on the NABP "National Specified List of Susceptible Products." Pfizer US Pharmaceuticals representative Peggy Staver discussed Pfizer's efforts to address counterfeit drugs via enhanced business practices, regulatory and legislative action, industry initiatives, and various technologic solutions.

After evaluating a number of resources and recommendations including Florida's Specified Drug List criteria the Coalition developed criteria to serve as a guideline for determining which prescription drugs should be listed. Suggestions recommended by the Coalition include:

- The addition of Viagra[®] to the NABP "National Specified List of Susceptible Products";
- The exclusion of veterinary prescription drugs and devices from the scope of the Coalition and NABP's "National Specified List of Susceptible Products"; and

(— more —)

**NABP's NDAC Assembles for Inaugural Meeting and
Soon After Develops Formal Recommendations**

Page 3

- The inclusion of prescription drug products that are noted to be in limited supply due to a national shortage for significant periods of time.

The recommendations of the Coalition have been forwarded to the NABP Executive Committee for review and final approval. The Executive Committee will release its final decisions regarding the criteria and the “National Specified List of Susceptible Products” in the upcoming weeks.

NABP is the independent, international, and impartial Association that assists its member boards and jurisdictions in developing, implementing, and enforcing uniform standards for the purpose of protecting the public health.

FOR IMMEDIATE RELEASE
P04-103
November 15, 2004

Media Inquiries: 301-827-6242
Consumer Inquiries: 888-INFO-FDA

FDA ANNOUNCES NEW INITIATIVE TO PROTECT THE U.S. DRUG SUPPLY THROUGH THE USE OF RADIOFREQUENCY IDENTIFICATION TECHNOLOGY

The Food and Drug Administration (FDA) today stepped up its efforts to improve the safety and security of the nation's drug supply through the use of radio frequency identification (RFID) technology. FDA launched this effort by publishing a Compliance Policy Guide (CPG) for implementing RFID feasibility studies and pilot programs that are designed to enhance the safety and security of the drug supply. This action continues FDA's commitment to promote the use of RFID by the U.S. drug supply chain by 2007.

In a related action, the FDA announced that it is creating an internal "RFID Workgroup" whose charge is to monitor adoption of RFID in the pharmaceutical supply chain, pro-actively identify regulatory issues raised by the use of this new technology, and develop straightforward processes for handling those issues. FDA believes that the workgroup will improve communication with members of the supply chain on RFID related issues and should facilitate both the performance of pilot studies and the collection of data needed to formulate policy.

RFID is a state-of-the-art technology that uses electronic tags on product packaging to allow manufacturers and distributors to more precisely keep track of drug products as they move through the supply chain. It is similar to the technology used for tollbooth and fuel purchasing passes.

The FDA also applauded the initiatives announced by the pharmaceutical companies Pfizer, GlaxoSmithKline, and Purdue Pharma. Pfizer announced its plans to place RFID tags on all bottles of Viagra intended for sale in the United States as expeditiously as possible in 2005. GlaxoSmithKline announced that it intends to begin using RFID tags in the next 12 to 18 months on at least one product deemed susceptible to counterfeiting.

Purdue Pharma announced that it is placing RFID tags on bottles of OxyContin to make it easier to authenticate as well as track and trace this pain medication. Based on the availability of sufficient RFID tags, Purdue also plans to tag bottles of Palladone, a newly approved product to treat persistent, moderate to severe pain. OxyContin, which is a controlled substance has been subject to abuse as well as theft and diversion. FDA also acknowledged the leadership of Johnson & Johnson in establishing standards for RFID technology and participating in RFID pilot studies. Johnson & Johnson will continue to collaborate with industry partners to develop standards for ePedigree.

"Radio Frequency Identification technology is an innovative response to the challenge of counterfeit drugs," said Health and Human Secretary Tommy G. Thompson. "It is our goal to insure that the drugs available in the United States are among the safest in the world. However, we still must continue to be on guard against those who would exploit patients by selling counterfeit drugs."

"Today's actions were designed with one goal in mind: to increase the safety of medications consumers receive by creating the capacity to track a drug from the manufacturer all the way to the pharmacy," said Dr. Lester M. Crawford, Acting FDA Commissioner. "This use of innovative technologies to protect the public health is exactly the type of bold leadership we expect to see more of in this arena. We hope that other manufacturers, wholesalers, and retailers will follow this example by also becoming early adopters of RFID."

RFID technology makes it easier to ensure that drugs are authentic, and it also creates an electronic pedigree, or record of the chain of custody, from the point of manufacture to the point of dispensing.



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News Release

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November 15, 2004

For more information contact:

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Electronic Safety Net – NABP Exploring the Creation of a Clearinghouse for Pedigree Data

The National Association of Boards of Pharmacy® (NABP®) is pleased to announce that it is taking further steps to protect the public health and maintain the integrity of the United States drug supply. Earlier this year, NABP released its Model Rules for the Licensure of Wholesale Distributors. These Model Rules contain provisions requiring the documentation, recording, and maintenance of a pedigree (Chain of Custody Record) for each package of drugs. The Model Rules anticipate that these records will be created and stored electronically. We note that the states of Florida and California have passed laws that either require or allow electronic pedigree records.

NABP supports the Food and Drug Administration's (FDA) policy that the use of radio frequency identification (RFID) technology is the best means to improve the security of the nation's drug supply. Electronic pedigrees will track and trace a drug product through the distribution system, from the time it leaves a drug manufacturer until it is dispensed to a patient by a pharmacist. We also support the need for access to relevant pedigree information in order for regulators to conduct investigations.

To facilitate the collection and maintenance of electronic pedigree information, NABP is announcing that it will establish a Task Force of state regulators, manufacturers, wholesalers,

(— more —)

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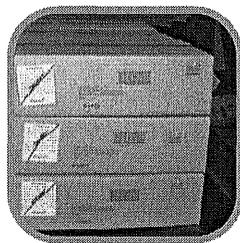
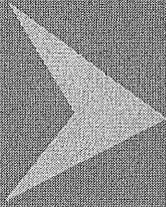
retailers, government regulators, and information technology experts to explore the feasibility of creating and maintaining a clearinghouse for relevant information to establish an electronic pedigree. The Task Force will establish ways to facilitate the exchange of information in an effort to maintain the integrity and safety of the US drug distribution system. Additionally, the Task Force will work with EPC Global to create the necessary standards for the development of e-pedigree software. The NABP Task Force may also explore ways to establish an accreditation program for e-pedigree software platforms to assure connectivity of systems throughout the US that need to communicate to each other.

We would like to emphasize that NABP will act as an honest broker to facilitate the creation of policies and business rules for the exchange of information among trading partners. We envision that trading partners will make their own arrangements for exchange of information and use the advantages of the NABP Clearinghouse to improve these exchanges.

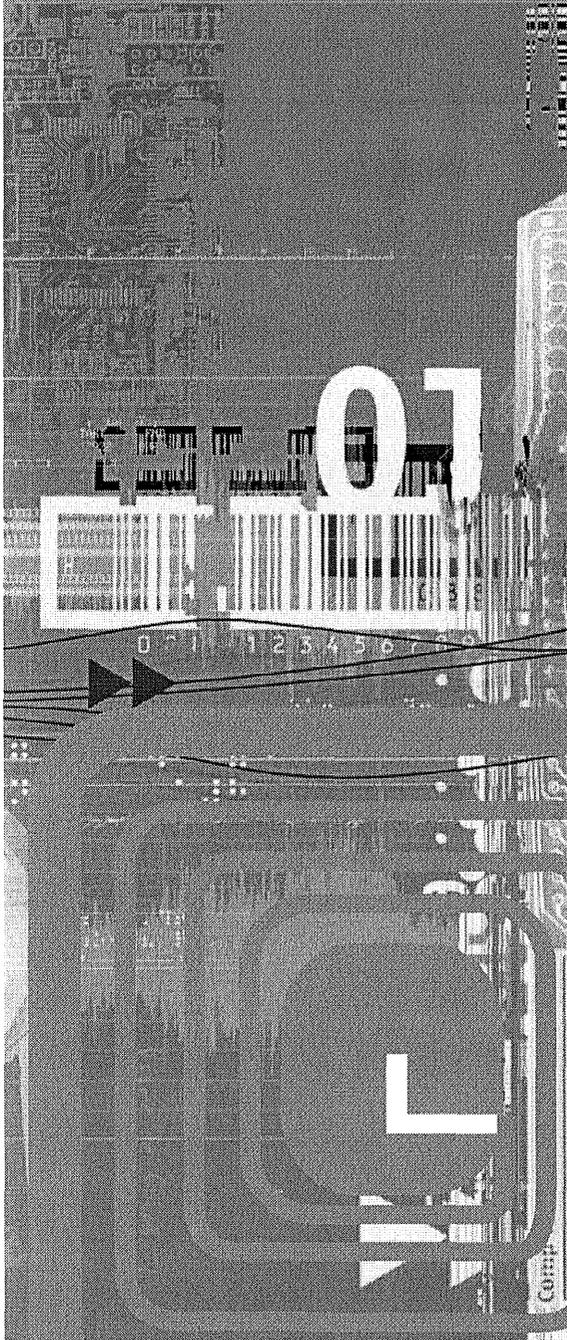
In February of this year, NABP released its revised Model Rules for the Licensure of Wholesale Distributors, which is part of the Association's *Model State Pharmacy Act and Model Rules*. The Model Rules were developed through a broad consensus process involving state and federal regulators, wholesale drug industry experts, national pharmacy organizations, and consumer groups. The Model Rules focus on critical areas of the licensure and regulation of wholesale distributors, identified by FDA and the states, that are essential to combating counterfeit drugs. Included in the Model Rules are specific provisions concerning the documentation, recording, and maintenance of a pedigree for drugs distributed through the wholesale distribution system.

Therefore, today we are announcing a major initiative intended to realize these goals as e-pedigree information becomes more widely available over the next few years.

NABP is the independent, international, and impartial Association that assists its member boards and jurisdictions in developing, implementing, and enforcing uniform standards for the purpose of protecting the public health.



An Industry Working Group Report on
Jump-Starting RFID/EPC
in the Pharmaceutical Supply Chain



September 2004
Executive Summary

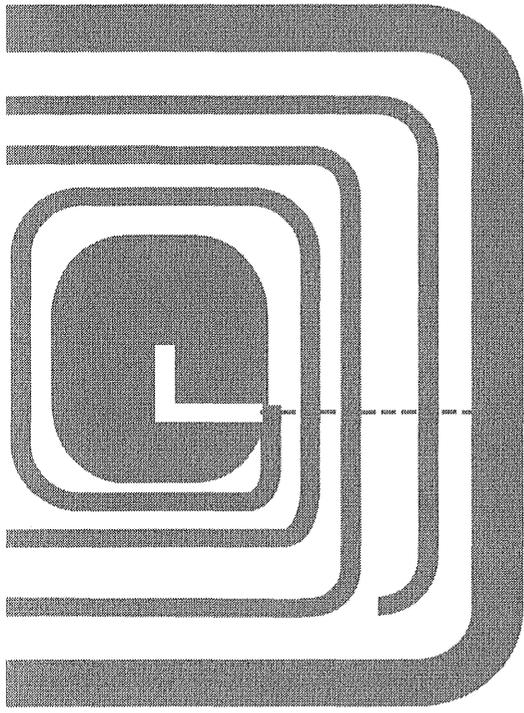


Table of Contents:

1. Management Overview	1
2. Project Approach	4
3. Tag Design	5
4. Technical Design	7
5. Working with Key Governing Bodies	8
6. Special Project Decisions	8
7. Verifying the Solution	9
8. Verification Results	10
9. Key Conclusions	11
10. The Future of Leveraging RFID/EPC across the Pharmaceutical Industry	14
11. Glossary	16

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RFID could be used to create a safe and secure supply chain, streamline reverse logistics, and increase the accuracy and efficiency of distribution and pharmacy operations.

1. Management Overview

A group of companies across the pharmaceutical supply chain came together in 2003 to explore the use of radio frequency identification (RFID) and Electronic Product Code (EPC) technology¹—a pioneering effort in terms of its practical scope and industry breadth. This working group included the pharmaceutical manufacturers Abbott Laboratories, Barr Laboratories, Johnson & Johnson, Pfizer, and Procter & Gamble; pharmaceutical wholesalers Cardinal Health and McKesson Corp.; retail pharmacies CVS Pharmacy and Rite Aid; and industry trade associations including the Healthcare Distribution Management Association (HDMA) and National Association of Chain Drug Stores (NACDS).² Accenture served as program manager for the group.

Together, the participants wanted to assess the business value of emerging RFID/EPC technologies, standards, and processes, and to work toward establishing an industry operating model that addressed pharmaceutical industry business issues. The technology's use had gathered momentum and uptake in other industries. The project team sought practical experience with RFID/EPC to explore its potential within the pharmaceutical space.

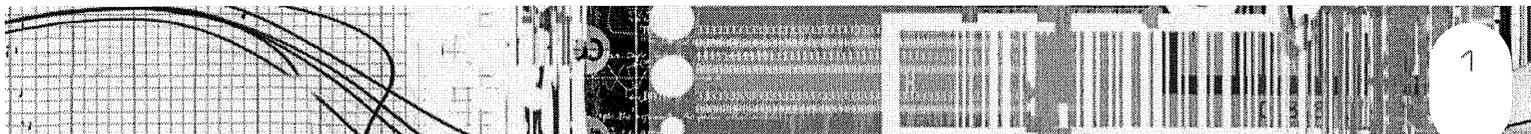
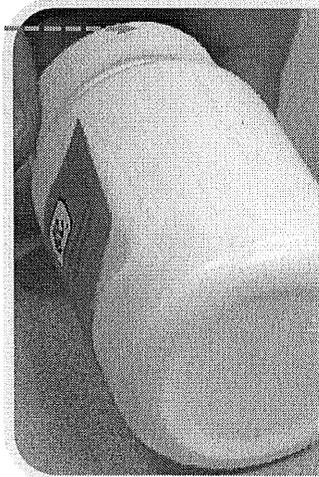
From October 2003 through September 2004, the project team designed, tested, implemented, and verified a complete supply chain solution. The principal objectives were to assess whether RFID/EPC could be used to help create a safe and secure supply chain, streamline reverse logistics, and increase the accuracy and efficiency of distribution and pharmacy operations. A scenario-based approach was used to validate the solution, new processes, and benefits against the related business issues.

In an eight-week test, preceded by an eight-month design period, the 9 participant companies selected 10 products for the project, working through 16 business scenarios in 15 project locations. Nearly 13,500 units of real product were tagged, shipped, received, handled, tracked, and traced through the project's system, providing the project with first-hand experience in working with tags and EPC reader technologies.

This initiative was a "proof of concept" of RFID/EPC technology in the pharmaceutical distribution channel, and seen as potentially the first step towards broader adoption of RFID/EPC across the value chain. This report summarizes the findings of the organizations involved in the project, collectively known as "Release 1, Group 1." Five additional companies known as "Release 1, Group 2" later joined the initiative, and will complete their work in late 2004. The findings from the Release 1, Group 2 activities will be published as an addendum to this report.

¹See Section 11 for Glossary.

²FDA and EPCglobal representatives also attended key meetings at the Steering Committee level.



Industry Context — The Growth of RFID/EPC

For some time, the consumer products, retail, and transportation industries had taken the lead in researching and applying RFID technologies for wide-spread use. A comprehensive study of RFID's potential to enhance pharmaceutical product manufacturing, distribution, and retail operations was a logical extension of those efforts. Some specific regulatory mandates unveiled in 2003 created a sense of urgency for exploring RFID in order for companies to comply. Two notable mandates were:

- The Florida Pharmaceutical "Pedigree Papers" requirements mandate that histories be maintained that identify previous sales and product information dating back to the drug manufacturer.
- Under Georgia's "Credit for Returned Expired Drugs" regulations, all wholesale drug distributors must make adequate provisions for the return of expired prescription drugs for up to six months after the labeled expiration date for prompt credit or replacement (to be received within 60 days). These regulations place the financial burden of expired product entirely on the wholesale drug distributors.

Industry and military initiatives have also propelled the reality of wide-spread RFID usage. Wal-Mart's RFID mandate has been widely credited with a general acceleration of the technology throughout the United States. By 2005, the retailer's top 100 suppliers must have RFID identification tags on shipping crates and pallets. In addition, Wal-Mart has also mandated that its Class 2 controlled pharmaceutical products suppliers use RFID tags bearing EPCs at the unit level by June 2004. The U.S. Department of Defense for its part will require all of its suppliers to put RFID tags on their shipping pallets and cases being delivered to the department's depots by January 2005.

Building Safe and Secure Supply Chains

As noted in a recent NACDS report, the World Health Organization estimates that 5-8 percent of drugs worldwide are counterfeit—meaning such drugs could represent from \$7 billion to \$26 billion of the \$327 billion global market. The FDA's current anti-counterfeiting taskforce is investigating methods to secure the pharmaceutical supply chain by examining new technologies that utilize RFID. It has stated that it should be feasible to use RFID to track all drugs at the unit level in 2007. Other healthcare organizations are either advocating RFID or are predicting its inevitability.

"RFID tagging of products by manufacturers, wholesalers, and retailers appears to be the most promising approach to reliable product tracking and tracing."

"Combating Counterfeit Drugs" Report, FDA, February 18, 2004

Key Findings

At a fundamental level, the project achieved its objectives of demonstrating RFID/EPC's potential to address industry needs as described below. In assessing the outcomes, however, it is critical to once again note that this project was a proof of concept. It was conducted in a very controlled environment with a limited scope. As would be expected with a project of this nature, it included many manual processes that ultimately will require automation to achieve the desired benefits from this technology. There are many issues yet to be addressed and much more work remains before this technology and the resulting business applications are scaleable and ready for industry-wide adoption.

- Satisfying Increased Regulatory Requirements — The system effectively tracked selected pharmaceutical products from the manufacturer's distribution facilities through the supply chain to the point of dispensing, thereby helping to show their location on the distribution channel and electronically capturing all necessary "pedigree" information. However, the technology employed must improve significantly and the intra-industry information systems must be built before this requirement can be satisfied.



- Satisfying Increased Trade Channel Requirements – The project demonstrated the ability to manually tag pharmaceutical units and cases for selected products to enable track-and-trace capabilities in a manner similar to those required in emerging retailer mandates.
- Increasing Product Security and Consumer Safety – The system provided individual unit serialization that has the ability to enable track-and-trace functionality that could help prevent counterfeit product from entering the supply chain.
- Increasing Efficiency of Returns and Recalls – Since detailed information such as lot number, expiration date, and transaction date/time/location is available for each individual EPC, the project showed that the effort to identify product location when processing recalls and returns could potentially become less complicated and labor intensive.
- Increasing Labor Productivity – When conducting activities that currently require bar-code scanning of each individual item (such as shipping, receiving, or cycle counting), the project demonstrated the potential of RFID/EPC to increase labor productivity by allowing multiple items to be scanned at one time. Furthermore, since shipping and receiving would be more accurate, the administrative effort to follow up on shipment/receipt discrepancies may be reduced. It should be noted, however, that tag readability and reliability must improve significantly before this process is scalable. There may be an incremental increase in the labor effort required as a result of changing systems and processes during the initial adoption of RFID/EPC.
- Increasing Order Accuracy – RFID/EPC technologies can provide validation of shipment and arrival at different points in the supply chain, thereby reducing over- or short-shipments of product, and increasing customer satisfaction.

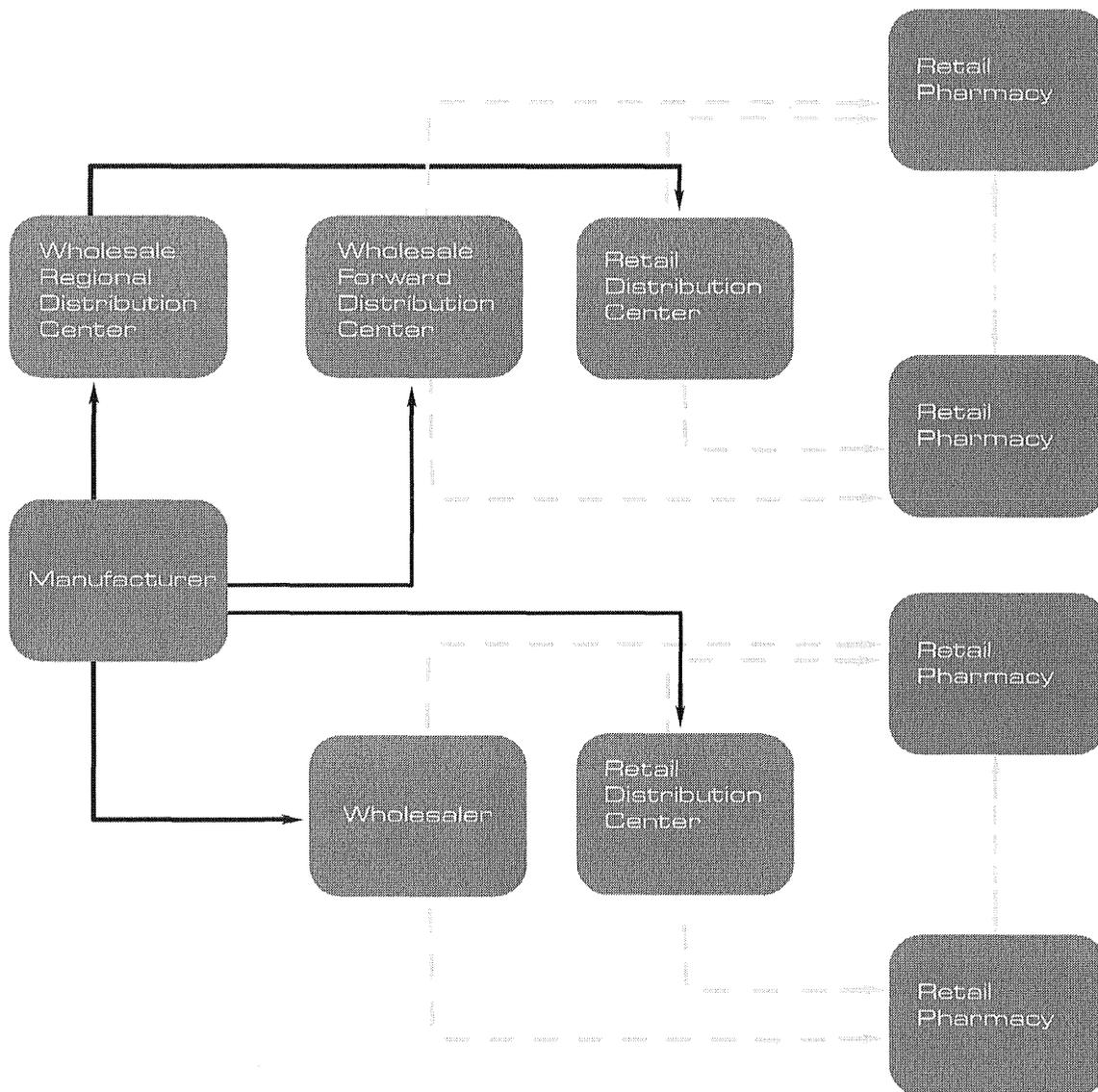
The final sections of this executive summary further discuss this project's findings. They also outline the considerable challenges ahead that will require a concerted effort by the industry and regulatory bodies alike to work through.

2. Project Approach

The project focused on assessing the ability of RFID and EPC applications to improve specific work processes—what the project team called business scenarios. These scenarios addressed four key categories: EPC Management, Safe and Secure Supply Chain, Streamlined Reverse Logistics, and Accurate Operational Efficiencies. (The sidebar at right shows a complete list of the 16 scenarios.) Ten products and 15 distribution, wholesale, and retail locations were selected for the project.

In order to quickly and cost-effectively plan and execute this project and avoid any business interruption, a separate, standalone parallel process and system were created with no modifications to packaging or production processes and no integration with existing information technology (IT) systems. There was no attempt to validate the system according to FDA electronic records regulations.

Figure 1. Defined Product Flow Path



Project Business Scenarios EPC Management

- Commission – (1) Manual update with product description, lot number, and expiration date (i.e., pedigree product information); (2) manual initialization of link between unit EPC and case EPC
- Decommission 1 – Automatic decommission of a unit EPC or case EPC after a designated time period of inactivity in “suspense” status
- Decommission 2 – Manual decommission of case or unit EPC tags

Safe and Secure Supply Chain

- Regulatory Compliance – Tracking product through the supply chain to create a pedigree
- Counterfeit Compliance 1 – Identification of counterfeit product based on Product Authenticity Reporting
- Counterfeit Compliance 2 – Automatic alert of counterfeit product based on invalid case or unit EPC tags
- Counterfeit Compliance 3 – Automatic alert of counterfeit product following the reuse of EPC tags after a period of inactivity or no reads
- Logistical Error – Identification of a supply chain logistical error based on valid case or unit EPC tags

- Product Theft 1 – Identification of missing or stolen product based on Shipping and Receiving Summary Reporting
- Product Theft 2 – Automatic alert of missing case or unit EPC resulting from theft occurrence on inbound shipment

Streamlined Reverse Logistics

- Product Expiration Management 1 – Identification of short-dated, recalled, or expired product via Inventory Management Reporting
- Product Expiration Management 2 – Identification of short-dated/expired/recalled product on receipt
- Expired/Recalled Product Return – Short-dated, expired, or recalled product return managed through return of EPC tags
- Product Recall Management – Manufacturers' ability to alert supply chain partners who have received product being recalled, and summarize the distribution history of the recalled product via Product History Reporting

Accurate Operational Efficiencies

- Shipping Operations – Outbound order shipping accuracy verification
- Receiving Operations – Inbound order receiving accuracy verification

3. Tag Design

The original design called for a plain tag—chip, antenna, and plain inlay with an EPC number printed on the front label—which would support business processes in lieu of bar codes and enable unit-level serialization. The tag needed to be small enough to be placed on pharmaceutical packaging without covering any existing labeling, it needed to be a UHF tag which is conducive to processes focused on shipping and receiving, and it needed to comply with EPCglobal Class 0 standards. The 1.2" x 1.4" tags selected from Matrics met these requirements. They came with factory-programmed EPC numbers with a known set of test numbers provided by Matrics to serve as a control (manufacturer-specific “real” EPC numbers were not obtained from EPCglobal).

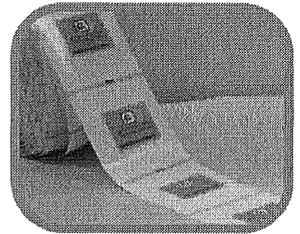
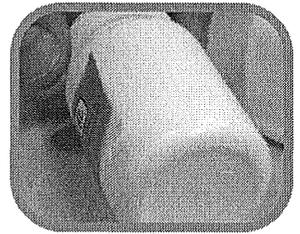
As the project team worked through the design with the participants' packaging, regulatory, and quality assurance experts—along with EPCglobal and the FDA—a number of issues arose that provoked the need for changes and additional features:

- Removable Tags and Adhesives – The project involved tagging trade packages containing real product. Pharmacists typically remove the product from these packages and dispense the medication to patients in vials.³ Even though it was not expected such products would ever be dispensed in the original trade package, to avoid consumer concerns the group worked toward making tags removable to reduce the chances that tagged product would end up in a consumer's hands. At the same

³There was one exception: one product was in a blister pack and designed to be consumer dispensable.

time, the team needed to find an adhesive that would allow the tags to stay on during handling through the supply chain and avoid potential negative interactions with packaging or drug composition.

A group of specialists in labeling and quality assurance designed an innovative two-ply "coupon-style" tag. A clear base layer remains on the product for its lifetime, but the actual RFID tag, while adhering during the course of normal handling, can still be peeled off. With the two-ply "peel label" solution, manufacturers were able to use an adhesive that had been pre-approved for the clear base. Matrics (who made the tags) and CCL (who converted the tags into the two-ply labels) were able to use an adhesive that was appropriate for the RFID tag and that would have sufficient tack to attach to the base film.



- Design and Placement –
Though tags needed to be small, they also had to be highly visible. Manufacturers wanted to ensure the tags were removed from their products prior to dispensing to consumers. Retailers were similarly keen to avoid consumer concerns. The tag label was designed using a bright orange color to ensure visibility for pharmacists.
- Tag Label Design –
The project team went through several iterations on the information printed on the tag label. This was as a result of the group's desire to align with the public policy guidelines established by EPCglobal and the fact that the specific approach for implementing the guidelines was still evolving. (Many of the guidelines had originally been developed within the context of consumer packaged goods, which were not appropriate for pharmaceutical products.) Dialogue between the project team, EPCglobal, and the FDA resulted in the final tag label design that included wording ("Inventory control tag. Tag may be removed"), a human-readable EPC number, and the EPCglobal logo.

After the project was completed, the tags were removed from the products, and the products were put back into inventory for normal distribution.

Figure 2. Physical Architecture Overview

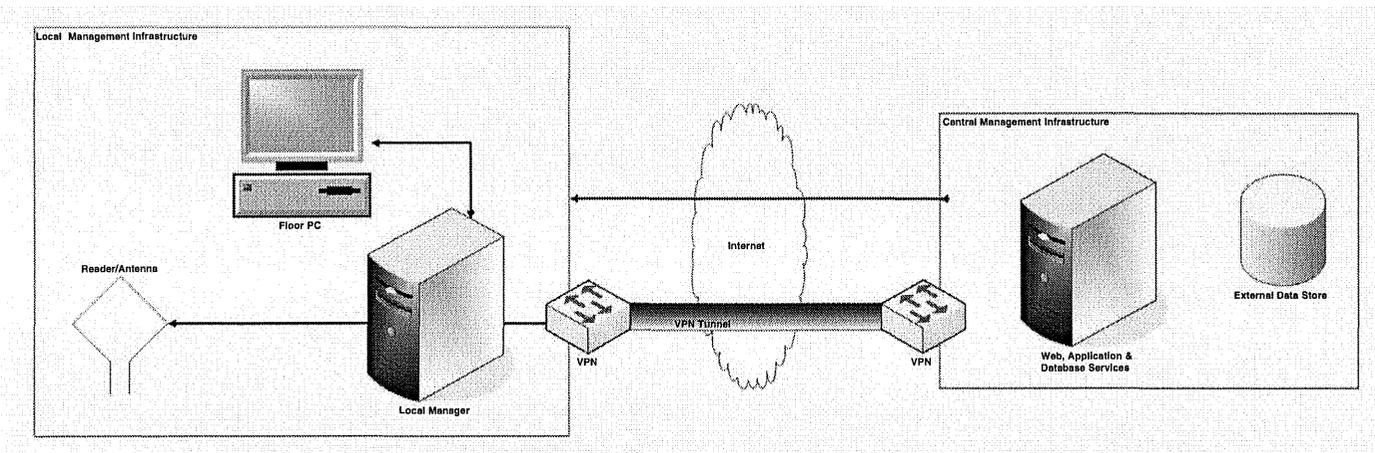
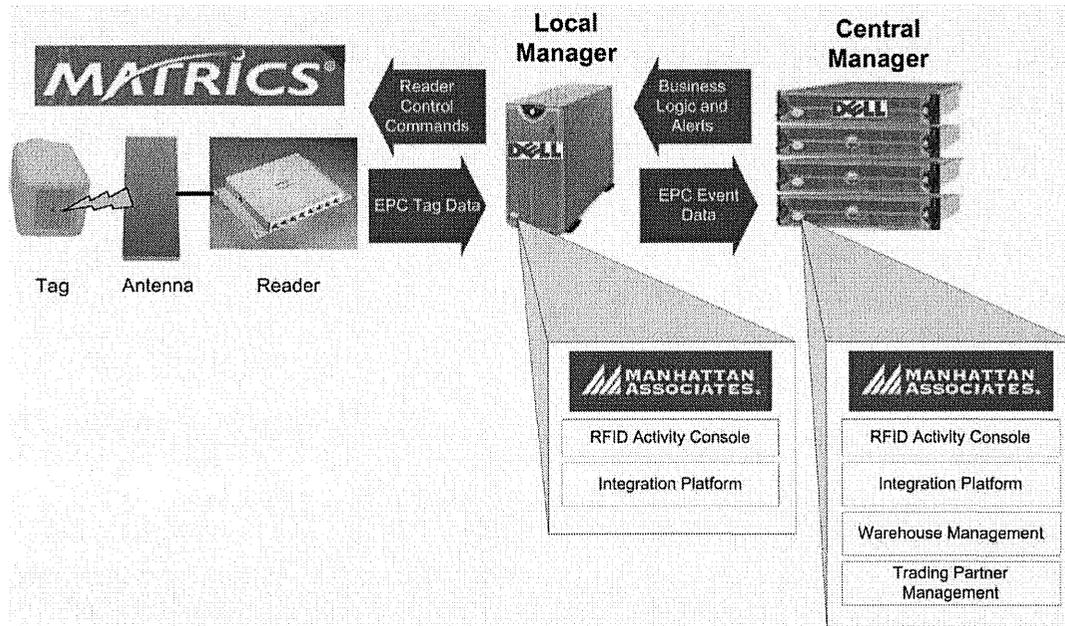


Figure 3. Conceptual Vendor/Product Fit



4. Technical Design

The goal of the project was to determine if RFID/EPC technology could enable and improve areas where key business issues exist. It did not set out to prove that the project’s technical solution was an exact right fit for each company’s specific situation. The technical infrastructure spanned 10 organizations that collected, analyzed, and acted on data generated by EPC movements. The architecture utilized a distributed network of readers and servers composed of four primary components:

- The RFID reader and antenna provided the input for the entire system. This component collected tag data from products and cases. Readers and antennas were located at each node in the supply chain.
- The local manager temporarily stored reader tag data, acted as the reader controller, and formatted EPC data so that it could be sent to the central manager. Each company had a local manager that could control many readers.
- The central manager was where the bulk of the functional logic resided and where tag data was permanently stored. The central manager was hosted in an Accenture data center, which included the capability to centrally monitor the local managers.
- A PC with a Web browser was used to access the application on the local and central managers, and control the readers.

The team advocated a buy (versus build) approach, and sought components aligned with emerging EPCglobal standards and which would allow flexibility for expansion during future releases. The architecture also needed to provide a secure channel for data collection, distribution, and storage.

Manhattan Associates’ solution was selected since it provided the required functional capabilities along with a bundled RFID middleware capability. As discussed earlier, Matrics tags were selected. Consequently, this factor drove the reader selection decision. It should be noted that vendors selected for this implementation were selected based on the specific functional requirements outlined by the project team. No particular preference or vendor qualification beyond the scope of this project is indicated or implied.

The figure above shows the primary components in the project environment and where they fit into the infrastructure.

5. Working with Key Governing Bodies

Given that RFID/EPC is very new to the pharmaceutical space, it was important to understand the direction and policies of key public policymakers such as the FDA and EPCglobal to make the project's activities effective.

FDA

From the project's outset, participants sought guidance by the FDA on certain regulatory issues such as labeling, electronic records, and the effect of the electromagnetic energy associated with RFID on product quality. Regarding labeling and electronic records, the FDA decided to exercise "enforcement discretion" as applied to this specific project.

However, the FDA did request that manufacturers share the results of any product quality testing they conducted that investigated whether there were any effects of electromagnetic energy on drug efficacy, potency, and strength.⁴ The pharmaceutical manufacturers developed and executed a testing protocol for the products and technology involved in this initiative, which was shared with the pharmaceutical industry. Once the analysis was complete, the results were shared with the FDA. As initially expected, based on the measurements taken, no adverse effects were found on the products that were tested, and the team moved forward using live product during this project. Testing proved a valuable exercise, since it provided factual data on the effects of electromagnetic energy on product quality.

EPCglobal

In addition to setting industry-driven standards for EPC, EPCglobal is also providing guidelines on the visual appearance of tags and communications for consumer awareness. EPC standards have evolved based on requirements driven by industries such as consumer products and retail. To complete this project, the team coordinated with EPCglobal to adjust the tag's visual and verbal characteristics, so that they were appropriate for pharmaceutical products. As the industry moves forward with RFID, EPCglobal's focus and standards will expand and mature to help make RFID projects in the pharmaceutical space more effective.

⁴ Only solid dosage form products were subjected to this testing and were used in the project.

6. Special Project Decisions

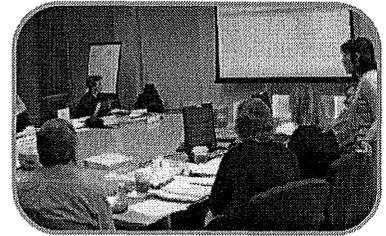
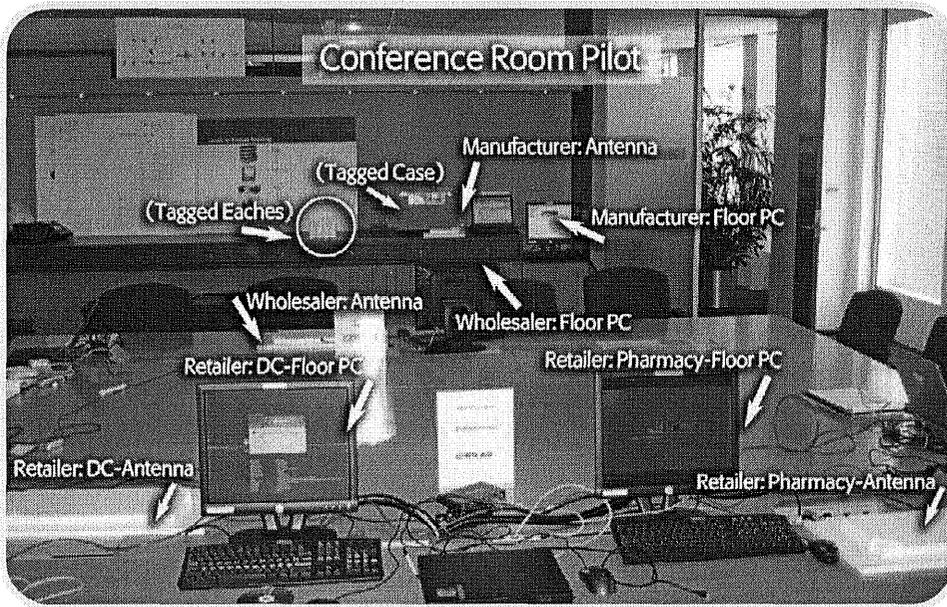
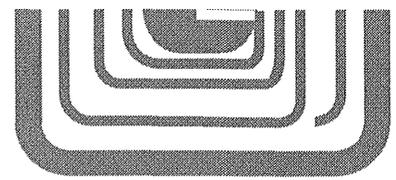
Inferences Regarding Case Integrity

Due to the inherent physics limitations of UHF radio waves and their inability to penetrate certain materials (e.g., liquids and metals), initial tests indicated that not all units within a case could be consistently read by a reader. An important component in the project was the decision to make inferences about case integrity and authenticity. That is, even if only a portion of the individual units within a case were read, all the units could be inferred to be within the case by their association with the case tag. Depending on future business requirements and processes, inference logic may be unacceptable. Alternate approaches involving customized packaging/reader antennas, the use of high-frequency tags, and adjustments to processes—as well as matured technical solutions—may need to be leveraged to make unit-level tags trackable nearly 100% of the time.

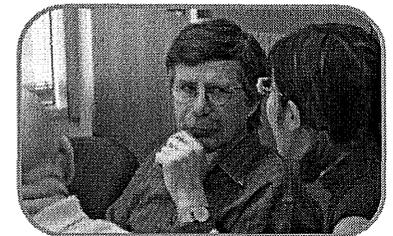
Limitations to Data Visibility

All participants in the project have major concerns with the potential to allow competitors to gain visibility into confidential company data such as inventory levels, shipping/receiving schedules, and prices. The project reinforced the need to establish sound, principle-based data-sharing work processes. For purposes of this proof of concept, the intent was to work with each organization to create a simple solution that demonstrated the project's ability to restrict confidential data. The final data visibility scheme was developed using three guiding principles:

1. Visibility was favored over restricted access. It was understood that in potential future releases, data access and visibility would likely become more restrictive.
2. Authorization rules were kept simple. The processing logic behind data access and visibility was such that there was no confusion among users as to why an organization's visibility was enabled or restricted.
3. The solution demonstrated the ability to keep sensitive data confidential. The project exhibited the ability to restrict access to certain data based on the users' identity and their possession of the appropriate tag information.



The team conducted a conference room pilot to simulate a real-life supply chain—from manufacturer to wholesaler to retailer.



7. Verifying the Solution

Working through the various business scenarios the team had established, and going live with the selected RFID technology to execute them, comprised a stage of work called Verification. Prior to Verification, the team conducted a conference room pilot from April through May 2004, to simulate a real-life supply chain from manufacturer to wholesaler to retailer. This involved testing the system, training users, and creating a demo of the new environment to show interested parties outside the project.

Additional final preparations included:

- Supply Chain Analysis – Documenting how and when product would move through the supply chain. To the extent possible, the team wanted to test each scenario for each

product at each location. Doing so required the team to conduct a supply chain analysis that laid out step-by-step volume flows describing what, how, and when the nine participant companies' locations would be shipping to each other.

- Exception Processing – In order to make the scenarios as realistic as possible (and to demonstrate how RFID might enable the handling of them), the team planned into Verification a number of exception simulations and forced these exceptions to occur. The five "exception groups" were theft, counterfeit/diverted, logistical error, expired, and recall.

To the extent possible, the team wanted to test each scenario for each product at each location.

8. Verification Results

The project was intended to assess the feasibility of leveraging RFID/EPC technology in an end-to-end supply chain context. The Verification stage of the project showed positive movement in that direction in two ways.

First, the Verification stage demonstrated that the RFID/EPC tags and readers were largely successful in and of themselves as mechanisms for tracking and tracing product.

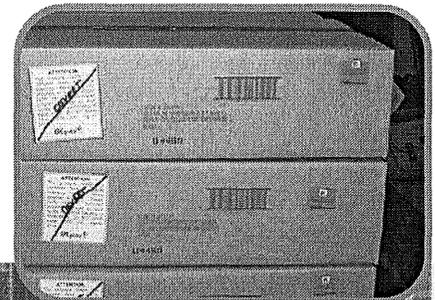
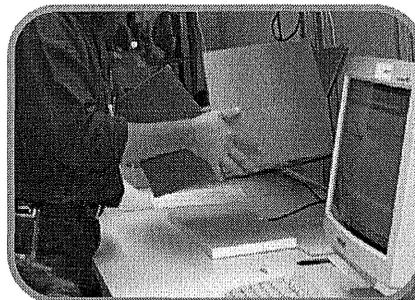
The project team set out to track 10 “real” products (not just empty bottles) through 15 locations. The manufacturers were required to verify the readability of the tags before applying them to the products. Then they were able to commission individual EPC numbers for specific product units and cases. The common hardware components selected for the project were quite reliable. Solid-dose packaging (bottles) as well as blister packaging could be read and tracked. In this limited proof of concept, the system was able to dramatically increase the visibility of the project’s selected products as they moved through the supply chain.

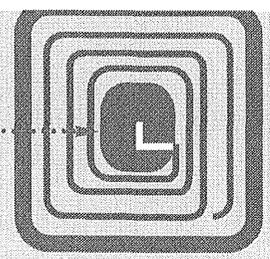
The application tracked tag readability statistics during Verification. The project team was able to read 98.6% of the case tags. In addition, when units were inside a case, the team was able to read 96.8% of the unit tags. Once Verification was complete, 99.9% of returned tags were functioning.

As the project progressed, and as personnel at various locations became more comfortable with the technology and how it worked, read rates improved. In addition, personnel found that success in read rates was often related to 1) time and diligence spent trying to read (e.g., holding the units/cases to reorient the tag in relation to the antenna), and 2) the number of antennas implemented.

Second, the Verification stage demonstrated the ability of this project to use RFID/EPC technology to execute 16 pharmaceutical industry scenarios at all 15 locations for all 10 products — a major undertaking.

The project’s system and processes were able to simulate in a live environment a range of conditions in the supply chain. Nearly 30 participant personnel gained experience in working with the 16 scenarios, which allowed them to see how RFID/EPC can surface information about “suspicious” or irregular shipments such as potentially counterfeit or stolen products. By having continual real-time access to pedigree information on specific units, they were provided with much-improved visibility into where product was at all times and could query the system to track down missing product.





9. Key Conclusions

The project helped establish key facets of an industry operating model.

By creating a proof of concept that engaged major sectors of the supply chain, participants gained insight into what processes and supporting systems need to be in place to construct an industry operating model. The safety and security of the supply chain was a critical focus of the project. The new operating model will ultimately require unit-level serialization of products which could enable systematic detection of counterfeit product if it enters the supply chain, a previously unavailable capability. In addition, the project:

- Assessed the potential for RFID/EPC to electronically address important regulatory mandates such as the Florida Pedigree Requirements. This technology offers the potential to eliminate the need for a paper-based pedigree system, which is labor intensive and unreliable.⁴
- Helped to establish business rules and processes to facilitate returns, and designed a recall process that may provide a more efficient manner to execute this process using RFID/EPC technology.
- Developed and executed testing protocols that provided data indicating that electromagnetic energy did not affect the efficacy, potency, and strength of this project's solid-dosage products.
- Contributed research and developed workable solutions on tag frequency, label color, size, wording, and location on packages that could represent going-in positions for the industry.

The project allowed participants to rapidly learn and create innovative responses to significant project issues.

The project team addressed and resolved several critical practical matters in this first broad application of RFID/EPC. For example:

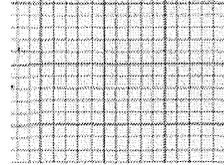
- Numerous obstacles on EPC tags were overcome to prove that pharmaceutical products can be tagged at the unit level. The project team showed that human readable numbers can go on tags and be used as a method of redundancy in case the tag is not functioning. It established an innovative two-ply tag system that worked well and satisfied the needs of manufacturers for adhering to the bottle during normal handling, but that could also be removed to reduce the chances of tags getting into the hands of consumers.
- The project arrived at some tentative solutions to address data visibility and security—a practical start in surfacing and exploring an issue that will likely be a key adoption hurdle for RFID/EPC in the industry.

The selected technology suite was completely appropriate and workable for the parameters of this project.

The primary objective was to focus on assessing business value, not on perfecting the technology. Furthermore, the project team needed to choose components that fell within the agreed-upon time and budgetary limits of this project. The team selected commercially available solutions and implemented them so that business scenarios could be run and experiences gained with reasonable effectiveness. It was understood that the solution would not be optimized for each location. For example, the single antenna used in the project was chosen for its simplicity and ease of use. Naturally, in a scaled-up version of the project, there would be multiple antennas throughout the facilities and dramatically enhanced capabilities (e.g., multidirectional reading).

⁴Discussions with regulatory bodies would be required to finalize such a capability.





It should be noted that the level of complexity to do a “simple proof of concept” was greater than anticipated given all the different participant companies involved. Such complexity is likely to grow much above what was present in this simple test environment as integration requirements grow.

The project underscored the importance of meeting infrastructure prerequisites to prepare for industry-wide adoption of RFID/EPC.

There are immediate measures that manufacturers, wholesalers, and retailers can take as preconditions for being effective with RFID/EPC technologies. For example, the broader lessons and issues on this project can be addressed through smaller scale initiatives within the four walls of organizations looking to implement RFID/EPC.

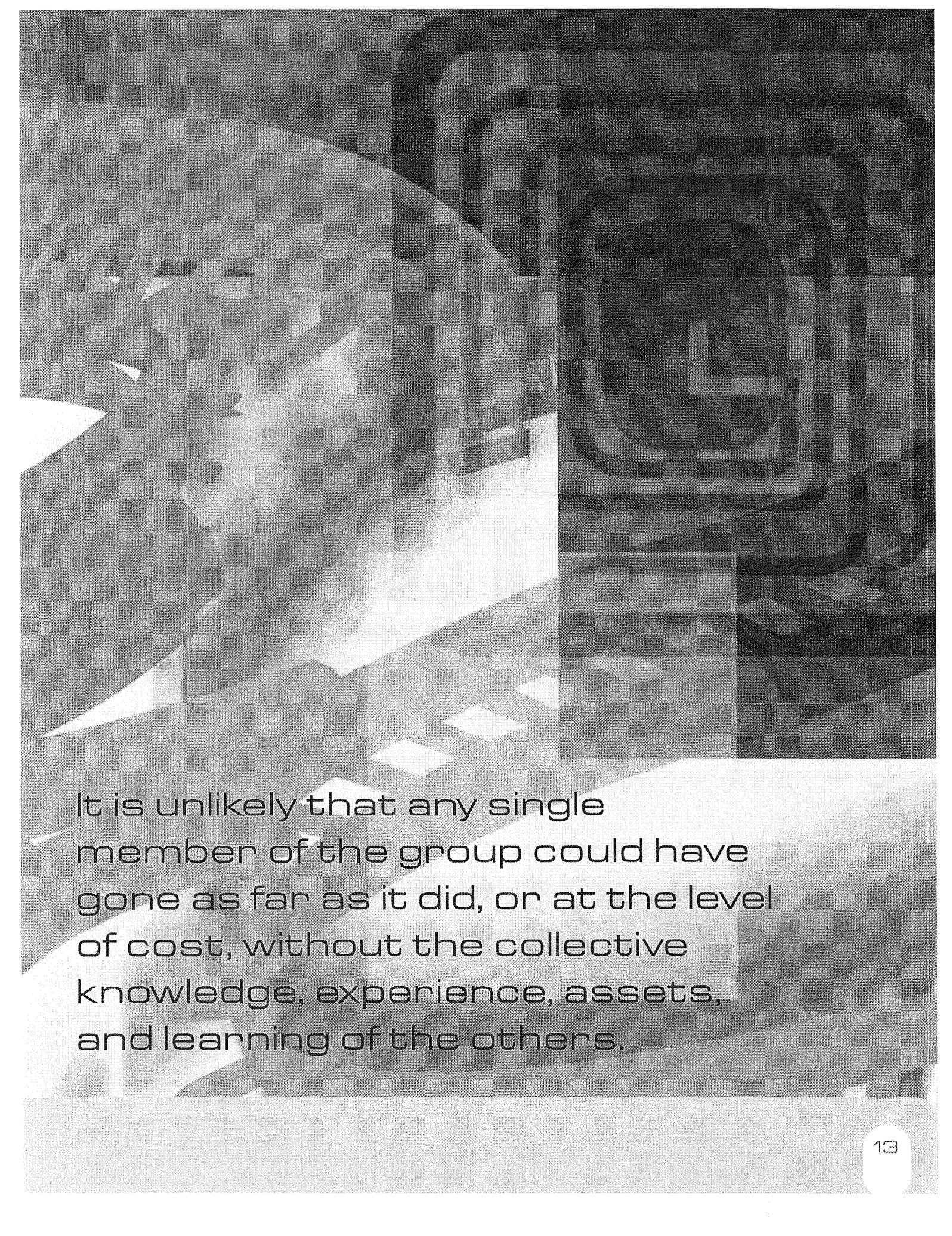
Implementing RFID/EPC technology affects many disciplines within an organization, and companies must work on integrating their efforts internally.

Implementing RFID/EPC technologies in any company requires close coordination and involvement across the organization—representatives from information technology, quality assurance, regulatory affairs, public relations, packaging, and operations for manufacturing, distribution, and stores. One specific example was the need to address public perceptions about the industry’s goals in exploring RFID/EPC. Reassuring consumers will be a major task that many functional groups will need to address.

A collaborative, cross-supply-chain approach proved effective in pooling resources and sharing development assets in order to gain benefits.

It is unlikely that any single member of the group could have gone as far as it did, or at the level of cost, without the collective knowledge, experience, assets, and learning of the others. No single firm could test the RFID/EPC technology and duplicate the interaction of the entire supply chain. Manufacturers, wholesalers, and retailers worked well together to address industry issues. The collective voice and collaboration of the supply chain participants were among the advantages to this group approach. For example, the project team identified and brought to the attention of EPCglobal and the FDA the need for standards and business practices relating to the use of RFID/EPC technologies that address the unique needs of the pharmaceutical industry.

The presence of an independent, trusted third party was also essential to keeping the group on a single path—facilitating collaboration, completing the project in accordance with the agreed-upon timeline, and coordinating external communications about the project. The coordination from a technical perspective was also important. Many different organizations and individuals (data center administrators, VPN engineers, facility engineers, network specialists, security specialists, etc.) needed to be orchestrated and move in concert to complete the design, deployment, and support activities.



It is unlikely that any single member of the group could have gone as far as it did, or at the level of cost, without the collective knowledge, experience, assets, and learning of the others.

10. The Future of Leveraging RFID/EPC across the Pharmaceutical Industry

Full-scale implementation on an industry-wide basis will be more complex than many believe, requiring more time than anticipated to refine issues unique to the pharmaceutical industry. Requirements for systems and packaging—especially in addressing data sharing and consumer concerns—in this highly regulated environment will present greater costs and efforts than those of other industries.

Other key conclusions about RFID/EPC's future include the following:

The technology must continue to evolve for an effective full-scale industry implementation.

RFID technology is improving every day. Vendors, hearing recent feedback about practical applications of the technology, are responding appropriately and quickly. An example of an issue being addressed by vendors is tag quality. At each step of the process of converting the tag into the label, a sizeable percentage was not useable due to problems with the tags, labels, or printing. The rate of defective finished tag labels (approximately 20%) would not be acceptable outside this project's limited scope.

Tag manufacturing and converting processes will need to improve significantly to provide tags with defect rates at least as low as other packaging components that pharmaceutical manufacturers currently use. The technology will also need to advance such that tags will function effectively with liquids, biologics, and cold chain products, among others, as well as in mixed-tote shipments.

Finally, tag costs need to decrease significantly.

Additional technology issues that must be addressed include:

- Greater consideration will have to be given to how RFID hardware interacts with other devices.

- In order to support the type of distributed network that an RFID implementation requires, updates will need to be made at all locations to support communications to new RFID data exchange partners.
- The testing of hardware after deployment is critical to ensuring that both networks and hardware are configured properly. This can be a time-consuming activity that needs to be taken into account when multiple organizations are all trying to coordinate and move to the same schedule.

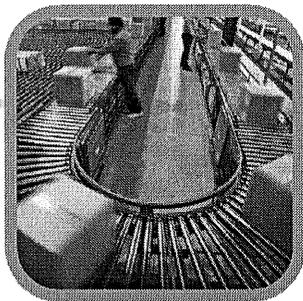
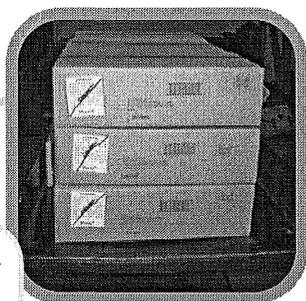
The participants' understanding and experience in working with RFID/EPC in the pharmaceutical industry has grown tremendously; but they need to keep learning.

The project was highly valuable in how it surfaced issues that the team either did not contemplate going in or did not believe would present difficulties. The highly regulated nature of the industry and privacy concerns drove many of these. For example, time-consuming issues were encountered around tag size, wording, acceptable adhesives, and location, to name a few. Working through these issues has provided valuable insight.

Other issues, however, will require additional study. For example, it will be critical to determine how to devise scalable solutions that address data security and visibility. So will solidifying the steps to obtain validation for systems and processes, as well as approaching the significant effort to integrate RFID/EPC technology with core transaction systems. The table at right shows the range of potential issues to widespread adoption of RFID/EPC.

The industry needs to continue to actively engage with Federal/state regulatory agencies, standards-setting organizations, and industry trade associations to gain involvement in forthcoming releases of this project.

Creating reasonable consistency of standards globally should be a key goal. It will also be critical to mutually establish timetables that reflect the state and effectiveness of RFID/EPC technology and associated processes, and the pharmaceutical industry's experience in leveraging them.



Challenges to Industry Adoption

Key Project Characteristics	Potential Issues for Widespread Adoption
The solution operated with a centralized system and a single instance for all companies.	What would be the development time and investment implications of creating a decentralized, heterogeneous environment?
Tags were placed on packages manually, on the exterior, at the manufacturers' distribution sites.	How could tags either become integral to packaging or at least be applied automatically?
There was no integration of systems; this system was a stand-alone, parallel system that required duplicate data entry.	What would be the development time and investment implications of integrating RFID technology and applications with core transaction and other legacy systems?
There was "full" visibility of information (or more visibility than would probably be permitted outside the project).	What would be the process for sorting through and managing restrictions on visibility—and how would those outcomes impact the value of RFID/EPC?
The team made inferences regarding case integrity.	What steps would be needed to achieve close to 100% readability at the unit level?
The project focused on a subset of processes that when improved by the use of RFID/EPC would provide varying amounts of benefits to each segment of the supply chain.	How could separate components of the supply chain be addressed that do not provide benefits to all supply chain segments—e.g., pharmaceutical retail operations and warehouse management—without undercutting the learning and value of having an end-to-end supply chain involved?
The system was not validated.	What would be the process for obtaining validation?
Only cases and units were tagged at the manufacturer.	What about pallets, interpacks, and totes? What about co-packers or repackaging occurring at locations other than manufacturers?
Solid dosage products with easy handling requirements were selected.	What about liquids and biologics with "difficult" handling characteristics (e.g., refrigeration requirements)?
EPC test numbers were used.	What happens when "real" EPC numbers are used?
A single antenna was used in a secluded area of the distribution center.	How would multiple antennas placed in ideal locations (some of which may already have little space, or environments with physically challenging conditions such as susceptibility to extreme temperatures, shock, dirt, and damage) be effectively installed?
The project operated in a virtual team environment, with a central coordinating group working with local contacts at each company.	How would a centralized management structure work, when a larger team and more complex activities would need to occur locally at each company?
Reasonably easy control of consumer privacy issues could be achieved by manually removing tags from packages.	What issues would be involved in mass tagging?
Given its narrow scope, the project played a very limited role in educating consumers about RFID/EPC.	What effort would be involved in educating consumers about RFID/EPC's benefits and dispelling misconceptions?
The project included large companies from three segments of the pharmaceutical supply chain—manufacturers, wholesalers, and chain drug retailers.	How can other segments of the pharmaceutical value chain (biotechs, hospitals, clinics, independent pharmacies, mass merchants, secondary wholesalers, etc.) be included to broaden industry adoption to achieve greater benefits? How can small businesses be involved?

Moving Forward...

This project achieved its stated objectives—assessing the potential for RFID/EPC technology to provide business value in an end-to-end supply chain context, and helping to establish an industry operating model. Perhaps most important, it established a forum for the industry to start asking the tough questions and providing companies with the knowledge and confidence to move forward with RFID/EPC. Fortunately, the enthusiasm for this group's efforts has only grown since its inception. The group has already begun discussing how to take the next steps towards making the use of RFID/EPC in the pharmaceutical industry a reality, and hopes that others in the industry will join in discussing how to move forward.

11. Glossary

RFID

Radio Frequency Identification technology (RFID) is an advanced method to collect product, event, and/or transaction data quickly and easily. Items to be tracked are tagged with a small chip and antenna. When the tag is in close proximity of a reader, it receives a low-powered radio signal and interacts with a reader exchanging identification data and other information. Once data is received by the reader, it can be sent to a computer for processing.

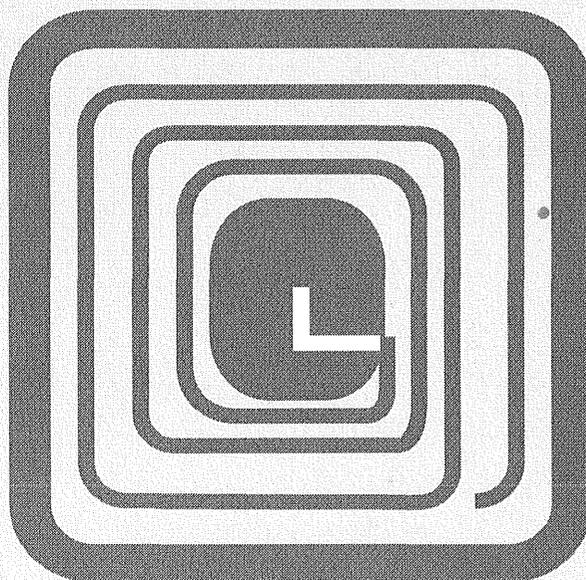
EPC

The Electronic Product Code™ (EPC) is an identification scheme for universally identifying physical objects via RFID tags and other means.⁵ EPC technology allows everyday objects to be uniquely identified and connected in a dynamic, automated supply chain that joins businesses and consumers together in a mutually beneficial relationship.

Bar Coding and RFID/EPC

Bar coding is a line-of-sight technology, meaning that each individual item has to be handled to scan the bar code with a reader. In addition to being labor intensive and time consuming, this method has potential for error in reading the same unit twice or missing a unit because it is done at the item level, not the serial number level. RFID tags enable automatic, non-line-of-sight identification, reducing the possibility of errors and the labor necessary to achieve the same results. Although the EPC numbering standard uniquely identifies products, its implementation will evolve over time with applications driven by market and consumer demand. Therefore, bar codes and RFID tags will coexist for some time to come.

⁵ EPC Tag Data Standards, Version 1.1 Rev. 1.24

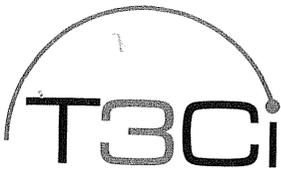


For more information, please contact:

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ATTACHMENT I



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Mountain View, CA 94043-5228
www.t3ci.com
Tel: 650.969.5200
Fax: 650.969.5207

RECEIVED BY CALIF.
BOARD OF PHARMACY

2004 JUL 28 AM 10:53

July 27, 2004

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

Dear Ms. Harris:

T3Ci is an applications software company located in Mountain View, California. Our enterprise software provides drug counterfeit and diversion detection as well as electronic drug pedigree for the pharmaceutical market. T3Ci's areas of expertise are RFID and enterprise applications.

During a recent pharmaceutical conference in Washington DC, we learned that California was considering a "pedigree law" modeled on the Florida pedigree law. Given our coming commercial solution and our leadership position in this area, we are requesting a meeting with the California Board of Pharmacy to present our technology solution to the counterfeit, diversion and electronic pedigree issues.

T3Ci was founded in October 2003. We currently have 12 employees in California and we hope to grow to become a \$100-250 Million company with 500+ California employees over the coming 5-7 years. Our first customer is Procter & Gamble seeking a solution to the so called Wal-Mart RFID mandate. We are currently in discussions with 14 of the 20 largest pharmaceutical manufacturers and the largest pharmaceutical distributors. Three of these major drug companies have agreed to pilot our system for detecting counterfeit drugs and diversion starting in September this year. We believe these will be the "first ever" pharmaceutical pilots of a counterfeit, diversion and electronic pedigree system.

Our goal with the meeting would be to inform the California Board of Pharmacy of the technology that will become available for counterfeit, diversion and electronic pedigree this fall. We have spoken to some 25 large pharmaceutical suppliers, distributors and pharmacies. They have all indicated a strong interest in RFID technology and associated systems. It is their view that the current "paper pedigree law" in Florida is expensive and cumbersome. We wish to demonstrate to you that our type of technology solution has significant advantages over a paper-based system.

We will make ourselves available at a time and date of your convenience between August 12 and September 10. Our presentation and a Q&A session would take between 60 and 90 minutes. We look forward to meeting you.

Sincerely,

A handwritten signature in black ink, appearing to read 'Peter Rieman'. The signature is fluid and cursive, with a long horizontal stroke extending to the right.

Peter Rieman
Executive Vice President
Direct: 1-650-969-5203, email: prieman@T3Ci.com

NEUSTAR[®] T3Ci

California State

Agenda

- T3Ci/Neustar Introduction
- Pharmaceutical Integrity Problem and Solution
 - Pharmacist PC view
- Historian Applications
 - Manufacturer anti-counterfeit monitor
- Clearinghouse Basics
- Status and Commercial Intent

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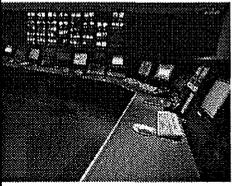
T3Ci- The Tag Track Company Inc.



- Founded in October 2003 by:
 - Dr. Jonathan Golovin
 - Dr. Shantha Mohan
 - Peter Rieman
 - Dr. Richard Swan
- Headquartered in Mountain View, CA
- EPC Global member since 2003
 - Strong participants in standards
- Approximately \$10 million in funding by Venrock Associates, SAP, Red Rock Ventures and Founders
- Provides:
 - RFID System of Record (Historian)
 - RFID applications suite
 - Clearinghouse with associated applications and services
 - Pharmacist (e-pedigree) EPC-IS
- Target Markets
 - Pharmaceuticals
 - Wal-Mart CPG

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NeuStar



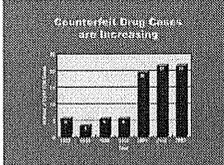
- Neutral, third-party infrastructure and clearinghouse operator to the communications industry
 - Exclusively charged with operating shared, mission-critical, infrastructure services vital to telecom and internet industries
 - Deemed neutral third party by U.S. Government (FCC)
 - Open, transparent, industry governance structure
 - Quarterly neutrality and infosec audits
- Established in 1996 as an independent business unit within Lockheed Martin
 - Spin-off in 1999 to preserve neutrality after Lockheed acquisition of Comsat
 - Funded by Warburg-Pincus, Deutsche Bank, and ABS Capital
- Headquartered in Sterling, VA; 5 locations worldwide; 350+ employees
- Profitable, cash flow positive, over \$150M/year revenues, and significant, consistent growth

1.8 Billion calls and 10's of millions of internet transactions each day... all rely on NeuStar

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Pharmaceutical Integrity Problem

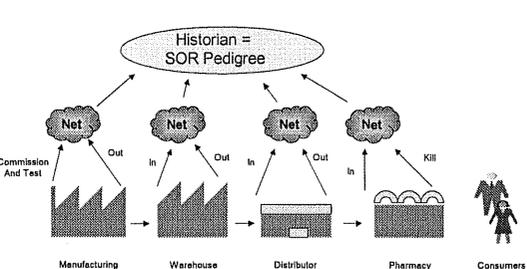
- Common Goals
 - Safe, secure drug supply chain
 - Product integrity
 - Compliance with state laws/ FDA recommendations
 - Minimize liability
- Goals for Participants
 - Doctors and Pharmacists
 - Quick, accurate verification, minimal costs
 - Commercial privacy
 - Wide adoption of single standard
 - Distributors
 - Quick, accurate verification, minimal costs
 - Commercial privacy
 - Wide adoption of single standard
 - Charge back verification
 - Manufacturers
 - Overall efficiency and low cost
 - System also detecting/managing gray market, recalls, theft, deductions, recirculation, expiration, inventory and claims



Source: Combating Counterfeit Drugs - FDA 2004

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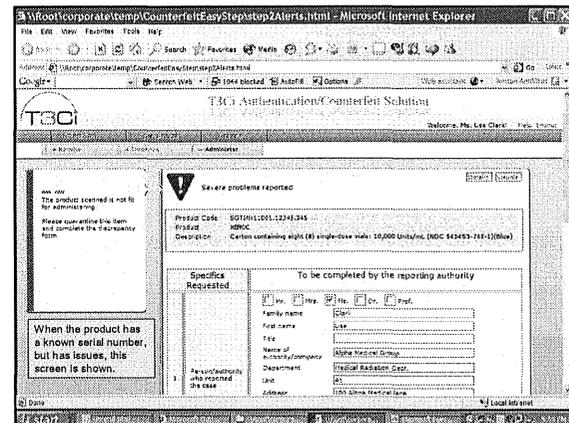
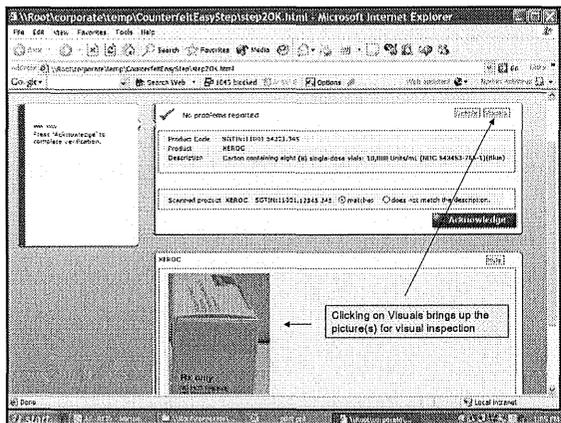
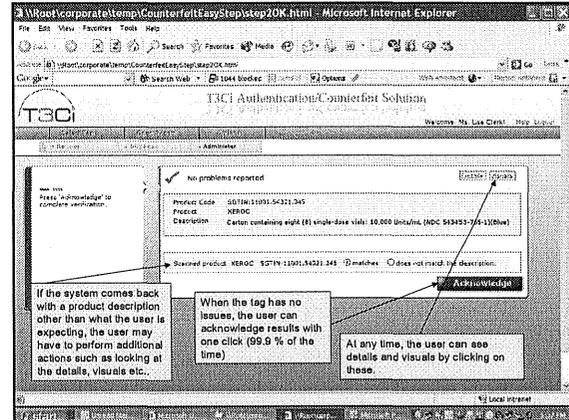
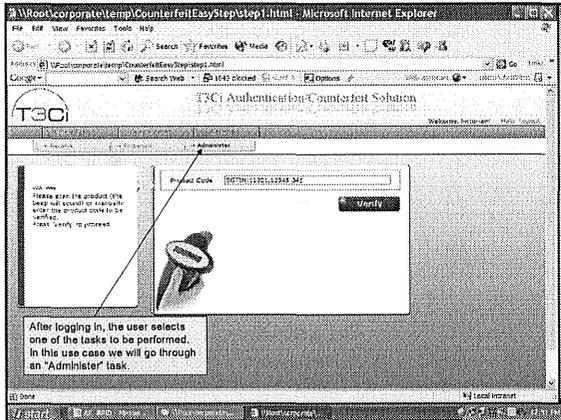
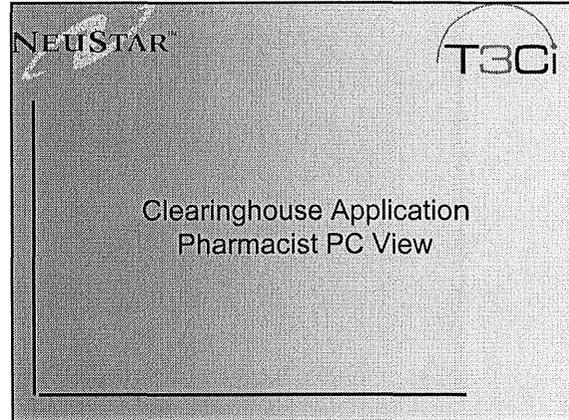
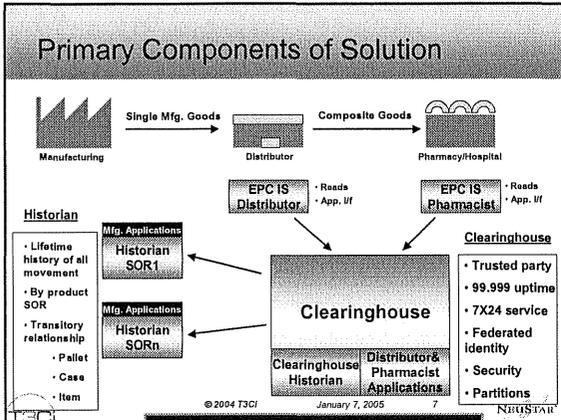
T3Ci Historian is the e-Pedigree SOR (System of Record)

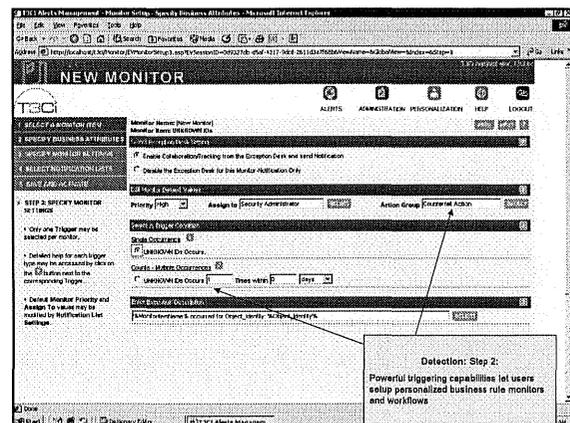
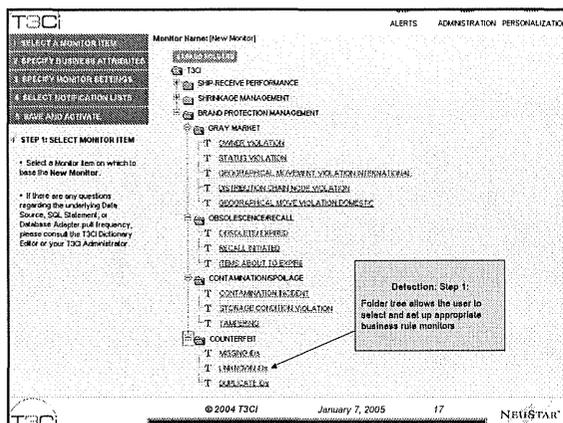
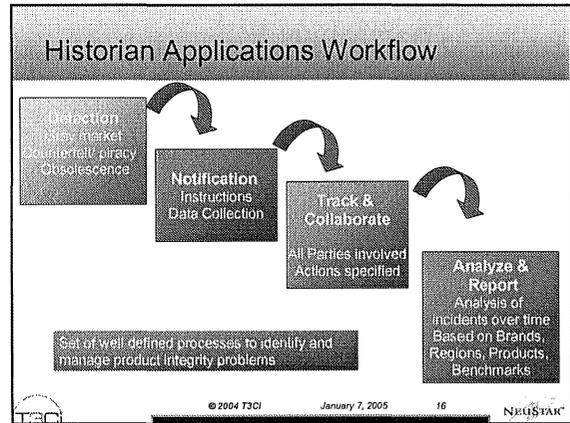
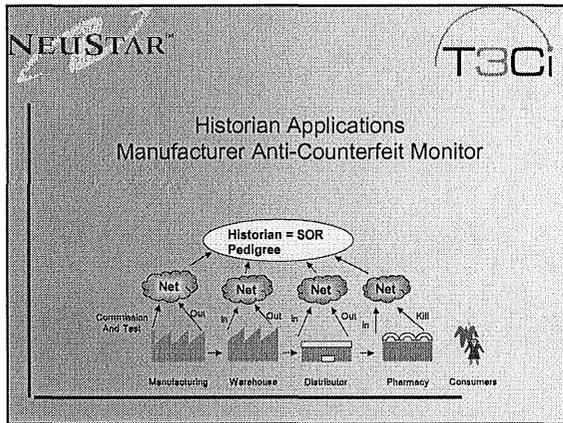
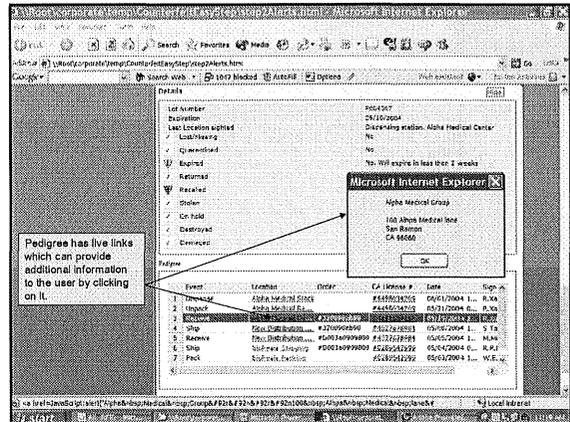
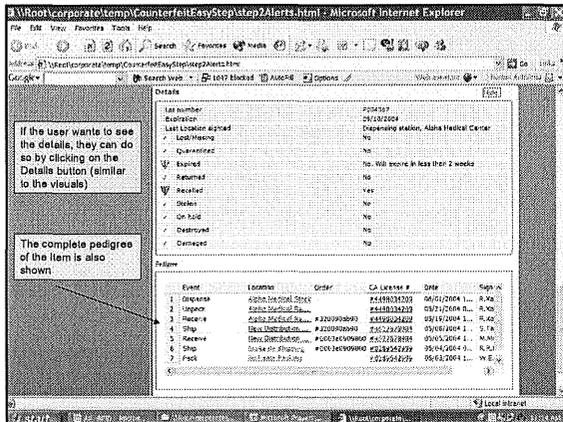


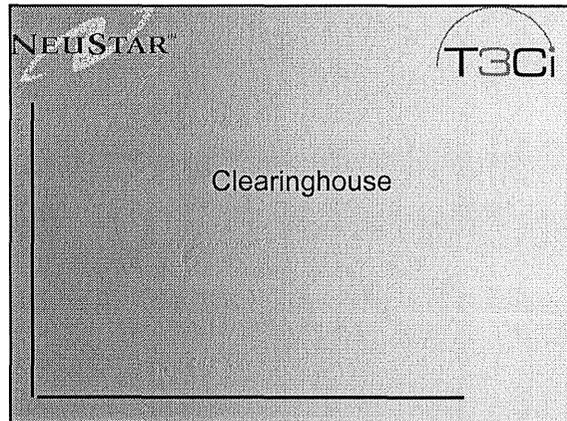
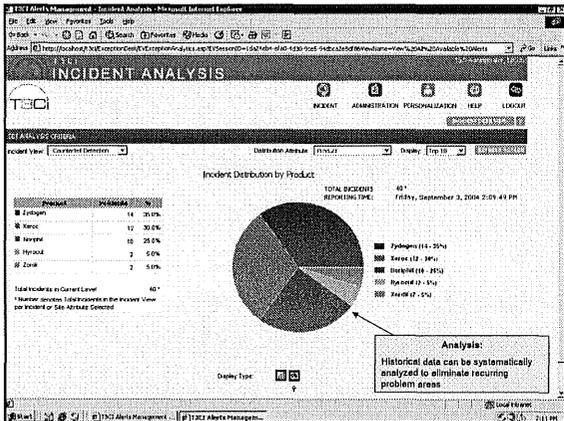
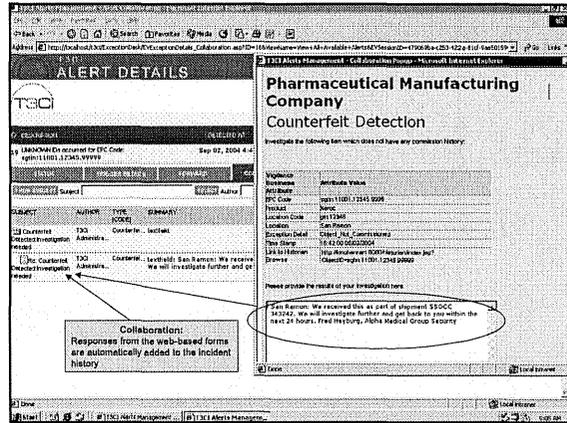
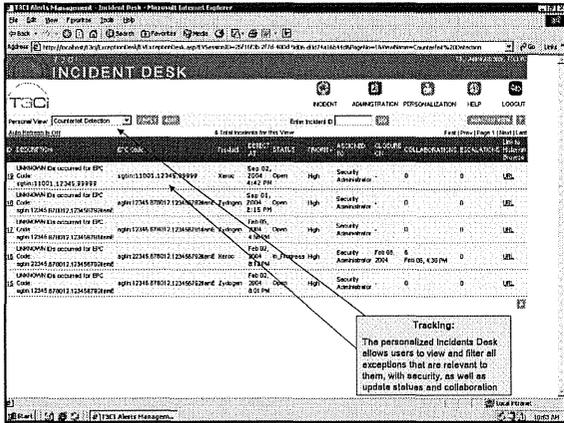
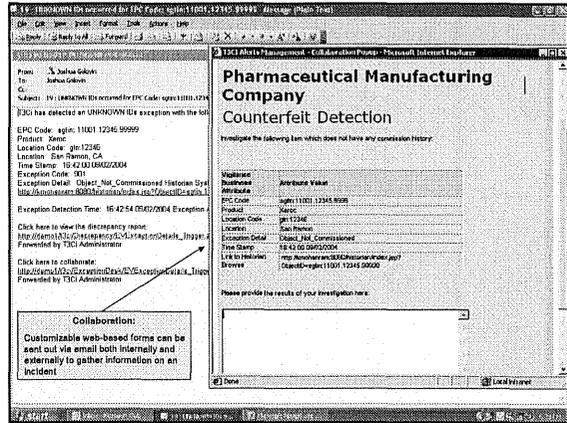
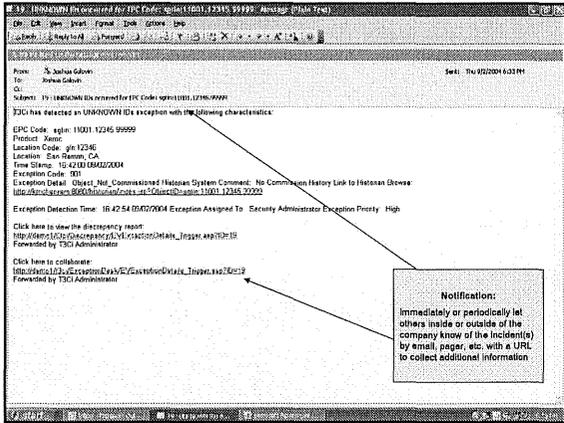
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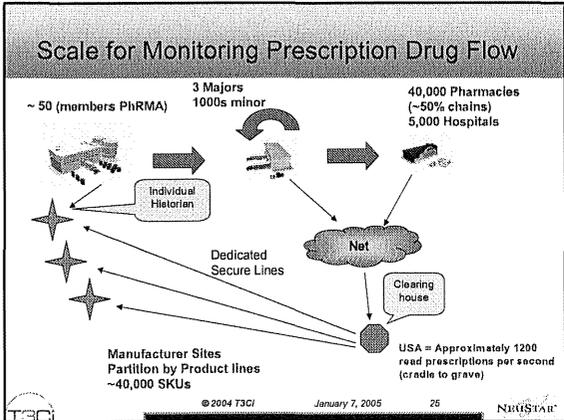
Manufacturing Warehouse Distributor Pharmacy Consumers

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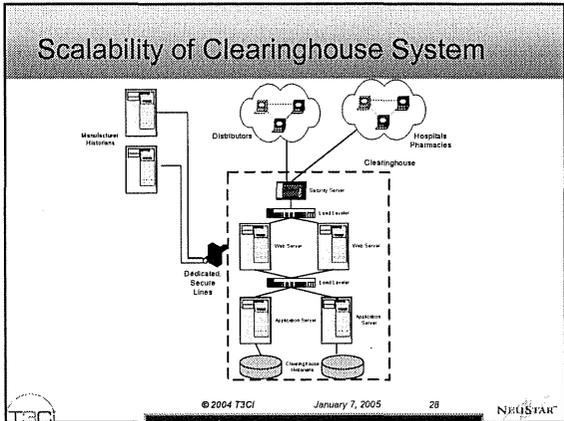
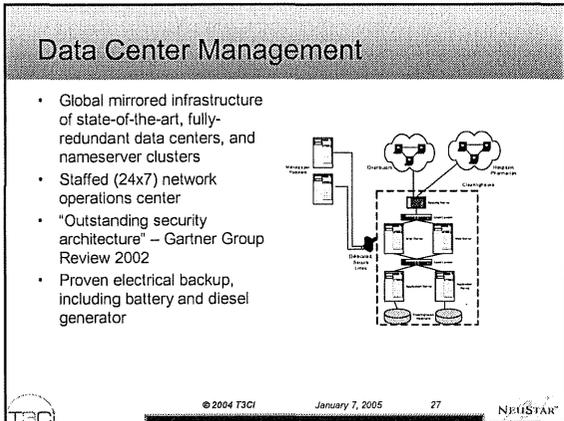








- ### Why A Clearinghouse?
- Turnkey service
 - All aspects of product integrity and compliance supported by outside party
 - Extreme Availability and Response Requirement
 - Industry cannot afford to count on 100s or 1000s of different systems to be available to generate pedigrees
 - Neutral
 - Unbiased provision of service to all participants
 - Not tied to a specific manufacturer, distributor or retailer
 - Commercial privacy
 - Support mixed shipments without revealing commercially sensitive information to competitive manufacturers
 - Contractually specified information handling rules
 - Allows for dedicated, secure lines to larger entities
 - Cost Effective
 - Development and deployment costs minimized
 - Lowest adoption costs for small distributors and pharmacies
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- ### NeuStar Credentials
- Unmatched scope and scale of Registry operations
 - Unique combination of telephony and Internet know-how
 - Established, scalable infrastructure and resources
 - Proven experience with 99.999% SLRs
 - Active contributor to Industry development and progress
 - Respected Industry technology and policy expertise
 - Demonstrated track record of making partnerships work
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- ### Status
- **System of Record (Historian)**
 - Alpha- June 2004
 - Beta- in progress
 - EPC Service currently provided to several Wal-Mart 100 suppliers with live EPC data
 - **Anti-Counterfeit Monitoring and Analysis Application**
 - First conference room pilot with major Pharma- November 2004
 - Application
 - **Clearinghouse**
 - Extensive infrastructure in place
 - MOU signed
 - Joint technical and commercial development started
 - **Pharmacy e-Pedigree EPC-IS**
 - Logipharma demo September 13th-15th
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ATTACHMENT J



December 14, 2004

Ms. Patricia Harris
California State Board of Pharmacy
400 R Street, Suite 4070
Sacramento, California 95814-6237

Re: Intracompany Transactions

Dear State Board Members and Ms. Harris:

By way of this letter, we would request that the California State Board of Pharmacy (the "Board") consider our request to allow for an exemption from the registration and licensure process for out-of-state distributors that solely provide intracompany transactions of dangerous drugs and dangerous devices into California. We believe that this exemption is warranted based upon the following.

First, we define "intracompany transactions" similar to the definition adopted in the current version of the NABP Model Rules (*see NABP Model Rules for Licensure of Wholesale Distributors, Definition section, page 5*):

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

Under the NABP Model Rules, the definition of "Wholesale Distribution" specifically excludes "intracompany transactions" (*see NABP Model Rules for Licensure of Wholesale Distributors, Definition section page 6*). In adopting the NABP approach to California, the result would be that a licensed facility located within California could receive a shipment of dangerous drugs or dangerous devices from an entity physically located outside of California (but not licensed with the California Board) provided that the out-of-state facility shipping those products is: (1) appropriately licensed in the state in which that facility is located; and, (2) the products shipped would go exclusively to those related entity(s) (e.g., which would be a division, subsidiary, parent and/or affiliated or related company under the common ownership and control of a corporate entity). However, if the out-of-state entity chose to ship product to an unrelated facility or entity, this would mandate that this out-of-state entity obtain an out-of-state

distributors license with the California Board since this type of distribution to an unrelated entity would fall outside of the definition of being an intracompany transaction.

We believe this approach in exempting out-of-state licensure for distributors that solely provide intracompany transactions into California is practical and retains the safeguards the Board is trying to achieve for the following reasons. First, this approach reduces the amount of bureaucracy and unneeded paperwork which would be required in licensing all out-of-state entities. This will alleviate the burden both to the government in trying to issue these licenses as well as the burden imposed upon those businesses trying to obtain these licenses in a timely and efficient manner. Second, the need to license such related out-of-state entities is unnecessary. From the Board's standpoint, jurisdiction exists over the transaction and affected parties at issue. The in-state entity which receives the shipment from the related out-of-state entity is licensed with the Board. The Board has the ability to bring an enforcement action against the in-state entity for any transgressions which may result from an inappropriate shipment into California by the related out-of-state entity. This includes any action that the State may decide to take against that in-state entity's corporate parent. Third, traceability of all transactions can be readily accounted for given the relationships of the entities involved. Specifically, unlike unrelated entities, there will be documentation and systems continuity between related entities allowing for the quick and efficient retrieval of any paperwork needed to validate transactions involving products. This specifically relates to the ability to trace the movement of such product from the drug or device manufacturer through the distribution chain and ultimately through to those products' sale into California.

Lastly, in the event the Board is still concerned with what entities are allowed to avail themselves of the intracompany transaction exemption, we would request that the Board perhaps consider an approach adopted in Nevada. In Nevada Board of Pharmacy's current draft regulations, that Board provided an additional requirement for an intracompany transaction (or transfer) to be valid. That additional requirement is that such transactions can only occur where the distributor is a publicly traded company. Specifically, Nevada provides the following language in its current draft regulations which are to be finalized by that Board (see Sec. 11. NAC 639.593):

3. The sale or distribution of a prescription drug by *intracompany* transfer will not be considered to be a wholesale transaction. As used in this subsection, "*intracompany* transfer" means any sale, distribution or other transaction involving a prescription drug in which:
 - (a) A wholesaler licensed by the Board *or the appropriate similar authority of another state* sells, distributes or otherwise provides a prescription drug to a wholesaler or pharmacy licensed by the Board;
 - (b) Both the transferring wholesaler and the transferee are wholly owned by a common owner; and
 - (c) The common owner is a publicly traded corporation.

This additional requirement would provide the Board with an additional level of validity where there might be a concern as to the legitimacy of entities or the ability to find these entities. In this case, the Board would not need to go any further than to the filings required by the U.S. Securities and Exchange Commission (SEC) to validate the legitimacy of this distribution entity and the facilities under its control. Also, these publicly available documents would provide the Board with access to more information than would be currently available from privately held companies. This again, should help: (1) to validate the legitimacy of these companies; (2) in the ability to investigate both the in-state and out-of-state related entities; and, (3) to allow for a more efficient and effective mechanism for such transactions to occur, thus alleviating the need for the more cumbersome, time consuming and costly issuance of licenses where such shipments are limited solely to intracompany transactions.

We appreciate your review of our request and thank the Board in advance for considering our suggestion. Please feel free to contact me at (614) 757-7721 if you have any additional questions.

Sincerely,



Robert P. Giacalone, R.Ph., J.D.*
Vice President, Regulatory Affairs
and Chief Regulatory Counsel

cc: Cassi Baker

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ATTACHMENT K

College of Pharmacy



**Western
University**
OF HEALTH SCIENCES

The discipline of learning. The art of caring.

*Presented by: Jesse F. Martinez, PharmD, FASCP
Executive Director of External Affairs and Development
Sam Shimomura, PharmD, FASHP, CGP
Associate Dean Professional and Student Affairs*

***An information item to the Board of Pharmacy,
Enforcement Committee, on a
Pharmacist-in-Charge C.E. program.***

December 15, 2004

Background

We are responding to a call from our WesternU Dean's Advisory Council and our Dean, Dr. Max Ray that WesternU provide leadership in offering a course of study in the skills required to become a pharmacist-in-charge as established by the California Board of Pharmacy.

There have been key changes made in our 12-week Advanced Elective course in our curriculum this year. Both the community pharmacy practitioner track and the community pharmacy management track with an emphasis in independent pharmacy ownership will include training in the requirements to serve as a pharmacist-in-charge.

In addition, we plan to develop a 15-hour "certificate" course designed to prepare a licensed pharmacist in the knowledge, skills and requirements to serve in a pharmacist-in-charge position. We plan to offer this "certificate" program to all interested licensed pharmacists in convenient sites in southern and northern parts of the state starting in the second quarter of 2005.

Resources

The vision for the pharmacist-in-charge "certificate" C.E. program is a format which includes an experiential component with workshop discussions and lectures presented by experts with "real world" experience. Our faculty will include attorneys, pharmacy managers, industrial security representatives, medical waste disposal experts and faculty from the WesternU College of Pharmacy. We are also asking for participation from the Board of Pharmacy. A member of the State Board of Pharmacy and/or State Board Inspector with expertise in the Community Pharmacy & Hospital Outpatient Pharmacy Self-Assessment form would make a valuable addition to the training program. The final format that includes the BOP representative is open at this time.

Course of Content

The core for the pharmacist-in-charge certificate program will be in the areas of compliance in the BOP's self assessment form. An advisory group will be convened to review the content of the Advanced Elective course and select relevant portions to include in the PIC "certificate" program. We want the content to be meaningful to PICs presently in this position and candidates considering this position.

Funding

WesternU will take full responsibility for funding the pharmacist-in-charge "certificate" program. We have already generated interest within the private sector for funding. There is a considerable interest from pharmacy chains and others that lack specific training programs for pharmacist-in-charge and are prepared to support such a program.

ATTACHMENT L

Changes in Pharmacy Law for 2005

The Assembly and Senate bills listed in this article were signed in 2004, and unless otherwise specified, take effect January 1, 2005. The new and amended statutes are paraphrased or summarized below, but you are urged to review the exact language of the statutes at the Board's Web site www.pharmacy.ca.gov.

SB 1307 (Figuroa) Chapter 857, Statutes of 2004

Electronic Pedigree for Dangerous Drugs (New)

B&PC 4034—requires an electronic “pedigree” by January 1, 2007. Said pedigree will 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 application of the pedigree requirement in pharmacies will be subject to review during the Board's sunset review in 2008.

Embargoed Dangerous Drugs or Devices (New)

B&PC 4084 and 4085—allows Board inspectors to embargo dangerous drugs or devices that are suspected of being adulterated or counterfeit by affixing a tag or other marking to the drug. If a Board inspector determines that an embargoed dangerous drug or device is not adulterated or counterfeit, the inspector may remove the tag or marking. It is unlawful for any person to remove, sell, or dispose of an embargoed dangerous drug or device without the Board's permission.

Furnishing Dangerous Drugs to Specified Entities and Violation Penalty (New)

B&PC 4126.5—permits pharmacies to furnish dangerous drugs only to:

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

Violation of this section by either a pharmacy whose primary or sole business is filling prescriptions for patients of long-term care facilities or a person engaged in a prohibited transaction with such a pharmacy may result in a fine of \$5,000 per violation.

Surety Bond for Wholesalers (New)

B&PC 4162—requires applicants for the issuance or renewal of a wholesaler license to submit a surety bond of \$100,000 or other equivalent means of security to the Board. The purpose of the bond is to secure payment of any administrative fine imposed by the Board and any cost recovery ordered. If the applicant's annual gross income for the previous tax year is less than \$10,000,000, a surety bond for \$25,000 will be accepted. Additionally, a surety bond of \$100,000 may be required for any licensee who has been disciplined by any state or federal agency or has been issued an administrative fine pursuant to the Pharmacy Law. This section becomes effective January 1, 2006.

Pedigree Required (New)

B&PC 4163—presently allow manufacturers and wholesalers to acquire or furnish dangerous drugs or devices only from or to those authorized by law to possess or furnish those dangerous drugs or devices. This section is in effect until January 1, 2007, when it will be repealed unless a later enacted statute is enacted before that date. If this section is repealed, the new section will prohibit a wholesaler or pharmacy from selling, trading, or transferring a dangerous drug at wholesale without a pedigree. Additionally, a wholesaler or pharmacy may not acquire a dangerous drug without receiving a pedigree. This section becomes operative on January 1, 2007.

Extension May be Allowed for Implementing Pedigree Requirement for Wholesalers (New)

B&PC 4163.5—authorizes the Board to extend the time allowed for implementing electronic technologies to track the distribution of dangerous drugs within the state if the Board determines that manufacturers or wholesalers cannot meet the requirement by January 1, 2007. The pedigree requirement compliance date may then be extended until January 1, 2008.

Extension May be Allowed for Implementing Pedigree Requirement for Pharmacies (New)

B&PC 4163.6—authorizes the Legislature to extend the time allowed for pharmacies to implement electronic tracking the distribution of dangerous drugs within the state if the Legislature determines that it is not economically and technically feasible for pharmacies to comply with the requirement by January 1, 2007. The date for compliance with the requirement may be extended to January 1, 2009.

Wholesaler Tracking System of Individual Sales of Dangerous Drugs (Amended)

B&PC 4164—effective January 1, 2006, will require licensed wholesalers that distribute controlled substances, dangerous drugs or devices within or into California to report all sales of those products that are subject to abuse. Wholesalers will be required to develop and maintain a system for tracking individual sales of dangerous drugs at preferential or contract prices to pharmacies that primarily or solely dispense prescription drugs to patients of long-term care facilities.

No Business License for any Wholesaler Not Licensed by the Board (New)

B&PC 4168—prohibits a county or municipality from issuing a business license to a wholesaler who does not have a current wholesaler license issued by the Board.

Wholesaler Sales Requirements (New)

B&PC 4169—prohibits the following:

- The purchase, trade, sale, or transfer of dangerous drugs or devices at wholesale to a person or entity that is not licensed with the Board as a wholesaler or pharmacy;
- The purchase, trade, sale, or transfer of dangerous drugs that the person knew or should have known were adulterated or misbranded;
- The purchase, trade, sale, or transfer of dangerous drugs or devices after the beyond use date on the label; and
- The failure to maintain records of the acquisition or disposition of dangerous drugs or devices for at least three years.

Violation of this section may result in a fine for each violation.

Excessive Furnishing of Dangerous Drugs by a Wholesaler to a Pharmacy (Amended)

B&PC 4301—defines acts of unprofessional conduct and authorizes the Board to take action against a wholesaler who clearly excessively furnishes dangerous drugs to a pharmacy that primarily or solely dispenses prescription drugs to patients of long-term facilities.

Fee Bases Increased (Amended)

B&PC 4400—authorizes an increase in the fee bases for initial and renewal license applications and penalties.

AB 2184 (Plescia)

Chapter 342, Statutes of 2004

Automated Drug Systems in Skilled Nursing and/or Intermediate Care Facilities (New)

B&PC 4119.1—allows a pharmacy to provide pharmacy services to a skilled nursing facility or an intermediate care facility through the use of an automated drug delivery system that need not be located at the same location as the pharmacy. Operation of the drug delivery system must be under supervision of a pharmacist who need not be physically present and is allowed to supervise the system electronically.

AB 2660 (Leno)

Chapter 191, Statutes of 2004

Prescription Labeling Requirements (Amended)

B&PC 4040, 4052, 4060, 4076, 4111 and H&SC 11150—permits pharmacists to sign orders for controlled substances when initiating or adjusting drug regimens under

protocol; requires pharmacists to register with the DEA if they are authorized to initiate or adjust drug therapy under protocol for controlled substances; permits the possession of a controlled substance dispensed pursuant to a drug order signed by a pharmacist; requires a prescription label to include the name of the practitioner, including a pharmacist, who ordered the drug; permits pharmacists to order controlled substances pursuant to a protocol; no longer requires the name of the supervising physician (of certified nurse midwives, nurse practitioners, physician assistants) to be on prescription labels.

AB 2682 (Negrete McLeod)
Chapter 887, Statutes of 2004

Out-of-State Distributor to Become Nonresident Wholesaler and Exemptee-in-Charge to Become Designated Representative-in-Charge (New)

B&PC 4161—requires any person located outside California that ships, mails, or delivers dangerous drugs or devices into this state at wholesale to be considered an “**out-of-state distributor**” and be licensed by the Board. (However, those who ship, mail or deliver dangerous drugs or devices only to wholesalers in this state are exempt from the license requirement.) An out-of-state distributor’s license may not be issued or renewed until the out-of-state distributor identifies and notifies the Board of the designation of an exemptee-in-charge. The exemptee-in-charge will be responsible for the company’s compliance with all laws governing wholesalers. The nonresident wholesaler must identify and notify the Board of a new exemptee-in-charge within 30 days of the date that the prior exemptee-in-charge ceases to be the exemptee-in-charge. This section is in effect until January 1, 2006.

After that date, an out-of-state distributor will be known as a “**nonresident wholesaler**,” requiring a license issued by the Board. A separate license will be required for each place of business owned or operated by a nonresident wholesaler. Such license will be renewed annually and non-transferable. At the time of initial application for licensure or renewal of a nonresident wholesaler license, the applicant must submit in writing to the Board the following information within 30 days of a change in that information:

- Its agent for service of process in this state;
- Its principal corporate officers, if any, as specified by the Board;
- Its general partners, if any, as specified by the Board; and
- Its owners if the applicant is not a corporation or partnership.

A report containing the above information must be made within 30 days of any change of ownership, office, corporate officer, or partner. A nonresident wholesaler must comply with all directions or requests for information from the Board, or regulatory or licensing agency of the state in which it is licensed. Nonresident wholesalers must maintain records, in a readily retrievable form, of dangerous drugs and devices sold, traded, or transferred to persons in this state and must at all times maintain a valid, unexpired license, permit or registration in the applicant’s state of residence.

The Board will not issue or renew a nonresident wholesaler license until the applicant identifies a “**designated representative-in-charge**” (previously exemptee-in-charge) and

notifies the Board in writing of that person's identity and license number. Additionally, the Board must be notified within 30 days of a change in the designated representative-in-charge. The designated representative-in-charge will be responsible for the company's compliance with all laws governing wholesalers. The Board may issue a temporary license under certain conditions and for periods of time that the Board determines to be in the public interest.

Surety Bond for Nonresident Wholesaler License (New)

B&PC 4162.5—requires an applicant for the issuance or renewal of a nonresident wholesaler license to submit a surety bond of \$100,000 for each site to be licensed, or other equivalent means of security acceptable to the Board, such as an irrevocable letter of credit, or a deposit in a trust account or financial institution, payable to the Pharmacy Board Contingent Fund. The Board may accept a surety bond of \$25,000 if the nonresident wholesaler's annual gross receipts of the previous tax year is ten million dollars or less, but the surety amount would revert to \$100,000 if the nonresident wholesaler has been disciplined by any state or federal agency or has been issued an administrative fine pursuant to this section. The Board may make a claim against the bond if the licensee fails to pay a fine with 30 days of the issuance of the fine or when the costs become final. A single surety bond or other equivalent means of security acceptable to the Board will satisfy the bond requirement for all licensed sites under common control as defined in Section 4126.5. This section becomes effective January 1, 2006, and extends to January 1, 2011, unless an enacted statute repeals or extends those dates.

SB 1159 (Vasconcellos)
Chapter 608, Statutes of 2004

Furnishing Hypodermic Needles and Syringes Without Prescription (Amended)

B&PC 4145, 4147 and H&SC 11364—authorizes a pharmacist or physician to furnish hypodermic needles and syringes for human use without a prescription if one of the following is met: (1) the person is known to the furnisher and the furnisher has previously been provided a prescription or other proof of a legitimate medical need requiring a hypodermic needle or syringe to administer a medicine or treatment or (2) pursuant to authorization by a county, or a city, until December 31, 2010, a pharmacist may sell or furnish 10 or fewer hypodermic needles or syringes to a person for human use without a prescription if the pharmacy is registered with a local health department in the Disease Prevention Demonstration Project, which would be created to evaluate the long-term desirability of allowing licensed pharmacies to sell or furnish nonprescription hypodermic needles or syringes to prevent the spread of blood-borne pathogens, including HIV and hepatitis C.

SB 1913 (Business and Professions Committee)
Chapter 695, Statutes of 2004
Omnibus Measure

Delivery of Dangerous Drugs or Devices (New)

B&PC 4059.5—requires dangerous drugs or devices delivered to a pharmacy to be signed for by and delivered to a pharmacist but also authorizes a pharmacy to take delivery of dangerous drugs or devices when the pharmacy is closed and no pharmacist is on duty if:

- The drugs are placed in a secure storage facility in the same building as the pharmacy;
- Only the pharmacist-in-charge or a pharmacist designated by the pharmacist-in-charge has access to the secure storage facility after dangerous drugs or devices have been delivered;
- The secure storage facility has a means of indicating whether it has been entered after dangerous drugs or devices have been delivered;
- The pharmacy maintains written policies and procedures for the delivery of dangerous drugs or devices to a secure storage facility;
- The agent delivering dangerous drugs or devices leaves documents indicating the name and amount of each dangerous drug or device delivered in the secure storage facility.

The pharmacy shall be responsible for the dangerous drugs and devices delivered to the secure storage facility and for obtaining and maintaining records relating to the delivery.

Prescriber Dispensing Dangerous Drug to Emergency Room Patient (New)

B&PC 4068—permits a prescriber to dispense a dangerous drug, including a controlled substance, to an emergency room patient if **all** of the following apply:

- The hospital pharmacy is closed and there is no pharmacist available in the hospital;
- The dangerous drug is acquired by the hospital pharmacy;
- The dispensing information is recorded and provided to the pharmacy when the pharmacy reopens;
- The hospital pharmacy retains the dispensing information and, if the drug is Schedule II or III controlled substance, reports the dispensing information to the Department of Justice pursuant to H&SC 11165;
- The prescriber determines that it is in the best interest of the patient that a particular drug regimen be immediately commenced or continued, and
- The prescriber reasonably believes that a pharmacy located outside the hospital is not available and accessible at the time of dispensing to the patient.

Records of Manufacture, Sale, Acquisition and Disposition of Dangerous Drugs or Devices (New)

B&PC 4081—requires all records of manufacture, sale, acquisition, or disposition of dangerous drugs or devices to be open to inspection during business hours and retained for at least three years from the making. A current inventory must be kept by every manufacturer, wholesaler, pharmacy, veterinarian, laboratory, clinic, hospital, or institution who maintains a stock of dangerous drugs or devices. The name “exemptee-in-charge” will be changed to “designated representative-in-charge” on January 1, 2006. After that date, the owner, officer, and partner of a pharmacy, wholesaler, or veterinary food-animal drug retailer shall be jointly responsible with the pharmacist-in-charge or representative-in-charge for maintaining the records and inventory. The pharmacist-in-

charge or representative-in-charge shall not be criminally responsible for acts of the owner, officer, partner, or employee that violate this section and of which the pharmacist-in-charge or representative-in-charge had no knowledge, or in which he or she did not knowingly participate.

Site Licenses (New)

B&PC 4107—prohibits the Board from issuing more than one site license to a single premise except to issue a veterinary food-animal drug retailer license to a wholesaler or to issue a license to compound sterile injectable drugs to a pharmacy.

Environment for Compounding Sterile Injectable Products (New)

B&PC 4127.7—As of July 1, 2005, requires a pharmacy to compound sterile injectable products in one of the following environments:

- An ISO class 5 laminar airflow hood within an ISO class 7 cleanroom with a positive air pressure differential relative to adjacent areas;
- An ISO class 5 cleanroom;
- A barrier isolator that provides an ISO class 5 environment for compounding.

Veterinary Teaching Hospital (New)

B&PC 4170.5—permits veterinarians in a veterinary teaching hospital operated by an accredited veterinary medical school to dispense and administer dangerous drugs and devices and controlled substances from a common stock.

Foreign Graduates (Amended)

B&PC 4200—adds certification by the Foreign Pharmacy Graduate Examination Committee to requirements for pharmacist licensure.

Pharmacist/Intern Ratio and Intern Hours Requirement Changed (New)

B&PC 4208 and 4209— defines “intern,” details requirements for registration and qualifying for pharmacist licensure examinations. Intern affidavits (hours and experience) must be certified under penalty of perjury by a pharmacist under whose supervision such experience was obtained or by the pharmacist-in-charge at the pharmacy while the pharmacist intern obtained the experience. Interns must have at least 1,500 hours of intern experience before applying to take the pharmacist licensure examination. Section 4114 authorizes pharmacists to **supervise two intern pharmacists at one time.**

Compounding by Pharmacy Technicians (Amended)

H&SC 11207—clarifies language that permits a pharmacy technician to compound, prepare, fill or dispense a prescription for a controlled substance when assisting a pharmacist.

ATTACHMENT M



ENFORCEMENT COMMITTEE MEETING

Meeting Summary December 15, 2004

Department of Consumer Affairs
400 R Street, 1st Floor Hearing Room, Suite 1030
Sacramento, CA 95814

Present: William Powers, Chair
Stan Goldenberg, R.Ph., Board President and Member
David Fong, Pharm.D.

Staff: Patricia Harris, Executive Officer
Virginia Herold, Assistant Executive Officer
Robert Ratcliff, Supervising Inspector
Judi Nurse, Supervising Inspector
Dennis Ming, Supervising Inspector
Joan Coyne, Supervising Inspector
Board of Pharmacy Inspectors
Joshua Room, Deputy Attorney General

Call to Order

Enforcement Committee Chair William Powers called the meeting to order at 9:30 a.m.

Importation of Prescription Drugs

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

The committee was provided a copy of SB 19 that was introduced by Senator Ortiz on December 6, 2004. The purpose of the bill is to establish the California Rx Program, to be administered by the Department of Health Services. The bill would authorize the department to negotiate drug rebate agreements with drug manufacturers to provide for program drug discounts. The bill would authorize any licensed pharmacy or drug manufacturer to provide services under this program. The bill also establishes eligibility criteria and application procedures for California residents to participate in the program.

The bill would also require the Department of Consumer Affairs to implement, as part of the California Rx Program, a Prescription Drug Resource Center Web site to educate California consumers about options for lowering their prescription drug costs. The Web site shall include information about public and private drug coverage and drug discount programs that are available to California seniors and other consumers and tips for cutting costs on medications, including guidance concerning generic drugs.

In addition, the Web site shall include information about ordering prescription drugs from Canada and other countries. The Web site is to include a list of pharmacies that the Board of Pharmacy has determined meet pharmacy management practices required of pharmacies licensed to operate in California and the United States and a list of medications that can be ordered through the Web site from licensed pharmacies in Canada and other countries.

The department may either provide a direct link for consumers to pharmacies in Canada and other countries or provide a link for consumers to other Web sites if the Board of Pharmacy determines that the pharmacies listed in those other Web sites meet pharmacy management requirements that apply to California licensed pharmacies.

Also the committee was provided with a press release issued by the federal FDA regarding action it took against a company for the importation of prescription drugs into the U.S.

Request from Safeway Inc. for Waiver of California Code of Regulations section 1717(e) to Install and Use an Automated Dispensing Device

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 Asteres ScriptCenter, at various Long Drug Stores in California.

The board granted to Longs Drug Stores a waiver of the prohibition(s) stated by that section 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).

The Board of Pharmacy received a second request for waiver of California Code of Regulations section 1717(e) to install and utilize a self-service dispensing unit. This waiver request is from

Safeway Inc. to use the dispensing units at its various Safeway and /or Vons Pharmacies in California. Ron Bingaman, R.Ph., Corporate Pharmacy Director for Safeway Inc. presented the request for the waiver. He reported that since the October board meeting, Longs has placed a unit in one of its pharmacies. From November 30 to December 14th, Mr. Bingaman stated that 281 patients had signed up to use the system, 33 patients had used the system. Over all 52 prescriptions were dispensed and 10% of the 52 (or 5 prescriptions) were picked-up after hours.

The Enforcement Committee advanced to the Board of Pharmacy the request from Safeway Inc. for waiver of 1717(e) to use a self-service dispensing unit; however, the committee did not make a recommendation regarding the request. Prior to the discussing the request from Safeway, board member David Fong recused himself.

Proposed Regulation Change to Delete California Code of Regulations section 1717(e) and to Add Section 1713 – To authorize the Use of Drop Boxes for Prescriptions and to Authorize the Use of an Automated Dispensing Device for Refill Prescriptions Medications

At its October meeting, the Board of Pharmacy approved two waivers of section 1717(e). The first waiver allowed Longs Drug Stores to use a secure drop box for receiving prescription orders from patients. The second waiver authorized the use of a self-serve, automated dispensing device for patients to pick-up their refilled prescriptions.

Based on this action, the board then approved a proposed regulation change to allow these practices without a waiver. The proposal relocates existing provision 1717(e) into a new section 1713 and provides the authorization for both the drop boxes and self-service automated dispensing device. The proposed language authorizes a patient to deposit a prescription in a secure container that is at the same address or adjoining the licensed premises and the pharmacy is responsible for the security and confidentiality of the prescriptions deposited in the container. The proposed regulation also allows a patient to access his/her filled prescriptions from an automated dispensing device under the following 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).

While the board approved the regulation change, it has not been noticed for a regulation hearing. President Goldenberg directed that the proposal be placed on the December Enforcement Committee agenda for additional review and discussion.

President and Committee member Goldenberg encouraged Asteres to work with a neutral third party to formally study the use of the automated dispensing unit and its impact on patients. It was believed that such a study would better support the proposed regulation and to address the concerns that have been expressed that such a dispensing device removes the pharmacist from the refill process and patient access.

Request from Advanced Pharmacy Solutions for Waiver of California Code of Regulations, title 16, section 1717(e) to Allow for the Delivery of Prescription Medications to a Licensed Home Health Agency

Advanced Pharmacy Solutions requested a waiver of section 1717(e) so that they may deliver Synagis to a licensed home health agency for administration at a patient's residence. It was suggested that the board's counsel review the basic interpretation of 1717(e) in that the regulation does allow for the delivery to a licensed home health agency.

Concern was expressed that about the storage of this prescription medication at the home health agency prior to delivery to a patient specifically in some situations where the delivery may be throughout California. It was also asked as to what happens to the medication if it is not administered to the patient.

The Enforcement Committee recommended that the Board of Pharmacy support this waiver request and suggested that Dr. Roache attend the January board meeting to answer any questions that the board may have.

Proposed Amendment to Business and Professions Codes section 4104 – Mandatory Reporting to the Board of Pharmacy of Impaired Licensed Individuals

Supervising Inspector Joan Coyne presented a request to amend B & P Code section 4104 that would mandate all pharmacies to report a licensed individual to the board if the licensed individual is known to have engaged in the theft or diversion or self-use of prescription drugs belonging to the pharmacy. Current statute only requires that a pharmacy have in place procedures to protect the public when a licensed individual is known to be chemically, mentally or physically impaired to the extent it affects his or ability to practice pharmacy. The law does authorize the board to adopt regulation that would establish requirements for reporting to the board the conduct or incidents described in the law. Currently there is no regulation in place that requires a pharmacy to report impaired licensees to the board.

Supervising Inspector Coyne reported that as supervisor of the Pharmacist Recovery Program (PRP)/Probation team, she oversees the investigations on licensees that self-use of drugs and alcohol. Her team monitors probationers and recovery program participants. She reviewed recent cases involving impaired pharmacists.

She stated that her review indicated that a substantial number of incidents of theft and self-use of drugs, improper use of alcohol and obvious mental impairment by practicing pharmacists were never reported to the board. In many instances the discovery was made while the pharmacist was at work filling and dispensing prescriptions for patients. It was only after additional

incidents with subsequent employers or an arrest was the impaired pharmacist or technician brought to the attention of the board.

Dr. Coyne explained that her research revealed that too many times, the pharmacy merely requested the resignation of the individual or terminated him/her from employment. And in some cases, the pharmacy would seek restitution for the stolen drugs in cash or a signed promissory note, followed by termination that allowed the pharmacist or technician to practice elsewhere. Usually the board didn't become aware of an impaired licensee until a serious prescription error was made or, a patient, co-worker or conscientious employer at a new work location reported the impaired licensee. It was also discovered through subsequent board investigations that individuals had lost prior jobs because of chemical, mental or physical impairment affected their practice. She added that her review showed 22 cases where subsequent investigations would probably not have materialized had a prior employing pharmacy been required to report an employee whose practice was affected.

She concluded her presentation by stating that an impaired pharmacist or technician is a threat to the health and safety of the public. Early discovery of an impaired individual will not only protect the public but will also allow intervention and hopefully rehabilitation of that individual.

She recommended Section 4101 be amended to read:

4104. (a) Pharmacies shall report to the board the identity of ~~have in place procedures for taking action to protect the public when~~ a licensed individual employed by or with the pharmacy if the licensed individual is known to be chemically, mentally, or physically impaired to the extent it affects his or her ability to practice the profession or occupation authorized by his or her license.
(b) Pharmacies shall report to the board the identity of ~~have in place procedures for taking action to protect the public when~~ a licensed individual employed by or with the pharmacy if the licensed individual is known to have engaged in the theft or diversion or self-use of prescription drugs belonging to the pharmacy within 30 days of admission or termination of employment.
~~(c) The board may, by regulation, establish requirements for reporting to the board conduct or incidents described in subdivision (a) or (b).~~

There was discussion as to clarify the requirement that a pharmacy must report the identity of an individual if the licensed individual "is known to have engaged" in the theft or diversion or self-use of prescription drugs belonging to the pharmacy. Dr Coyne replied that often times it is the pharmacy that has terminated the licensed individual because there is evidence to support that the licensed individual had engaged in the illegal conduct or the licensed individual has admitted to the acts. As a means to increase the likelihood of reporting by pharmacies of pharmacists suffering from drug or alcohol impairment (or mental or physical illness), or pharmacists engaging in theft/diversion of controlled substances, DAG Room suggested that the board may wish to consider amending Business and Professions Code section 4104 to confer immunity from civil liability arising from such reporting to the board.

The Enforcement Committee recommended that the Board of Pharmacy support the proposed amendments to Business and Professions Code section 4104 incorporating the clarifying changes that were discussed.

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

Over the last year, the Board of Pharmacy has been implementing the changes to the prescribing and dispensing requirements for Schedule II controlled substances. The board has been working very hard educating pharmacists and prescribers on the new requirements and has been coordinating efforts with the Bureau of Narcotics Enforcement (BNE), the Medical Board of California, other prescribing boards and the professional associations. Since January 2004 (and before), the board has provided over 30 presentations on SB 151 that have included telephone conference calls that have involved large number of individuals.

Starting 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, the board has prepared a series of articles that will appear in the January newsletter and on the board’s Web site.

Meanwhile, the Department of Justice (DOJ) is proposing some amendments and additional provisions to make technical changes to effectuate the administration of the CURES program.

The proposed amendments are as follows:

- DOJ would be the originating agency for fingerprint processing (instead of the Board of Pharmacy).

- DOJ would collect a fee for processing criminal background checks.
- The applicant class that must submit criminal background checks would be clarified.
- The Board of Pharmacy and DOJ would be authorized to make any examination of the books and records of any applicant or visit and inspect the business.
- The Superior Court would be authorized to order a prescriber not to order or obtain or use any additional prescription forms during a pending criminal action based on the request of the law enforcement agency bringing the criminal action.
- The approved security printers would be required to print security prescriptions forms with a vendor identification code issued by DOJ.
- The security prescription form would be required to have a check box by the name of each prescriber to be checked to identify the prescriber issuing the prescription when there are multiple prescribers on one security prescription form.

DOJ is requesting that the Board of Pharmacy support these proposed changes. Staff is recommending that the board support them and in addition is proposing additional amendments. It is staff's recommendation that the Board of Pharmacy no longer approve security printers. The board absorbed this workload initially to assist with the transition from the triplicate prescription form to the new tamper-resistant forms printed by "approved" printers. It is no longer necessary that both the Board of Pharmacy and DOJ approve the printer. It should be the sole responsibility of DOJ.

It was noted that the legislation introduced this year would probably address many more clean-up issues with SB 151.

The Enforcement Committee recommended that the Board of Pharmacy support the proposed amendments as proposed by the Department of Justice and the proposed amendment by staff that the Board of Pharmacy no longer approve security printers. The approval process would be the sole responsibility of the Department of Justice.

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 becomes effective January 1, 2005. The bill made various changes to the wholesaler requirements and distribution of dangerous drugs.

The Enforcement Committee will be monitoring the implementation of this legislation. One area of close oversight will be 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 be the method used to track a drug's pedigree. The manufacturer would tag the drug with a small chip and antenna. When the tag is in close proximity of a reader, it would receive a low-powered radio signal and interact with a reader exchanging identification data and other information. Once the reader receives data, it would be sent to a computer for processing.

McKesson reported that 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.

T3Ci, is an application software company that provides drug counterfeit, diversion detection and electronic drug pedigree for the pharmaceutical market. They demonstrated their technology solution for the electronic pedigree. 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.

Cardinal Health requested that the Board of Pharmacy consider an exemption from the registration and licensure process for out-of-state distributors that solely provide intra-company transactions of dangerous drugs and dangerous devices into California. It is their position that such an exemption is warranted because it is practical while retaining the safeguards that the board is trying to achieve. It is their position that this approach is practical because it reduces the unneeded paperwork, which would be required in licensing all out-of-state entities. It is also their position that it is not necessary to license such related out-of-state wholesalers.

They argue that the Board of Pharmacy has jurisdiction over the transaction and affected parties at issue. The in-state wholesaler, which receives the shipment from the related out-of-state wholesaler, is licensed with the board. The board has the ability to bring an enforcement action against the in-state wholesaler for any transgressions, which may result from an inappropriate shipment into California by the related out-of-state wholesaler. This would include any action that the board may take against the in-state entity's corporate parent. Third, all transactions would be traceable and readily accounted for given the relationships of the entities involved.

It was presented that these intra-company transactions for which Cardinal was requesting an exemption would only take place when there was a temporary shortage of a drug and the in-state licensed wholesaler was unable to fill the order. Staff counsel commented that the Board of Pharmacy doesn't have the authority to provide an exemption to the licensure requirement. Such an exemption would require a statutory change. Cardinal stated that it was their position that under the proposed change that takes effective January 1, 2005, an inter-company transfer would not constitute a transaction at wholesale. Counsel advised Cardinal submit their request and legal analysis in writing for board review and consideration.

Pharmacist-in-Charge Certification Program at the College of Pharmacy, Western University of Health Sciences

Jesse Martinez, Executive Director of External Affairs and Development and Sam Shimomura, Associate Dean Professional and Student Affairs at the College of Pharmacy, Western University of Health Sciences presented an overview of a course of study in the skills required to become a pharmacist-in-charge (PIC) in California. It will be a 12-week advanced elective course in their curriculum this year. Both the community pharmacy practitioner track and the community pharmacy management track with an emphasis in independent pharmacy ownership will include training in the requirements to serve as a PIC.

In addition, Western plans to develop a 15-hour "certificate" course designed to prepare a licensed pharmacist in the knowledge, skills and requirements to serve in a PIC position. They plan to offer the "certificate" program to all interested licensed pharmacists in convenient sites in southern and northern California starting in the second quarter of 2005.

The vision for the PIC “certificate” CE program is a format that includes an experiential component with workshop discussions and lectures presented by experts with “real world” experience. The faculty will include attorneys, pharmacy managers, industrial security representatives, medical waste disposal experts and faculty from the WesternU College of Pharmacy. They also asked for participation from the Board of Pharmacy. They requested that board member or inspector with expertise in community and hospital outpatient pharmacy self-assessment process be a part of the training program. The final format that would include a board representative is open at this time. It was explained that the core content of the PIC certificate program would be in the areas of compliance with the board’s self-assessment form.

Executive Officer Patricia Harris commended WesternU College of Pharmacy for the development of a PIC certificate program and expressed interest in the board’s willingness to participate in the development of such a program. One concern expressed is the commitment of board resources to actively participate in the training program. Supervising Inspector Robert Ratcliff agreed to work with WesternU College of Pharmacy to determine how best the board could support their efforts.

New Statutory Changes Effective January 1, 2005

The Enforcement Committee was provided with an overview of the new statutory changes that will become effective January 1, 2005. These changes will be in the board’s January newsletter. Comments were made clarifying some of the changes.

Meeting Dates for 2005

The Enforcement Committee set its meeting dates for 2005: March 9th – Burbank, June 22nd – Sacramento, September 13th – Burbank and December 7th – Sacramento.

Adjournment

Committee Chair William Powers adjourned the meeting at 12:45 p.m.

ATTACHMENT N



**Enforcement Team Meeting
December 1, 2004**

2:00 p.m. – 4:00 p.m.

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

Announcements/Introductions

Executive Officer Patricia Harris called the meeting to order at 2:00 p.m.

Quality Improvement Efforts

Supervising Inspectors Robert Ratcliff, Judi Nurse, Dennis Ming and Joan Coyne provided the quarterly management reports. Dr. Ratcliff reported that approximately 30% of the investigations were 90 days or older. He commended staff for their efforts and encouraged the completion of the cases especially consumer complaints that were more than 90 days old. Dr. Ming provided an overview of those counties (specifically the Bay Area) where routine inspections needed to be completed. He stated that all inspectors would assist the Compliance Team in completing these routine inspections in targeted areas. Dr. Ming also added that he anticipates that the inspection of pharmacies will be completed by May 2005.

Discussion of Enforcement Committee Meeting

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

Adjournment

The meeting was adjourned the meeting at 4:00 p.m.

ATTACHMENT O

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			31
Pleadings Filed	22	27			22
Pending					
Pre-accusation	68	63			
Post Accusation	79	82			
Total	155	165			
Closed**	19	28			19
Revocation					
Pharmacist	2	1			2
Pharmacy		1			
Other	2	10			2
Revocation, stayed; suspension/probation					
Pharmacist	1				1
Pharmacy					
Other		1			
Revocation, stayed; probation					
Pharmacist	5	4			5
Pharmacy		2			
Other					
Suspension, stayed; probation					
Pharmacist	1				1
Pharmacy					
Other					
Surrender/Voluntary Surrender					
Pharmacist	1	3			1
Pharmacy		1			
Other	4	1			4
Public Reprival/Reprimand					
Pharmacist	1				1
Pharmacy					
Other					
Cost Recovery Requested	\$49,126.50	\$75,991.00			\$125,117.50
Cost Recovery Collected	\$45,201.47	\$55,390.86			\$100,592.33

* 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			105
Pharmacy	20	19			20
Other	23	23			23
Probation Office Conferences	7	8			7
Probation Site Inspections	23	41			23
Probationers Referred to AG for non-compliance	0	1			0

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 12/31/04)

Program Statistics

In lieu of discipline	0	1			0
In addition to probation	3	3			6
Closed, successful	0	3			3
Closed, non-compliant	3	4			7
Closed, other	1	0			1
Total Board mandated Participants	42	69			69
Total Self-Referral Participants*	30	4			34
PRP Site Inspections**	11	7			18
Treatment Contracts Reviewed	38	35			73

Monthly the board meets with the clinical case manager to review treatment contracts for scheduled board mandated participants. During these monthly meetings, treatment contracts and participant compliance is reviewed by the PRP case manager, enforcement coordinator and lead inspector and appropriate changes are made at that time and approved by the executive officer. Additionally, non-compliance is also addressed on a needed basis e.g., all positive urines screens are reported to the board immediately and appropriate action is taken.

* By law, no other data is reported to the board other than the fact that the pharmacists and interns are enrolled in the program.

**Some PRP Participant Inspections are included in the Probation Site Inspections total.

As of December 31, 2004.

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			722
Closed	584	532			1116
Pending (at the end of quarter)	629	537			537

Cases Assigned & Pending (by Team)

Compliance Team	59	65			65
Drug Diversion/Fraud	57	72			72
Mediation Team	189	93			93
Probation/PRP	45	42			42
Enforcement	4	117			117

Application Investigations

Initiated	41	33			74
Closed					
Approved	13	22			35
Denied	2	6			8
Total*	27	35			62
Pending (at the end of quarter)	54	65			65

Citation & Fine

Issued	197	220			417
Abated	336	282			618
Total Fines Collected	\$113,136.00	\$119,406.00			\$232,542.00

* This figure includes withdrawn applications.

** Fines collected and reports in previous fiscal year.

ATTACHMENT P

Enforcement Committee

2004-2005

Second Quarter Report

October 1, 2004 – December 31, 2004

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:	<p>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</p>							
Time Frame	Number				Percentage			
	<i>Q1</i>	<i>Q2</i>	<i>Q3</i>	<i>Q4</i>	<i>Q1</i>	<i>Q2</i>	<i>Q3</i>	<i>Q4</i>
0 to 90 days	34	12			68%	8%		
91 to 180 days	13	26			26	17		
181 to 365 days	2	1			4	1		
366 to 730 days	1	0			2	0		
	<p>2. Investigation all other cases within 120 days. Quarter 1 & 2: same total stats as above</p>							
0 to 90 days	64	25			36%	16%		
91 to 180 days	73	51			41	33		
181 to 365 days	32	36			18	23		
366 to 730 days	1	5			2	3		

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

	Q1	%	Q2	%	Q3	%	Q4	%
0 to 90 days	177	31	149	30				
91 to 180 days	182	32	185	37				
181 to 365 days	148	26	109	22				
366 to 730 days	61	11	49	10				
731 + days	7	1	3	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: 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.*

CURES reports provided to supervising inspectors and/or inspectors to aid in an investigation or inspection:

- **Quarter 1:** 23
- **Quarter 2:** 13

CURES data used in complaint investigations:

- Quarter 1: 26
- Quarter 2: 0

CURES compliance issues found in inspections:

- Quarter 1: 14
- Quarter 2: 8

1782 Wholesaler Data Base: No changes first or second quarter

DEA 106 Theft/Loss: No changes first quarter.

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.*
- *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.*
- *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*

	<p><i>Oxycontin task force meetings in Ventura; FBI task force meetings; and diversion task force meetings in San Diego.</i></p> <p>7. Secure sufficient staffing for a complaint mediation team and to support an 1-800 number for the public. Nothing to report first or second quarter.</p>
	<p>8. Improve public service of the Consumer Inquiry and Complaint Unit.</p> <p>First Quarter:</p> <ul style="list-style-type: none"> ▪ <i>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.</i> ▪ <i>Board staff provided consumer information at an adult day care program in Carmichael on September 28.</i> ▪ <i>In September the board staffed a booth at the Yreka Health Fair where about 450 people attended the event.</i> ▪ <i>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</i> ▪ <i>Board has 21 consumer brochures available, including Health Notes.</i> ▪ <i>Board staff provided information about the board and discount programs for drugs at the Triple "R" Adult Day Program in Sacramento on September 28.</i> <p>Second Quarter:</p> <ul style="list-style-type: none"> ▪ <i>October 16th – board staffed a booth at UCD Healthy Aging Event in Sacramento.</i> ▪ <i>November 16th – board staffed booth at Senior Health Fair in Paso Robles.</i>
	<p>9. Automate processes to ensure better operations and integrate technology into the board's investigative and inspection activities.</p> <p><u>Investigative Activities:</u></p> <p>First Quarter:</p> <ul style="list-style-type: none"> ▪ <i>A request to provide the board the capability to download its entire CAS enforcement database into an 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.</i> ▪ <i>Developed new and improved reports for the automated audit program. This program is used to capture data from prescriptions.</i>

- *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.*

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 chunk 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*

	<p><i>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.</i></p> <ul style="list-style-type: none"> ♦ <i>Improved inspector data functionality allows an inspector to select corrections issued on a written notice and also added a print preview on written notices.</i> ♦ <i>Improved inspection Word file program to automatically update each time the file is accessed by staff to speed download time for inspectors.</i> ♦ <i>Data Scrub program - staff identified and fixed some minor issues with the program.</i> 																																			
<p>Objective 1.2</p> <p>Measure:</p>	<p>To achieve 100 percent closure on all administrative cases within one year by June 30, 2005.</p> <p>Percentage closure on administrative cases within one year.</p>																																			
<p>Tasks:</p>	<p>1. Pursue permanent funding to increase Attorney General expenditures for the prosecution of board administrative cases.</p> <ul style="list-style-type: none"> ▪ <i>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.</i> ▪ <i>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.</i> <p>2. Aggressively manage cases, draft accusations and stipulations and monitor AG billings and case costs.</p> <ul style="list-style-type: none"> ▪ <i>Case management and review of pending cases is a continuous process.</i> 																																			
	<table border="1"> <thead> <tr> <th></th> <th>Q1</th> <th>Q2</th> <th>Q3</th> <th>Q4</th> </tr> </thead> <tbody> <tr> <td>Status memos sent to AG</td> <td>26</td> <td>19</td> <td></td> <td></td> </tr> <tr> <td>Disciplinary Cases Closed:</td> <td></td> <td></td> <td></td> <td></td> </tr> <tr> <td> 0-365 days</td> <td>8</td> <td>8</td> <td></td> <td></td> </tr> <tr> <td> 366 + days</td> <td>13</td> <td>17</td> <td></td> <td></td> </tr> <tr> <td>Accusations reviewed</td> <td>27</td> <td>28</td> <td></td> <td></td> </tr> <tr> <td>Accusations needing revision</td> <td>10</td> <td>7</td> <td></td> <td></td> </tr> </tbody> </table>		Q1	Q2	Q3	Q4	Status memos sent to AG	26	19			Disciplinary Cases Closed:					0-365 days	8	8			366 + days	13	17			Accusations reviewed	27	28			Accusations needing revision	10	7		
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Accusations filed	22	27		
Stips/proposed decisions reviewed	18	20		
Cases reviewed for costs	12	12		

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*

5. Review and update disciplinary guidelines.

Objective 1.3:	Inspect 100 percent of all licensed facilities once every 3 years by June 30, 2004.
Measure:	Percentage of licensed facilities inspected once every 3 years
Tasks:	<p>1. Automate processes to ensure better operations and integrate technology into the board's investigative and inspection activities.</p> <ul style="list-style-type: none"> ▪ <i>For all quarters, see response to Objective 1.1, Task #9</i> <p>2. Inspect licensed premises to educate licensees proactively about legal requirements and practice standards to prevent serious violations that could harm the public.</p>

	<p><u>Inspection Statistics Background:</u> As of January 11, 2005: Total number of locations identified to inspect from those licensed at the time of the inspection program's inception (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 5,873; total number of inspections completed 5,401, total number of inspections to be completed by July 2005 are 472. (Percentage completed toward goal: 91.96%)</p> <p>Total number of locations identified to inspect (including sites licensed after 7/1/2001) was approximately 8,262; total number of inspections completed 7,157; total number of inspections to be completed by July 2005 are 1,105. (Percentage completed toward goal: 86.63%)</p>																														
	<table border="1"> <thead> <tr> <th data-bbox="438 621 722 658">Number</th> <th data-bbox="722 621 799 658"></th> <th data-bbox="799 621 892 658"></th> <th data-bbox="892 621 968 658"></th> <th data-bbox="968 621 1045 658"></th> </tr> </thead> <tbody> <tr> <td data-bbox="438 658 722 733">Inspections Completed</td> <td data-bbox="722 658 799 733"><i>Q1</i> 657</td> <td data-bbox="799 658 892 733"><i>Q2</i> 593</td> <td data-bbox="892 658 968 733"><i>Q3</i></td> <td data-bbox="968 658 1045 733"><i>Q4</i></td> </tr> <tr> <th data-bbox="438 733 722 770">Type</th> <td data-bbox="722 733 799 770"></td> <td data-bbox="799 733 892 770"></td> <td data-bbox="892 733 968 770"></td> <td data-bbox="968 733 1045 770"></td> </tr> <tr> <td data-bbox="438 770 722 845">Sterile Compounding</td> <td data-bbox="722 770 799 845">44</td> <td data-bbox="799 770 892 845">38</td> <td data-bbox="892 770 968 845"></td> <td data-bbox="968 770 1045 845"></td> </tr> <tr> <td data-bbox="438 845 722 919">Status 3</td> <td data-bbox="722 845 799 919">3</td> <td data-bbox="799 845 892 919">6</td> <td data-bbox="892 845 968 919"></td> <td data-bbox="968 845 1045 919"></td> </tr> <tr> <td data-bbox="438 919 722 973">Routine resulting in complaint invest.</td> <td data-bbox="722 919 799 973">9</td> <td data-bbox="799 919 892 973">9</td> <td data-bbox="892 919 968 973"></td> <td data-bbox="968 919 1045 973"></td> </tr> </tbody> </table> <p data-bbox="438 973 1423 1048">2. Implement changes to the Pharmacy Technician Program.</p> <p data-bbox="438 1048 1423 1176">3. Seek legislation to mandate that periodic inspections be done on all board-licensed facilities</p>	Number					Inspections Completed	<i>Q1</i> 657	<i>Q2</i> 593	<i>Q3</i>	<i>Q4</i>	Type					Sterile Compounding	44	38			Status 3	3	6			Routine resulting in complaint invest.	9	9		
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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	<p data-bbox="438 1328 1423 1402">1. Develop the board's website as the primary board-to-licensee source of information.</p> <ul style="list-style-type: none"> <li data-bbox="496 1425 1350 1462">▪ Public disclosure of disciplinary history on licensees is online. <p data-bbox="438 1500 991 1537">First Quarter Web Additions/Revisions</p> <ul style="list-style-type: none"> <li data-bbox="722 1570 1066 1607">✓ <i>Regulations updates.</i> <li data-bbox="722 1607 1326 1674">✓ <i>Added the option to join the Boards e-mail notification list.</i> <li data-bbox="722 1674 1385 1740">✓ <i>Posted Memo to Pharmacists on dispensing CII drugs without security or triplicate forms.</i> <li data-bbox="722 1740 1382 1806">✓ <i>Posted an audio recording of a presentation on SB 151</i> <li data-bbox="722 1806 1347 1839">✓ <i>Listed frequently asked questions on SB 151.</i> 																														

- ✓ *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*

2. Prepare two annual *The Scripts* to advise licensee of pharmacy law and interpretations.

- *March 2004 Script published*
- *January 2005 Script in production*

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.*

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 investigators of the Department of Justice on August 26.*

- *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 On 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.*

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.

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		
Number Referred to PRP	3	4		
Number Closed from PRP	4	7		

Probation Monitoring Program - # on probation	Q1	Q2	Q3	Q4
Pharmacists	105	106		
Pharmacies	20	19		
Other	23	23		

Citation and Fine	Q1	Q2	Q3	Q4
Citations Issued	197	220		
Fines Collected	\$113,136	\$119,406		

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.*

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 into 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		
Licensees	35	16		
Other agencies	16	19		
License Verifications	227	208		
Time Frame Records Requests Responded To	Q1	Q2	Q3	Q4
# & %				
Within 10 days	64 – 78%	49 – 73%		
Over 10 days	18 – 22%	18 – 27%		

	Time Frame License Verifications Responded To					
		<i>Q1</i>	<i>Q2</i>	<i>Q3</i>	<i>Q4</i>	
	# & %					
	Within 10 days	146 – 64%	134 – 64%			
Over 10 days	81 – 35%	74 - 36%				
Objective 1.7	Initiate policy review of 25 emerging enforcement issues by June 30, 2005.					
Measure:	The number of issues					
Tasks (Issues)	<ol style="list-style-type: none"> 1. Reimportation of drugs from Canada. <ul style="list-style-type: none"> ▪ Importation of Drugs 2. Modification to the Quality Assurance Regulation regarding patient notification. 3. Proposals regarding wholesale transactions. <ul style="list-style-type: none"> ▪ Sponsored legislation (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. <ul style="list-style-type: none"> ▪ Sponsored legislation SB 1913 6. Off-site order entry of hospital medication orders (Bus. & Prof. Code Section 4071.1). 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). 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 <ul style="list-style-type: none"> ▪ Statutory change (SB 1913), regulation proposal to implement. 21. Update of pharmacy laws related to PRP. 22. Update of pharmacy law related to pharmacy technicians. 23. Clean-up of “Letter of Admonishment” provision. 24. Use of “kiosks: for drop-off of prescriptions. 25. Use of self-services dispensing units for pick-up of refill prescriptions. 26. Implementation of SB 1307 regarding electronic pedigree requirement for dangerous drugs. 27. Mandatory reporting of impaired licensees. 					

