California State Board of Pharmacy
1625 N. Market Blvd, Suite N219, Sacramento, CA 95834
Phone (916) 574-7900
Fax (916) 574-8618
www.pharmacy.ca.gov

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

STATE BOARD OF PHARMACY
DEPARTMENT OF CONSUMER AFFAIRS
ENFORCEMENT COMMITTEE
MINUTES

DATE: September 16, 2009

LOCATION: Samuel Greenberg Board Meeting Room
Los Angeles International Airport
1 World Way
Los Angeles, CA 90045

COMMITTEE MEMBERS PRESENT:
Robert Swart, PharmD, Chair
Ramón Castellblanch, Public Member
Randy Kajioka, PharmD
Greg Lippe, Public Member

STAFF PRESENT:
Virginia Herold, Executive Officer
Anne Sodergren, Assistant Executive Officer
Robert Ratcliff, Supervising Inspector
Kristy Schieldge, DCA Staff Counsel (via conference call)
Tessa Fraga, Staff Analyst

Call to Order

Chair Swart called the meeting to order at 9:30a.m.

1. Overview of Proposals to Strengthen the Enforcement Programs of the Heath Care Boards of the Department of Consumer Affairs

Chair Swart provided that over the prior nine months, the Department of Consumer Affairs (DCA) has initiated a number of proposals aimed at strengthening the enforcement activities of the health care boards. He stated that the Board of Pharmacy is one of these agencies.

Chair Swart provided that these changes were initiated following problems identified at the Board of Registered Nursing (BRN) by the *Los Angeles Times*.

Chair Swart provided that the first major change was prioritization of fingerprinting of all licensees. He stated that fingerprinting allows a board to obtain federal and state background checks of applicants with respect to arrests and convictions entered into federal and state data bases by the courts and law enforcement agencies. Chair Swart explained that it also enables boards to obtain "subsequent" arrest and conviction information if a licensee is arrested or convicted in California.

Chair Swart provided that the board has been fingerprinting applicants for individual licenses (pharmacists, pharmacist interns, technicians, designated representatives), and the officers and owners of board-licensed facilities (pharmacies, wholesalers, clinics, etc.) for years. He stated that pharmacists have been fingerprinted as a condition of licensure since September 1947 – only 150 individuals with active licenses do not have prints on file with the California Department of Justice. Chair Swart indicated that other boards only began fingerprinting applicants in the late 1980s and later. He explained that as a result, knowledge about serious criminal convictions involving licenses substantially related to their professional practices may not reach the licensing board and these individuals are allowed to remain in practice, risking patient safety.

Chair Swart provided that the number of arrest and conviction reports (rap sheets) sent to the board on applicants and licensees is strongly dependent upon the speed with which local jurisdictions enter this information into the reporting system. He stated that in recent years, the number of these reports sent to the board have dramatically increased, and has exceeded the board's ability to respond timely to these cases. Chair Swart explained that as a result, the board submitted a budget change proposal early this year to ensure that it can immediately review and investigate reports of criminal convictions and arrests. He indicated that the board received 6.5 new positions effective July 1, 2009. Chair Swart stated that the last two of these positions will be filled by mid-September.

Chair Swart provided that the second major problem reported in the *LA Times* was the time it was taking the BRN to investigate complaints and complete enforcement actions, which exceeded 3.5 years. He stated that the BRN uses the Department's Division of Investigation to investigate its complaints, and problems with recruitment and retention of investigators has been a problem. Chair Swart advised that this delayed investigations. He explained that additionally the time it takes to secure complete work by the Attorney General's Office and Office of Administrative Hearings further added delays.

Chair Swart provided that DCA has responded with a series of proposals to strengthen the BRN's enforcement program as well as that of other health care boards.

Chair Swart provided that concurrently, the Senate Business, Professions and Economic Development Committee developed a series of proposals. He stated that the overall goal is to complete formal investigations from the time a complaint is received, through investigation and through final action on the stipulation or proposed decision by the board. Chair Swart indicated that the goal is 12-18 months – a very aggressive standard, but on that the public deserves.

Chair Swart provided that the committee will have a number of discussions about the board's enforcement program. He stated that whereas the board's timelines are better than the BRNs, they are not 12-18 months for most formal discipline. Chair Swart indicated that the board needs to retool its program. He advised that the board will also need additional staff. Chair Swart indicated that as such, staff is now working on budget change proposals to augment staff so we can reach this standard.

Chair Swart provided that a joint legislative proposal, Senate Bill (SB) 294 was amended ("gutted and amended" in the parlance of the Legislature) last week that carries some of the Administration's and Senate's proposals for improving DCA's enforcement programs. He advised that the Legislative Session ended for the year on September 11, 2009.

Executive Officer Virginia Herold provided an overview of the board's enforcement program. She advised that the board will retool its program and add additional staff in order to improve the timeline for closures of formal discipline cases.

Presentation to the Committee

Assistant Executive Officer Anne Sodergren provided an overview of the board's enforcement program. She stated that the Governor has established a goal for all investigation cases to be closed between 12 to 18 months. Ms. Sodergren explained that DCA has designed a new enforcement model to aid all boards with this timeline.

Ms. Sodergren reviewed the current processing times for the three types of investigations including criminal conviction investigations (150-290 days), "simple" field investigations (125-200 days), and "complex" field investigations (220-390 days). She highlighted the current processing time for final dispositions based on closure type as well as the current processing time for formal discipline.

Ms. Sodergren provided that there has been significant growth in the number of licensees that the board regulates. She stated that consequently, there has been growth in investigations and the number of complaints received. Ms. Sodergren reviewed the enforcement statistics for fiscal years 2004/2005, 2006/2007, and 2007/2008.

Ms. Sodergren provided that the board is working to identify internal improvements. She stated that these improvements include a reduction in time for the following: routing of complaints on-line, routing of draft pleadings on-line, on-line mail ballots, and the in house preparation of default decisions.

Committee Discussion

Chair Swart expressed concern about staff workload and staffing requirements in the event of a large case such as the Heparin case.

Ms. Sodergren provided that a staff augmentation would be required. She explained that a redirection of staff is needed when dealing with a public health threat.

Ms. Herold confirmed that the board would have to absorb the added workload by redirecting existing staff. She reviewed the board's current enforcement staff and their existing workload and timeframes.

Ramón Castellblanch questioned if any concern has been expressed by pharmacist organizations regarding the shortening of the timelines.

Ms. Sodergren provided that SB 294 was "gutted and amended" at the end of the legislative session and became a two-year bill. She explained that consequently, there probably has not been enough time for stakeholder groups to get involved and express their concerns.

Ms. Herold provided that stakeholder groups will have the opportunity to express their concerns. She stated that most of the board's convictions and related arrests are for DUIs. She reviewed the board's Pharmacists Recovery Program (PRP) and the requirements for PRP participants. Ms. Herold explained that the board utilizes the PRP as a monitoring program while continuing to discipline the licensee. She indicated that the Senate has set a sunset date for all diversion programs and will be evaluating the PRP.

Ms. Herold emphasized that a staff augmentation is needed in order to fulfill the board's obligations given the significant growth and increase in enforcement demands.

Randy Kajioka asked if any of the pharmacists and technician advocacy groups have challenged the burden of proof clause within the bill.

Ms. Herold provided that board staff met with the Chief Administrative Officer of the Office of Administrative Hearings who commented that the difference between the clear and convincing evidence standard and the preponderance standard in disciplinary cases involving licensees is minor.

Kristy Schieldge, DCA Staff Legal Counsel, provided that this is a legal issue that needs increased scrutiny. She stated that the standing legal standard for administrative licensing cases is clear and convincing evidence. Ms. Schieldge indicated that this standard is typically a higher standard for the board to meet.

Dr. Kajioka sought clarification regarding random drug testing policies and the requirement for a licensee to comply with testing if a complaint has been filed.

Ms. Herold reviewed the process for the regulator making the demand versus the employer making the demand. She stated that the board's PRP participants are pulled from practice if they test positive.

Ms. Herold provided that the board and its executive officers will continue to work with the Department.

Chair Swart provided that the board is in a good position to comply with DCA's new enforcement model and to make improvements.

There was no additional committee discussion.

Public Comment

No public comment was provided.

2. Proposed Regulation to Require Notification to the Board About Prior Convictions of Pharmacists at Time of Renewal

Chair Swart provided that the Administration has been advocating that all health boards within the Department implement a plan for securing fingerprints from all licensees regardless of when they were first licensed as well as requiring licensees at time of renewal to certify that they have not been arrested for or convicted of any crime within the renewal period (two years). He stated that this information augments the information received from the courts. Chair Swart advised that this board does not have such a requirement.

Chair Swart provided that in 2001, the Department of Justice (DOF) began transitioning to electronic submission of fingerprints, LiveScan. He indicated that fingerprint background information collected since that time is stored electronically. Chair Swart stated that pre-existing fingerprint information was not converted into this electronic format. He provided that given that full conversion of previous records is unlikely to occur, the committee should consider a recommendation to require pharmacist licensees to resubmit fingerprints as a condition of renewal.

Chair Swart provided that there was proposed legislation earlier this year authored by Senator Negrete-McLeod that would have established this requirement for departmental licensees. (The board had a support position on this bill.) He advised that the bill was stalled in a policy committee over issues involving the Contractors State License Board.

Chair Swart provided that staff proposes adding these requirements to pharmacists initially. He explained that to do this would require legislation or regulation. Chair Swart stated that staff proposes a regulation. He advised that after a two year implementation period for pharmacists, board staff recommend that the board consider imposing a similar requirement on designated representatives and pharmacy technicians.

Committee Discussion

Chair Swart sought clarification regarding the benefit for starting this process with pharmacists as opposed to technicians.

Ms. Herold explained that the pharmacist is the more influential individual. She provided that in order to update fingerprint information prior to 2001 that has not been converted into the electronic format, the board has proposed that pharmacists certify at the time of renewal that they have electronically submitted their fingerprints. Ms. Herold stated that this will apply to about 35,000 licensees over a two-year period. She indicated that the process has been divided between pharmacists and technicians in order to manage the workload.

Chair Swart suggested that the board review this process in one year to evaluate if the process can be accelerated.

The committee further discussed the fingerprint process and the availability of LiveScan.

Ms. Sodergren provided that DCA is working with DOJ to create an interface to link the LiveScan results with the licensee's records. She reviewed potential delays that may impact staff workload including rejected fingerprints and input errors.

Ms. Herold provided that the submissions will be audited.

Public Comment

No public comment was provided.

MOTION: To recommend to the board that it consider moving forward with the regulation.

M/S: Lippe/Swart

Support: 4 Oppose: 0

3. Discussion Regarding a Request to Use Pharmaceutical Manufacturer Patient Assistance Programs for Indigent Patients Receiving Care from County-Run Pharmacies

Chair Swart provided that the board has received a request from the LA County Department of Health Services seeking the ability for pharmacies serving medically indigent patients to better use the benefits of drug manufacturers' patient assistance programs.

Chair Swart provided that Dr. Amy Gutierrez, Director of Pharmacy Affairs with LA County Department of Health Services, has asked for this meeting to address an issue involving patient assistance programs.

Chair Swart provided that Dr. Gutierrez' wants to make it easier to:
1. identify and qualify patients for these programs, and
2. create a mechanism so that its pharmacies can provide these medications to patients from a pharmacy's stock immediately upon qualification, and then replace the stock when the dispensing pharmacy receives the patient assistance medication from the contracted pharmacy.

Presentation to the Committee

Dr. Amy Gutierrez provided an overview of the LA County Department of Health Services and the uninsured population that it serves. She stated that Los Angeles County has contracted with Cardinal Health to facilitate the enrollment of qualified patients in manufacturers' patient assistance programs. Dr. Gutierrez indicated that since January 2008, LA County believes it has recouped $2 m in drug value from its participation in these programs.

Dr. Gutierrez suggested the following:
1. allow LA County pharmacy to accept these medications, dispensed directly from another pharmacy, and placing the medications onto a specially designated shelf, which will be dispensed at the patient's next pharmacy visit. An LA County pharmacy prescription label would be affixed to the medication container, in keeping with Business and Professions Code section 4052.7.
2. allow the pharmacy to receive the medication from the mail order pharmacy, and mailing out directly to the patient at the last known address. This is less optimal, as some of their uninsured patients do not always have reliable addresses.

Dr. Gutierrez sought clarification regarding whether a licensed California pharmacy can place the content of the medication container that was issued by another licensed pharmacy (e.g., Medco mail order) to a patient back into stock, provided that the medication was never handled by anyone other than the two pharmacies.

Dr. Gutierrez provided that an estimated $8 m could be recouped per year if the suggested allowances are permitted.

Committee Discussion

Chair Swart asked if Medco has expressed any concern regarding their role with this process.

Dr. Gutierrez provided that the shipment provided by Medco is typically a replacement for medication that has already been dispensed. She indicated that medications are marked if they have been recovered and are then used for a different patient who qualifies for the program.

Dr. Kajioka expressed concern regarding contractual issues and whether the program requires that the manufacturer provide a patient specific label.

Dr. Gutierrez provided that manufacturers typically will not take back a drug with a patient specific label that was not claimed by the patient. She stated that these drugs are to be discarded or used for another patient that qualifies for the program.

Carolyn Brown, representing Cardinal Health, provided that patient assistance programs have been setup with the intent for patients to receive their medications in a timely manner.

Ms. Herold provided that the board would like to assist LA County with the requested allowances and will need to consult with its legal counsel on this issue. She indicated that the board will try to have a decision by the October Board Meeting.

Public Comment

Dr. Steve Gray, representing Kaiser Permanente, offered support for this request. He requested that Kaiser be involved to address this issue in a broader context.

Ms. Herold asked how likely it would be to have manufacturer participation.

Dr. Gray provided that, based on his opinion, manufacturers would be very interested. He commended manufacturers for their efforts in developing these programs. Dr. Gray provided an overview of the central fill system.

Ms. Herold provided that Health and Safety Code Section 150204 excludes controlled drugs.

Dr. Gutierrez provided that one record for each patient is essential for patient safety and to avoid duplicate therapy. She advised that without the requested allowances, pharmacies will have to shut down and patient care will be impacted.

There was no additional committee or public comment.

4. Presentation by Daiichi Sankyo on Third Party Logistics Providers (Licensed Wholesalers) and Drug Manufacturers

Chair Swart provided that Daiichi Sankyo has requested an opportunity to address the board on the use of third party logistics providers (called “3PLs”).

Chair Swart provided that third party logistic providers are defined in California Business and Professions Code as:

> **4045. Third-Party Logistics Provider or Reverse Third-Party Logistics Provider**
> "Third-party logistics provider" or "reverse third-party logistic provider" means an entity licensed as a wholesaler that contracts with a dangerous drug manufacturer to provide or coordinate warehousing, distribution, or other similar services on behalf of a manufacturer, but for which there is no change of ownership in the dangerous drugs. For purposes of Sections 4034, 4163, 4163.1, 4163.2, 4163.3, 4163.4, and 4163.5, a third-party logistics provider shall not be responsible for generating or updating pedigree documentation, but shall maintain copies of the pedigree. To be exempt from documentation for pedigrees, a reverse third-party logistic provider may only accept decommissioned drugs from pharmacies or wholesalers.

Chair Swart provided that the board does not differentiate the various type of wholesaler licenses it issues (reverse distributors, wholesalers, 3PLs), so it is not known specifically how many 3PLs are licensed with the board.

Presentation to the Committee

Dean Marioccia, representing Daiichi Sankyo Inc., thanked the board for the opportunity to educate the board on the third party logistics providers process. He introduced Kristie Breed (Daiichi Sankyo Inc.) and Robert Brown (Cardinal Health - Specialty Pharmaceutical Services).

Kristie Breed, representing Daiichi Sankyo Inc., provided an overview of Daiichi Sankyo Inc. and reviewed the company's supply chain. She advised that Daiichi Sankyo owns and is responsible for products that are at the 3PL. Ms. Breed indicated that the product belongs to the customer when it is picked up from the carrier. She stated that Daiichi Sankyo will aid the customer with an investigation in the event of drug theft during transit.

Robert Brown, representing Cardinal Health - Specialty Pharmaceutical Services, provided an overview of Specialty Pharmaceutical Services and the 3PL process. He stated that the 3PL provides quality assurance, regulatory support, and inventory visibility in real-time. Mr. Brown indicated that the contract packager, Daiichi Sankyo, and Specialty Pharmaceutical Services comply with all FDA and state/federal laws.

Committee Discussion

Chair Swart asked who transports during inbound receiving.

Mr. Brown provided that inbound receiving is generally transported by a common carrier and is coordinated by the shipper.

Chair Swart sought clarification regarding whether the wholesaler pays the manufacturer or the 3PL.

Mr. Brown provided that the wholesaler pays the manufacturer.

Mr. Brown extended an open invitation to the board to visit the 3PL operation in Reno, Nevada.

Ms. Herold provided that the board would need out-of-state clearance before making a visit.

Mr. Brown explained the difference between "freight on board origin" terms and conditions and "freight on board destination" terms and conditions. He provided that Daiichi Sankyo specifies "freight on board origin" terms and conditions with its downstream customers. Mr. Brown stated that the carrier assumes the risk of loss during transit.

Ms. Herold expressed concern with the increasing thefts from common carriers.

Public Comment

Ellis Ellis sough clarification regarding other customers of Daiichi Sankyo. Mr. Brown provided that from a 3PL perspective, the customer is dependent on who the manufacturer considers as their customer. He stated that the 3PL will ship to any customer with a valid California license.

Ms. Breed provided that Daiichi Sankyo does not work at the pharmacy level. She stated that they ship around 90% of their product to wholesale customers.

Mr. Ellis asked if the customer can see the inventory electronically.

Mr. Brown provided that the customer can not see the inventory while it is in the 3PL warehouses.

Discussion continued regarding inventory control.

There was no additional committee or public comment.

5. 2008 Report of the Research Advisory Panel of California

Chair Swart provided that the California Health and Safety Code establishes the Research Advisory Panel to oversee research involving use of controlled substances. He stated that section 11213 provides that:

> Persons who, under applicable federal laws or regulations, are lawfully entitled to use controlled substances for the purposes of research, instruction, or analysis, may lawfully obtain and use for such purposes such substances as are defined as controlled substances in this division, upon approval for use of such controlled substances in bona fide research, instruction, or analysis by the Research Advisory Panel established pursuant to Sections 11480 and 11481.

Chair Swart provided that pages 39 – 42 of this report provide the statutory mandate of the panel. He stated that the Board of Pharmacy has one representative on this panel – Dr. Peter Koo of UCSF.

No committee or public comment was provided.

6. Discussion of the Actions of the Department of Consumer Affairs Health Care Boards to Develop Regulations Required by SB 1441 (Ridley-Thomas, Chapter 548, Statutes of 2008) for Practitioner Recovery/Monitoring Programs

Chair Swart provided that SB 1441 created the Substance Abuse Coordination Committee (SACC) and required that this committee, by January 1, 2010, formulate uniform and specific standards in specified areas that each healing arts board must use in dealing with substance-abusing licensees, whether or not a board chooses to have a formal diversion program.

Chair Swart provided that this committee is subject to Bagley-Keene Open Meeting Act and is comprised of executive officers and bureau chiefs from specified boards and bureaus.

Chair Swart provided that given the timeline to develop these standards, earlier this year, the DCA created a workgroup consisting of staff from each of the healing arts boards. (The process is similar to process the board uses to promulgate a regulation.) He stated that the workgroup is responsible for developing recommended standards. Chair Swart indicated that the recommended standards are then vetted during a Uniform Standards Workshop, a public meeting akin to an informational hearing. He explained that the draft standards are then presented during a public meeting to the SACC for consideration and action.

Chair Swart provided that to date the SACC committee has met three times, most recently on September 1, 2009. He stated that during the meeting, the committee discussed the proposed uniform standards 7 – 12 as well as minor changes to standards previously considered by the committee. Chair Swart indicated that the next meeting of this committee is scheduled for September 30, 2009. He advised that additional SACC meetings are scheduled for:

- September 30, 2009
- November 16, 2009
- December 15, 2009

Chair Swart provided that there continue to be questions surrounding how each board will be required to implement these uniform standards, especially given that each board has separate statutory authority. He advised that the DCA legal office will be providing guidance on implementation issues as necessary.

Committee Discussion

Ms. Herold provided that goal of the SACC committee is to establish minimum standards for diversion programs to enhance consumer protection. She provided background on the formulation and the intent of the committee. Ms. Herold provided that the board's program has strong standards in place and will easily adhere to the new minimum standards.

Mr. Lippe asked if the board has designated a Diversion Program Manager for the Pharmacists Recovery Program (PRP).

Ms. Herold provided that in addition to the PRP inspector team, the board has two liaisons, Supervising Inspector Joan Coyne and Analyst Tessa Fraga, who work closely with the program's contractor to monitor the participants. She indicated that the PRP will be audited and the report will be publically released upon completion.

There was no additional committee discussion.

Public Comment

No public comment was provided.

7. Ongoing Discussion and Presentations About Prevention of Medication Errors

Chair Swart provided that recently Consumers Union published an update of the 1999 Institute of Medicine report of "To Error is Human- to Delay is Deadly," documenting the large number of medication errors in hospitals, where as many as 98,000 people die annually, needlessly, due to preventable errors.

Chair Swart provided that the conclusion or the 2009 Consumers Union report is that if anything, things have gotten worse in the last 10 years.

Chair Swart provided that California regulators have initiated action based on the initial IOM report. Since the 1999 report, the board secured legislation and underlying regulations to ensure that any medication error that reaches the patient must be subjected to a quality assurance review by the pharmacy to prevent a reoccurrence. He stated that this is a standard component checked during all board inspections of pharmacies.

Chair Swart provided that according to preliminary data from 2008-09, about 10 percent of the board's investigations involve medication errors. He stated that last fiscal year (as of June 1, 2009) the board closed 316 medication error complaints; 75 percent of these were substantiated.

Chair Swart provided that additionally, the California Department of Public Health has implemented statutory requirements to improve the care in hospitals. He indicated that a presentation is planned for the January 2010 Board Meeting on this subject. Chair Swart stated that generally the law required hospitals to develop an error reduction plan by 2002 that was submitted to the Department of Public Health, and had until 2005 to implement the plans. He advised that in 2009 the Department of Public Health began inspections of hospitals for compliance.

Chair Swart provided that the report is provided for review and possible future action by the board.

Committee Discussion

Dr. Kajioka noted the distinction between medical errors and medication errors.

Chair Swart provided that report did not address the proportion of the amount of patients receiving treatment and the number of prescriptions that have been filled in the last 10 years.

There was no additional committee discussion.

Public Comment

No public comment provided.

8. Implementation of the Board of Pharmacy's Ethics Regulation, 16 CCR Sections 1773 and 1773.5

Chair Swart provided that earlier this year, the board adopted a regulation to establish an ethics course as an enforcement option for those whose violations and resultant discipline had an ethics issue. He stated that the ethics course is designed to be ethics counseling, done by individual introspection, working one-on-one with a consultant, and in a group setting.

Chair Swart provided that the board will work with the Institute for Medical Quality to establish this course. He stated that the IMQ is a foundation of the CMA that operates a similar program for the Medical Board, and was the model the board used to develop the components for its ethics program.

Chair Swart provided that when the board was considering options for ethics violations, it formed a subcommittee of Board Members Rob Swart and Susan Ravnan. He stated that now in implementing the program, as the parameters for the course are developed, the board needs to decide if it wishes to form a subcommittee to work with senior board staff in developing the program, or

whether it wishes for staff to develop the program and bring the completed product to the board.

Chair Swart provided that the next steps are to pull administrative discipline files where the violation, in part, had an ethical component (e.g., fraud, dispensing medicine without a prescription), and work with a course provider in establishing the parameters.

Chair Swart provided that the board hopes to have the course ready for administration at the end of the year.

Committee Discussion

Ms. Herold asked if the committee would like to be involved with the development of the course.

Chair Swart indicated that the subcommittee would like to be involved in the development of the course.

Chair Swart provided that Board President Schell can appoint a new member to the subcommittee as one member has resigned from the board.

There was no additional committee discussion.

Public Comment

No public comment was provided.

9. Public Comment for Items Not on the Agenda

Ellis Ellis discussed recent changes to California law regarding controlled substances. He stated that pharmacists at the hospital level are required to sign for ephedrine. Mr. Ellis asked how the state would like to control this issue.

Ms. Schieldge provided that the committee will not discuss this issue.

The meeting was adjourned at 11:48 a.m.

Enforcement Program

Board of Pharmacy

Governor's Goal

- Close all cases between 12 to 18 months.
- Boards will be audited and Executive Officers held accountable.

New Enforcement Model

- Use of non-sworn investigators
- Use of in-house experts, paralegals and attorneys
- Improved access to records
- Automatic Suspension for incarceration
- Delegated authority to issue investigational subpoenas.

New Enforcement Model (con't)

- Policy for anomymous complaints
- Board member voting
- Default decisions and license surrenders
- Burden of proof
- Immediate cease practice order
- Suspension for positive drug test

New Enforcement Model (con't)

- Immediate stipulated settlement
- Mandatory revocation/license forteiture

Current Processing Time Investigations

- Criminal conviction investigations (150 – 290 days)
- “Simple” field investigations (125 days – 200 days)
- “Complex” field investigations (220 days – 390 days)

Current Processing Time
Final Disposition

- Closed – no further action (30 – 100 days)
- Closed – citation and fine w/o appeal (30 – 45 days)
- Closed – citation and fine w/ office conference (100 – 170 days)
- Closed – citation and fine w/ appeal (240 – 520 days)

Current Processing Time
Formal Discipline

- Pre-Accusation (262 – 387 days)
- Final Decision (150 – 255 days)
- If decision is non-adopted a minimum of 120 additional days

Complaints/Investigations

	FY 04/05	FY 06/07	FY 08/09
Initiated	**1480**	**2285**	**2515**
Closed	**1985**	**1657**	**2146**
Pending (at the end of FY)	**655**	**1484**	**2742**

Cases Pending by Team

	FY 04/05	FY 06/07	FY 08/09
Compliance Team	**87**	**94**	**194**
Drug Diversion/Fraud	**89**	**82**	**202**
Mediation/Enforcement Team	**108**	**322**	**126**
Probation/PRP	**40**	**61**	**98**
Criminal Conviction*			**1410**

* Unit Established Jan. 2009

Application Investigations

	FY 04/05	FY 06/07	FY 08/09
Initiated	**129**	**298**	**351**
Closed	**149**	**147**	**288**
Total	**149**	**147**	**288**
Pending (at the end of FY)	**39**	**186**	**338**

Citation and Fines

	FY 04/05	FY 06/07	FY 08/09
Issued	754	735	965
Closed	1004	657	1064
Total Fines Collected	$428,904.00	$436,711.70	$ 1,175,475.00

Administrative Cases

	FY 04/05	FY 06/07	FY 08/09
Referred to AG's Office	113	94	136
Pleadings Filed	73	88	72
Pending			
Pre-accusation	59	62	137
Post Accusation	77	56	99
Total	173	147	267
Closed	80	128	71

Internal Improvements

- Routing complaints on-line (approx. 30 day reduction in investigation time)
- Routing draft pleadings on-line (approx. 15 day reduction)
- On-line mail ballots (approx. 15 day reduction)
- Prepare default decisions (approx. 75 day reduction)

Third-Party Logistics Providers (3PL's): An Overview

California Board of Pharmacy
Enforcement Committee Meeting
September 16, 2009

Presented by:
Kristie Breed – Daiichi Sankyo Inc. (DSI)
Robert Brown – Specialty Pharmaceutical Services (SPS)

CardinalHealth
Essential to care™

Daiichi-Sankyo

Agenda

- Daiichi Sankyo (DSI)
- Specialty Pharmaceutical Services (SPS)
  - Third-Party Logistics (3PL) Overview
- Q & A

CardinalHealth
Essential to care™

Daiichi-Sankyo

Company Overview - DSI

• Daiichi Sankyo is a century-old pharmaceutical innovator – established in Japan in 1899 - one of the top 25 pharmaceutical companies in the world; with 16,250 employees worldwide

• In 1996, we formed a joint venture with the Parke-Davis division of Warner-Lambert to create a U.S. commercial organization; in 2001, we dissolved the joint venture and have grown to become an independent, fully integrated pharmaceutical company

• Daiichi Sankyo, Inc. (DSI) was established in April of 2006 as the U.S. subsidiary of Japanese pharmaceutical company Daiichi Sankyo Co., Ltd.; with 2,800 U.S. employees

• Headquartered in Parsippany, New Jersey, the company's strategic focus is on cardiovascular diseases

•DSI is licensed in California as a Drug Wholesaler

Daiichi Sankyo's Product lines

NEW for hypertension
AZOR
amlodipine and olmesartan medoxomil

Benicar
(olmesartan medoxomil)

BenicarHCT
(olmesartan medoxomil • hydrochlorothiazide)

Evoxac
(cevimeline HCl)
Evoxac

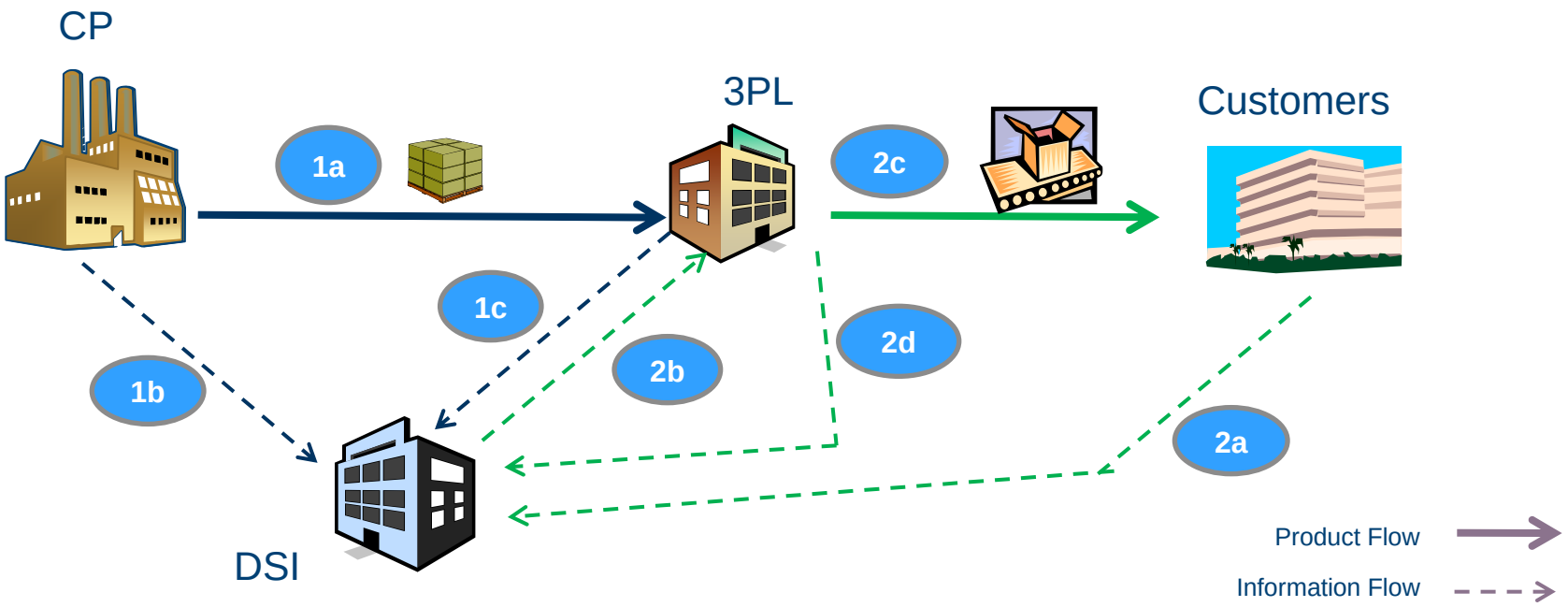
FLOXIN OTIC SINGLES
(ofloxacin otic) solution 0.3%

Welchol
(colesevelam HCl)

For more information, visit www.dsi.com

Daiichi-Sankyo

DSI's Supply Chain



1a. Contract Packager (CP) packages and ships product to 3PL
1b. CP transmits lot/shipment information to DSI
1c. 3PL transmits receiving information to DSI
2a. Customers transmit orders to DSI via EDI
2b. DSI transmits orders to 3PL for fulfillment
2c. 3PL picks, packs and ships orders to customers
2d. 3PL transmits product shipment and goods movement information to DSI

Daiichi-Sankyo

Company Overview - SPS

- Founded in 1995 by Cardinal Health specifically to meet the growing and unique needs of the healthcare industry
  - Operates as an independent entity from Cardinal wholesaling business
- Licensed as a wholesale distributor in CA
- Industry leader in third-party healthcare logistics
- Programs are customized for each individual Client (Manufacturer) using the model that best meets their needs

LaVergne, TN, Distribution Center

Reno, NV, Distribution Center

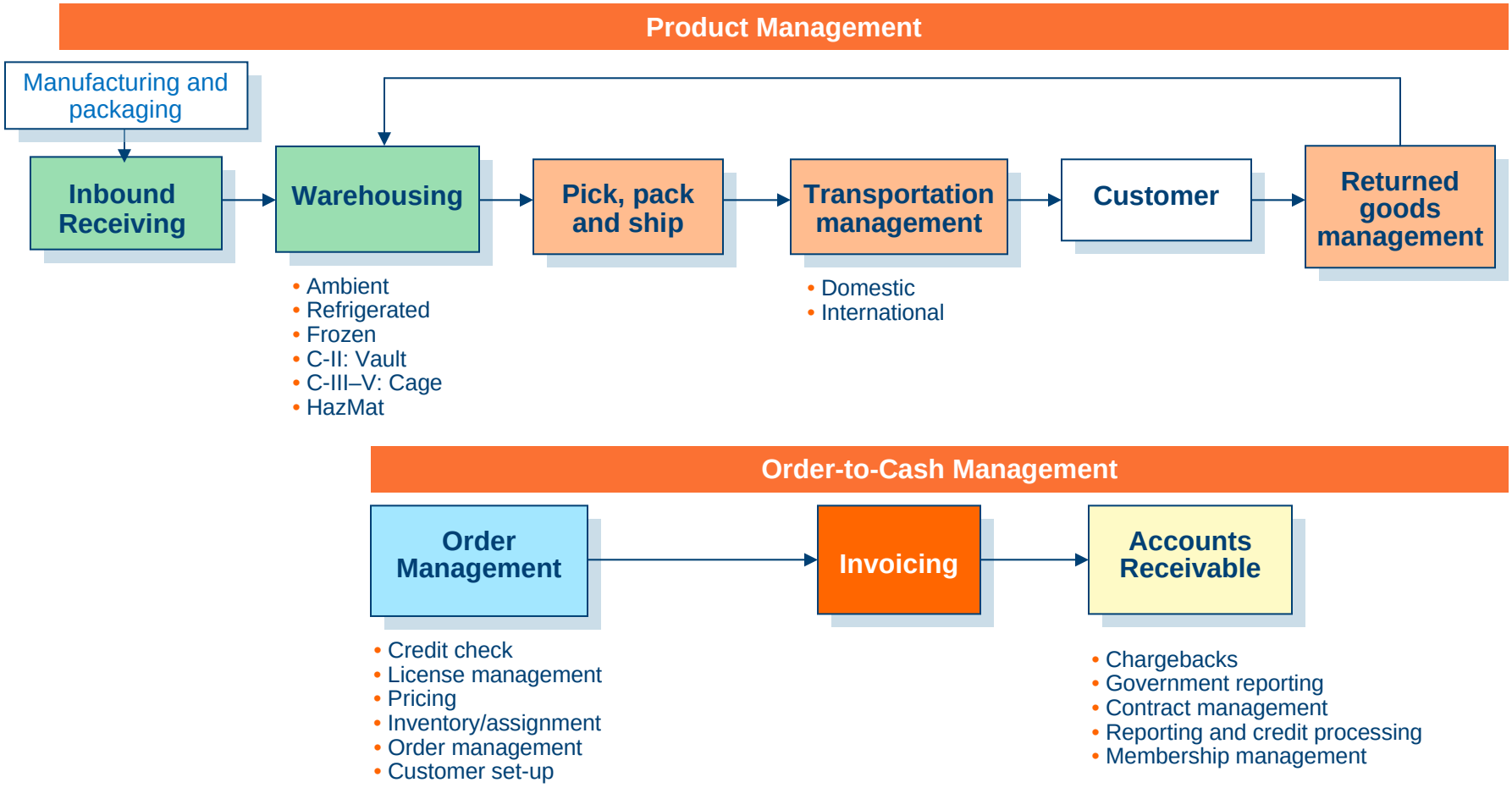
CardinalHealth
Essential to care™

Third-Party Logistics Background

Bus. & Prof. Code §4045: **Third-Party Logistics Provider or Reverse Third-Party Logistics Provider**

"Third-party logistics provider" or "reverse third-party logistic provider" means an entity *licensed as a wholesaler* that contracts with a dangerous drug manufacturer to provide or coordinate warehousing, distribution, or other similar services on behalf of a manufacturer, but for which there is *no change of ownership* in the dangerous drugs. For purposes of Sections 4034, 4163, 4163.1, 4163.2, 4163.3, 4163.4, and 4163.5, a third party logistics provider shall not be responsible for generating or updating pedigree documentation, but shall maintain copies of the pedigree. To be exempt from documentation for pedigrees, a reverse third-party logistic provider may only accept decommissioned drugs from pharmacies or wholesalers. (*Emphasis added*).

Third-Party Logistics Services



CardinalHealth
Essential to care™

Third-Party Logistics Summary

- DSI retains ownership of product entering 3PL until it is sold to customers
- 3PL provides Quality Assurance & Regulatory support, and inventory visibility in real-time
- CP/DSI/SPS all comply with FDA and state/federal laws

CardinalHealth
Essential to care™

Daiichi-Sankyo

Third-Party Logistics Providers (3PL's): An Overview

- Questions???

- Thank you