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

BUSINESS, CONSUMER SERVICES AND HOUSING AGENCY
DEPARTMENT OF CONSUMER AFFAIRS
GOVERNOR EDMUND G. BROWN JR.

ENFORCEMENT AND COMPOUNDING COMMITTEE REPORT

Amy Gutierrez, PharmD, Chair, Board President
Greg Lippe, Public Member, Vice Chair
Stan Weisser, Professional Member
Allen Schaad, Professional Member
Greg Murphy, Public Member

Report of the Enforcement and Compounding Committee meeting held on March 2, 2016.

I. ENFORCEMENT MATTERS

a. Update by the University of California, San Diego's Pilot Program to Permit Patients to Access Medications from an Automated Storage Device not Immediately Adjacent to a Pharmacy

At the Board of Pharmacy's April 2015 Board Meeting, the board approved an 18-month pilot study under the auspices of the UCSD School of Pharmacy involving use of an automated storage device for prescription medication for which staff of Sharp Hospital in San Diego and their families, who opt in, may pick up their outpatient medications from this device located in a hospital, instead of having to go to the community pharmacy. Consultation will be provided via telephone before medication can be dispensed to a patient.

This study was planned to start in June or July, 2015; however, at the September 9, 2015 Enforcement Committee meeting, Dr. Jan Hirsch, BS Pharm, PhD, spoke via telephone and anticipated the pilot study would not begin until December.

At the December 14, 2015 Enforcement Committee meeting, Dr. Jan Hirsch, BS Pharm, PhD, reported that they would launch the device, enroll patients and refine data collection tools and processes during the first quarter of 2016. During the third quarter of 2016, they will collect and review the data and report back to the board with their results.

At the Board of Pharmacy's February 2015 Board meeting, the board approved the committee's recommendation that UCSD collect drug classification data as part of the study.

At the Committee Meeting
Via telephone, Dr. Hirsch delivered a presentation on the progress of the implementation and reported that the program launched on January 20, 2016. Dr. Hirsh indicated that there are about 120 patients enrolled that want to use the ScriptCenter kiosk and confirmed that the

device was located in the secured, ground floor employee entrance at Sharp Memorial Hospital.

The committee heard many comments and questions from the public. Following this discussion, the committee recommended that UCSD track the number of employees and work hours of those who utilize the kiosk.

A copy of Dr. Hirsch's presentation is included in **Attachment 1**.

Committee Recommendation:
Recommend that the board ask UCSD for the number employees and work hours of those who utilize the kiosk as part of the study.

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b. Discussion and Update to the Board's Procedures to Waive Requirements During a Declared Emergency Pursuant to Business and Professions Code section 4062

On September 15, 2015, the board held an Emergency Board meeting in response to the wildfires in Lake and Napa counties. In light of the recent use of the policy it was brought to the board for evaluation and assessment to determine if changes to the policy are necessary.

At the October 28-29, 2015 Board meeting, this item was referred to the enforcement committee for discussion.

At the December 15, 2015, Enforcement Committee meeting, the committee recommended that the board modify the policy to delegate its authority pursuant to Business and Professions Code section 4062 to the board president for a period of 30 days.

At the February 25, 2016 Board meeting, the board approved the modified language. The new language will read as:

> In the event that the board is not able to convene a public meeting on regular notice or pursuant to the emergency meeting provisions of the Open Meetings Act, the board president may, on behalf of the board, exercise the powers delegated to full board pursuant to Business and Professions Code section 4062 for a period of 30 days.

At the Committee Meeting

Dr. Gutierrez reported that the board modified the policy language. Ms. Freedman clarified the board's intent with the policy language and indicated that the policy should read as:

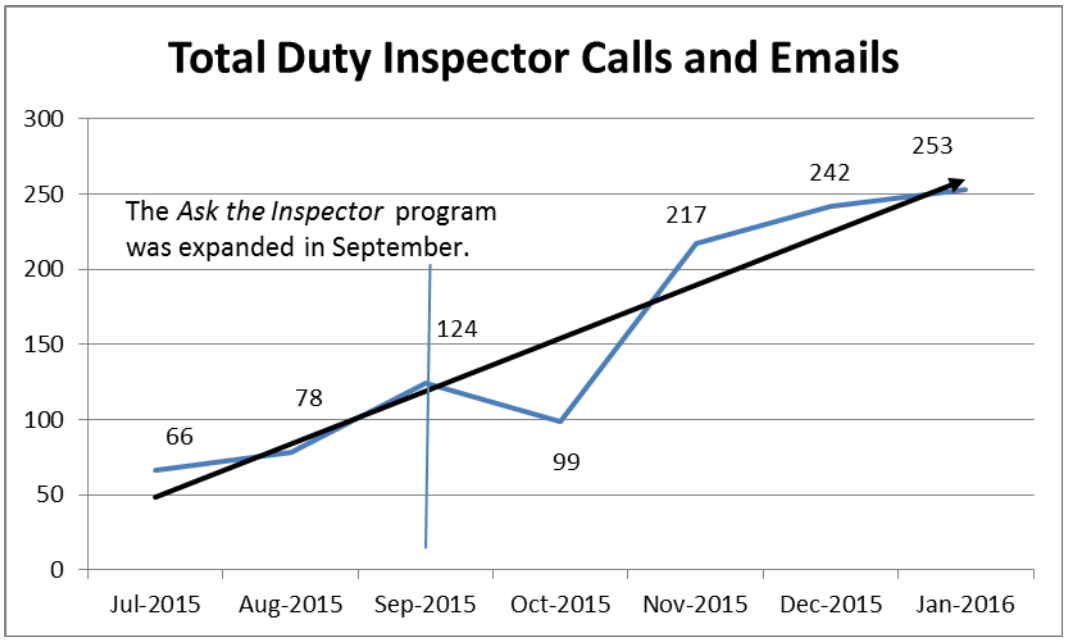
> In the event that the board is not able to convene a public meeting on regular notice or pursuant to the emergency meeting provisions of the Open Meetings Act, the board president may, on behalf of the board, exercise the powers pursuant to Business and Professions Code section 4062 for a period of 30 days.

There were no questions or comments.

c. Data Describing Duty Inspector Activities

From July 2015 through January 2016, the Complaint Unit resolved 166 *Ask the Inspector* inquiries. This is an average of 23 resolutions per month, with July being the lowest with 7 resolutions and January the highest with 40 resolutions. In addition, the Complaint Unit has screened 916 *Ask the Inspector* inquiries before escalating them to the weekly duty inspector for a response. This is an average of 130 inquiries per month.

Chart 1: *Ask the Inspector* Inquiries, by Month



Note: This graph includes inquiries resolved by the analyst as well as inquiries screened by the analyst and transferred to the weekly duty inspector for resolution.

The trend line shows the steady increase in calls and emails, an overall increase of 283%, from July 2015. The expansion of the *Ask the Inspector* service has caused a significant spike in activity for the Pharmacy board.

The board will continue to provide these statistics at future meetings.

At the Committee Meeting
Dr. Gutierrez reviewed duty inspector activity statistics.

Ms. Herold indicated that the board was working on an online FAQ directory. She estimated the FAQ's would be available in the next few months.

There were no questions or comments.

d. Automated Dispensing Machines – Available Drug Diversion Tools, Assessing Features Available, Training Provided to Pharmacy and Health Facility Staff. Summary of Presentations by:
1. Kaiser Permanente
2. BD CareFusion/Pyxis & Rx Auditor
3. Omnicell/Aesyent
4. Cerner Automated Cabinets
5. Talyst

At the September 9, 2015, Enforcement Committee meeting, staff suggested that a simple registration be established for pharmacies that operate each of these machines that identify their locations, as a beneficial step in board oversight and enforcement. The list could be updated as needed via form submission to the board when a pharmacy adds, moves or removes a machine. This registration could operate much like the off-site storage waivers for records waivers. At annual renewal of the pharmacy, the pharmacy license would update or confirm the list of machines it operates and where each is located. Staff has drafted proposed language for requiring every pharmacy that owns or provides dangerous drugs dispensed through an automated drug delivery system to provide the board, in writing, the location of each device.

At the Committee Meeting
The committee heard presentations that provided information on the secured log on features as well as the various types of reports that are available with each device. It was also noted that training and consultation is provided initially and over time.

e. Discussion on the Proposed Reconciliation and Inventory Report of Controlled Substances Regulation, Proposal to Add Title 16 California Code of Regulations Section 1715.65

This topic was not discussed at the committee meeting due to lack of time. **Attachment 2** contains the proposed language.

f. Enforcement Statistics

Attachment 3 includes the third quarter report of the Enforcement Statistics, SB 1441 Program Statistics and Citation and Fine Statistics.

II. COMPOUNDING MATTERS

a. Update on the Status of the Sterile Compounding Regulations, Title 16 California Code of Regulations Sections 1735 et seq., and 1751 et seq.

At the Committee Meeting
Ms. Herold provided an update on the sterile compounding regulations and indicated that board staff is compiling all the responses received and putting together the rulemaking file to be submitted for DCA legal review by mid-March. The board has set January 1, 2017 as the date for implementation.

Following this meeting the rulemaking file was submitted to DCA legal for review on March 10, 2016.

There were no questions or comments.

b. Summary of Presentation on FDA-Approved Alternative Testing Technologies to Assess Sterility and Potency in Compounded Medications in Use by Drug Manufacturers

At the Committee Meeting
The committee heard a presentation by Dr. Tony Cundell on the Alternative Sterility Testing of Compounding Sterile Preparations.

At the close of the presentation, Dr. Cundell concluded that alternative sterility testing methods for compounded sterile preparations, when properly validated, are supported by both the FDA and USP and their use will promote the safety compounded products and benefit the public health.

A copy Dr. Cundell's presentation is included in **Attachment 4**.

III. ADMINISTRATIVE MATTERS

c. Future Committee Meeting Dates

- June 1, 2016
- August 31, 2016

The full minutes of the March 2, 2016 Enforcement and Compounding Committee meeting, including copies of presentations, are provided in **Attachment 5**.

Attachment 1

Study of Expanded Use of an Automated Delivery Device

UPDATE 03-02-16

Jan D. Hirsch, BPharm, PhD
UCSD Skaggs School of Pharmacy & Pharmaceutical Sciences

UC San Diego
Health Sciences

Update

- ScriptCenter Kiosk
  - Up and Running!
- Update on Study
  - Reminder: Research Design & Questions
  - Employee Survey Results
  - IRB Amendment
  - Study Timeline

UC San Diego
Skaggs School of Pharmacy and Pharmaceutical Sciences

ScriptCenter Kiosk
Sharp Memorial Hospital

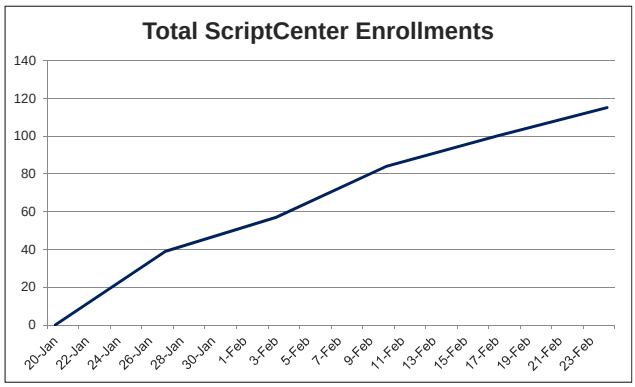
GO LIVE DATE = January 20th, 2016

Located at Sharp Memorial Hospital employee entrance on ground floor.
Secure access only.

UC San Diego
Skaggs School of Pharmacy and Pharmaceutical Sciences

ScriptCenter Kiosk
Activity 1/20/16 through 2/24/16

ENROLLMENT



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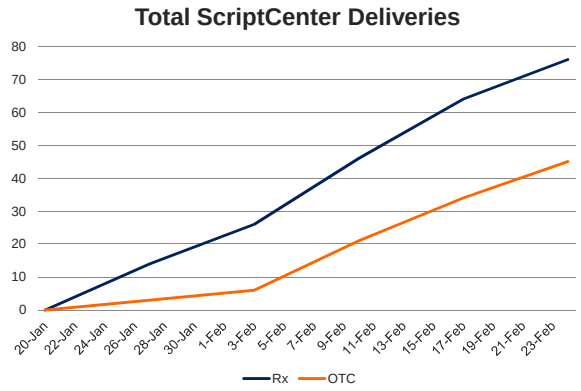
ScriptCenter Kiosk
Activity 1/20/16 through 2/24/16

DELIVERIES



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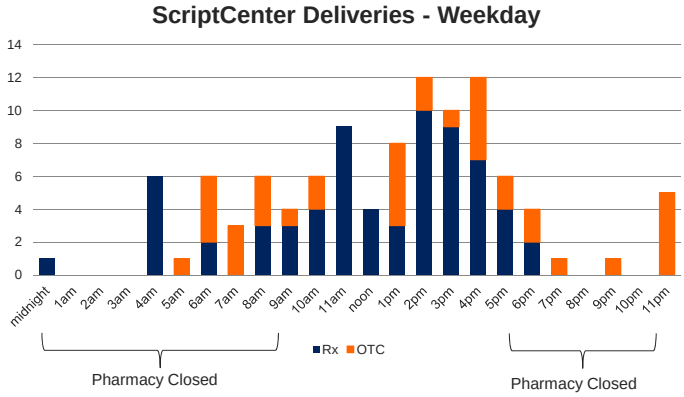
ScriptCenter Kiosk
Activity 1/20/16 through 2/24/16

DELIVERY TIMES - WEEKDAY



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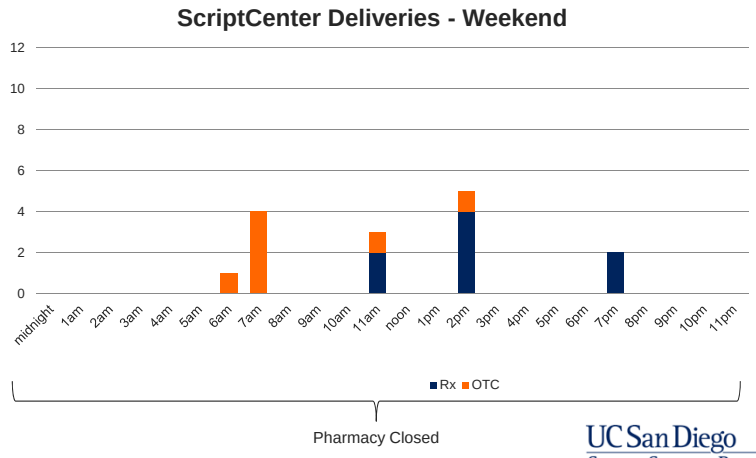
ScriptCenter Kiosk Activity 1/20/16 through 2/24/16

DELIVERY TIMES - WEEKEND



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Study Design

Quasi-experimental with non-randomized control group

- *Pre-Kiosk Implementation Survey (Sharp Employees)*

Kiosk Start

6 months pre-kiosk
(September 2015 – February 2016)

Regular Counter

- RTS rate*

Month 1 *(March)*

Kiosk

- RTS rate
- Consultation Log
- Time to Pick-up
- Kiosk Patient Satisfaction

Regular Counter

- RTS rate* *(May)*
- Consultation Log (1 week sample pts w/ new Rxs)
- Time to Pick-up*

Month 6
(August)

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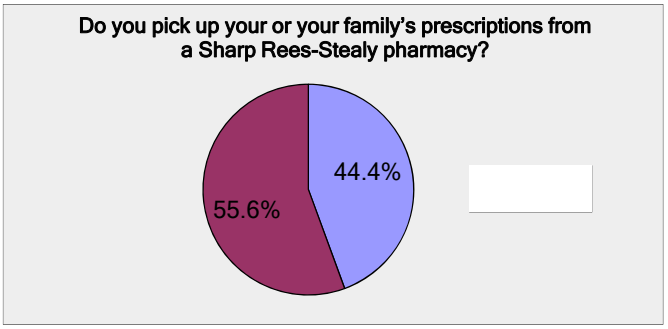
RTS = Return to Stock

* For employees and dependents

Pre-Kiosk Implementation Survey: Sharp Employees



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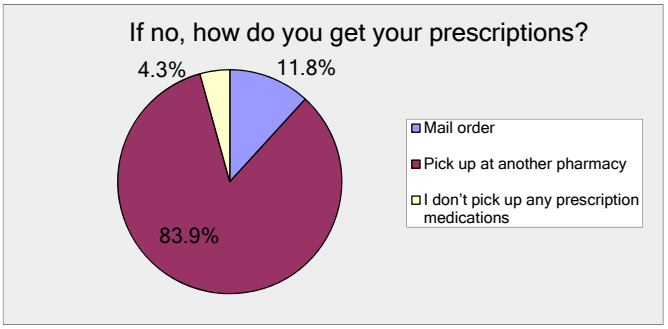
Pre-Kiosk Implementation Survey: Sharp Employees



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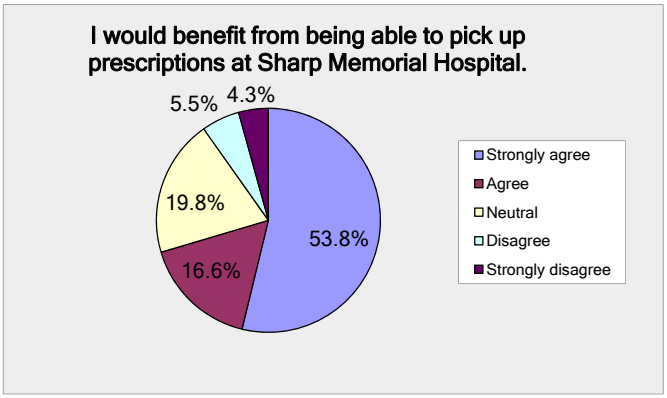
Pre-Kiosk Implementation Survey: Sharp Employees



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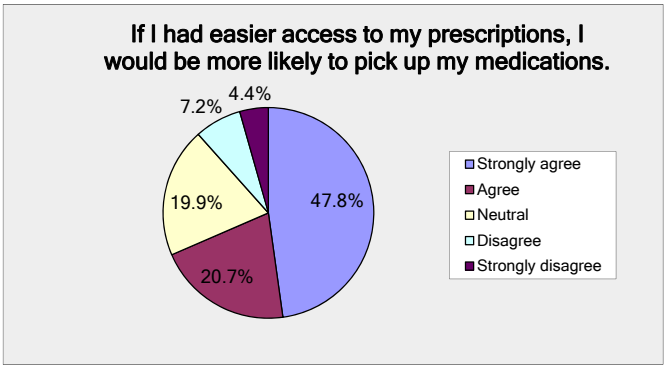
Pre-Kiosk Implementation Survey: Sharp Employees



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IRB Amendment: Therapeutic Categories

- December Enforcement Committee meeting
  - Requested to add analyses by therapeutic category

	Return to Stock Rate		Time to Pick Up		Number/Nature Questions for Pharmacist during Consultation		Patient Satisfaction
Therapeutic Category	Script Center	Regular Counter	Script Center	Regular Counter	Script Center	Regular Counter	Script Center Only
Anti-diabetics							
Anti-infectives							
Pain							
Anti-hypertensive							
Respiratory							
Mental Health							
Dermatology							
Etc.							

  - Can accomplish for “Return to Stock” and “Time to Pick Up”
  - Consultation and Satisfaction may be for multiple types of prescriptions

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Projected Study Timetable

- Q4 2015 — Pre-kiosk 6-month data collection phase begins
- Q1 2016 — Implement Kiosk device (1/20/16)
  Refine data collection tools & process
  Deployment of program/enroll patients
- Q2 & Q3 2016 — Post-kiosk implementation
  March – August — Data collection and analysis
- Q4 2016 — Report Results to Board

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Questions?

UC San Diego
SKAGGS SCHOOL OF PHARMACY AND PHARMACEUTICAL SCIENCES

Attachment 2

Title 16. Board of Pharmacy
Proposed Text

Adopt section 1715.65 in Article 2 of Division 17 of Title 16 of the California Code of Regulations to read as follows:

1715.65. Reconciliation and Inventory Report of Controlled Substances

(a) Every pharmacy, and every clinic licensed under sections 4180 or 4190, shall perform reconciliation and inventory functions to prevent the loss of controlled substances.
(b) The pharmacist-in-charge of a pharmacy or consultant pharmacist for a clinic shall review all reconciliations and inventories taken, and establish and maintain secure methods to prevent losses of controlled drugs. Written policies and procedures shall be developed for performing the reconciliation and inventory reports required by this section.
(c) Perform a Periodic Inventory: A pharmacy or clinic shall compile an Inventory Report of specific controlled substances at least every three months. The compilation of this Inventory Report shall require a physical count, not an estimate, of all quantities of federal Schedule II controlled substances and at least one additional controlled substance which may be specified by the board each year as based upon loss reports made to the board in the prior year. The Inventory Report shall be dated and signed by the individual(s) performing the inventory, and countersigned by the pharmacist-in-charge or consultant pharmacist.
    (1) The original or copy of the signed controlled substances Inventory Report shall be kept in the pharmacy or clinic and be readily retrievable for three years.
    (2) The biennial inventory of controlled substances required by federal law may serve as one of the mandated inventories under this section in the year where the federal biennial inventory is performed, provided:
        (A) A physical count of all controlled substances is performed, not an estimated count of how much medication is in a container.
        (B) The federal Drug Enforcement Administration biennial inventory was taken no more than three months from the last inventory required by this section.
(d) A new pharmacist-in-charge of the pharmacy shall complete an inventory as required by subdivision (c) within 30 days of becoming pharmacist-in-charge. Whenever possible an outgoing pharmacist-in-charge should complete an inventory as required in subdivision (c).
(e) Reconciliation with Inventory Report: The pharmacy or clinic shall review all acquisitions and dispositions of controlled substances as part of the inventory process to determine the expected stock of each controlled substance on hand, based on the prior Inventory Report. Records used to compile each reconciliation shall be maintained in the pharmacy or clinic for at least three years in a readily retrievable form.
    (1) Losses shall be identified in writing and reported to the board and, when appropriate, to the Drug Enforcement Administration.
    (2) Likely causes of overages shall be identified in writing and retained.

(3) Should the reconciliation identify controlled substances which had been in the inventory of the pharmacy or clinic during the prior six-month period, but for which there is no stock at the time of the physical count, the pharmacist-in-charge or consultant pharmacist shall determine there has been a loss of these controlled substances. These losses shall be reported in the manner specified by paragraph 1.

(f) Adjustments to the Inventory Report shall be made following reconciliation, only after the reporting and documenting of any losses or accounting made for overages.
   (1) Each adjustment to the Inventory Report made to correct the stock on hand count shall be annotated to show any adjustment in the number of controlled substances on hand in the pharmacy or clinic, and who made the annotation, and the date.
   (2) The pharmacist-in-charge or consultant pharmacist shall countersign the adjusted Inventory Report.
   (3) The original Inventory Report and amended Inventory Report following reconciliation shall be readily retrievable in the pharmacy or clinic for three years.

(g) The pharmacist-in-charge of a hospital pharmacy or of a pharmacy servicing skilled nursing homes where an automated drug delivery system is in use shall review at least once each month all controlled substances removed from or added into each automated drug delivery machine operated by the pharmacy. Any discrepancy or unusual access identified shall be investigated. Controlled drugs inappropriately accessed or removed from the automated delivery shall be reported to the board within 14 days.

(h) A pharmacy or clinic identifying losses of controlled drugs but unable to identify the cause within 30 days shall take additional steps to identify the origin of the losses, including installation of cameras, relocation of the controlled drugs to a more secure location within the pharmacy, or daily inventory counts of the drugs where shortages are continuing.

Authority cited: Section 4005, Business and Professions Code. Reference: Sections 4081, 4104 and 4332, Business and Professions Code.

Attachment 3

Board of Pharmacy Enforcement Statistics
Fiscal Year 2015/2016

Workload Statistics	July-Sept	Oct-Dec	Jan-Mar	Apr-June	Total 15/16
Complaints/Investigations					
Received	730	809	825		2364
Closed	751	658	704		2113
4301 letters	12	11	17		40
Pending (at the end of quarter)	2105	2269	2376		2376
Cases Assigned & Pending (by Team) at end of quarter*					
Compliance / Routine Team	787	945	910		910
Drug Diversion/Fraud	361	460	570		570
RX Abuse	95	158	141		141
Compounding	85	74	135		135
Probation/PRP	51	66	110		110
Mediation/Enforcement **	325	179	163		163
Criminal Conviction	401	367	339		339
Application Investigations					
Received	165	149	98		412
Closed					
Approved	118	94	71		283
Denied	32	17	22		71
Total ***	218	149	133		500
Pending (at the end of quarter)	138	125	97		125
Letter of Admonishment (LOA) / Citation & Fine					
LOAs Issued	56	54	46		156
Citations Issued	550	453	439		1442
Total Fines Collected ****	$451,827.69	$620,758.49	$501,390.41		$1,573,976.59

* This figure includes reports submitted to the supervisor and cases with SI awaiting assignment.

** This figure include reports submitted to the citation and fine unit, AG referral, as well as cases assigned to enf. Staff

*** This figure includes withdrawn applications.

****Fines collected (through 3/31/2016 and reports in previous fiscal year.)

Board of Pharmacy Enforcement Statistics
Fiscal Year 2015/2016

Workload Statistics	July-Sept	Oct-Dec	Jan-Mar	Apr-June	Total 15/16
Administrative Cases (by effective date of decision)					
Referred to AG's Office*	126	101	104		331
Accusations Filed	73	65	61		199
Statement of Issues Filed	17	14	7		38
Petitions to Revoke Filed	2	1	3		6
Pending					
Pre-accusation	271	269	279		279
Post Accusation	260	271	265		265
Total*	600	587	567		567
Closed					
Revocation					
Pharmacist	3	7	3		13
Intern Pharmacist	1	0	1		2
Pharmacy Technician	24	26	31		81
Designated Representative	1	0	0		1
Wholesaler	0	0	0		0
Sterile Compounding	0	0	0		0
Pharmacy	1	2	3		6
Revocation,stayed; suspension/probation					
Pharmacist	4	2	2		8
Intern Pharmacist	0	0	0		0
Pharmacy Technician	1	0	0		1
Designated Representative	0	0	0		0
Wholesaler	0	0	0		0
Sterile Compounding	0	0	0		0
Pharmacy	0	0	0		0
Revocation,stayed; probation					
Pharmacist	11	6	13		30
Intern Pharmacist	0	0	0		0
Pharmacy Technician	3	3	1		7
Designated Representative	0	0	0		0
Wholesaler	0	0	0		0
Sterile Compounding	0	1	0		1
Pharmacy	5	4	4		13
Surrender/Voluntary Surrender					
Pharmacist	3	7	5		15
Intern Pharmacist	0	0	0		0
Pharmacy Technician	4	9	9		22
Designated Representative	0	0	0		0
Wholesaler	0	0	0		0
Sterile Compounding	0	0	1		1
Pharmacy	5	3	6		14

Board of Pharmacy Enforcement Statistics
Fiscal Year 2015/2016

Workload Statistics	July-Sept	Oct-Dec	Jan-Mar	Apr-June	Total 15/16
Public Reproval/Reprimand					
Pharmacist	3	2	0		5
Intern Pharmacist	0	0	0		0
Pharmacy Technician	0	0	1		1
Designated Representative	0	0	0		0
Wholesaler	0	0	0		0
Sterile Compounding	1	0	1		2
Pharmacy	1	1	2		4
Licenses Granted					
Pharmacist	0	0	2		2
Intern Pharmacist	0	0	0		0
Pharmacy Technician	3	0	1		4
Designated Representative	0	0	0		0
Wholesaler	0	0	0		0
Sterile Compounding	0	0	0		0
Pharmacy	0	0	0		0
Licenses Denied					
Pharmacist	0	0	0		0
Intern Pharmacist	0	0	0		0
Pharmacy Technician	2	4	1		7
Designated Representative	0	0	0		0
Wholesaler	0	0	0		0
Sterile Compounding	0	0	0		0
Pharmacy	0	0	0		0
Cost Recovery Requested**	$355,106.58	$308,117.75	$331,045.40		$994,269.73
Cost Recovery Collected**	$314,805.00	$85,183.45	$164,468.62		$564,457.07

* This figure includes Citation Appeals

** This figure includes administrative penalties

Immediate Public Protection Sanctions					
Interim Suspension Order	3	1	2		6
Automatic Suspension / Based on Conviction	1	0	0		1
Penal Code 23 Restriction	8	6	6		20
Cease & Desist - Sterile Compounding	1	0	0		1

Board of Pharmacy Enforcement Statistics
Fiscal Year 2015/2016

Workload Statistics	July-Sept	Oct-Dec	Jan-Mar	Apr-June	Total 15/16
Probation Statistics					
Licenses on Probation					
Pharmacist	149	151	161		151
Intern Pharmacist	3	3	3		3
Pharmacy Technician	37	36	35		36
Designated Representative	3	3	3		3
Pharmacy	42	43	49		43
Sterile Compounding	6	9	9		9
Wholesaler	2	2	2		2
Probation Office Conferences	35	27	24		27
Probation Site Inspections	106	139	83		139
Successful Completion	5	6	5		6
Probationers Referred to AG for non-compliance	0	0	3		3

As part of probation monitoring, the board requires licensees to appear before the supervising inspector at probation office conferences. These conferences are used as 1) an orientation to probation and the specific requirements of probation at the onset, 2) to address areas of non-compliance when other efforts such as letters have failed, and 3) when a licensee is scheduled to end probation.

As of March 31, 2016.

SB 1441 – Program Statistics

Licensees with substance abuse problems who are either on board probation and/or participating in the Pharmacist Recovery Program (PRP)

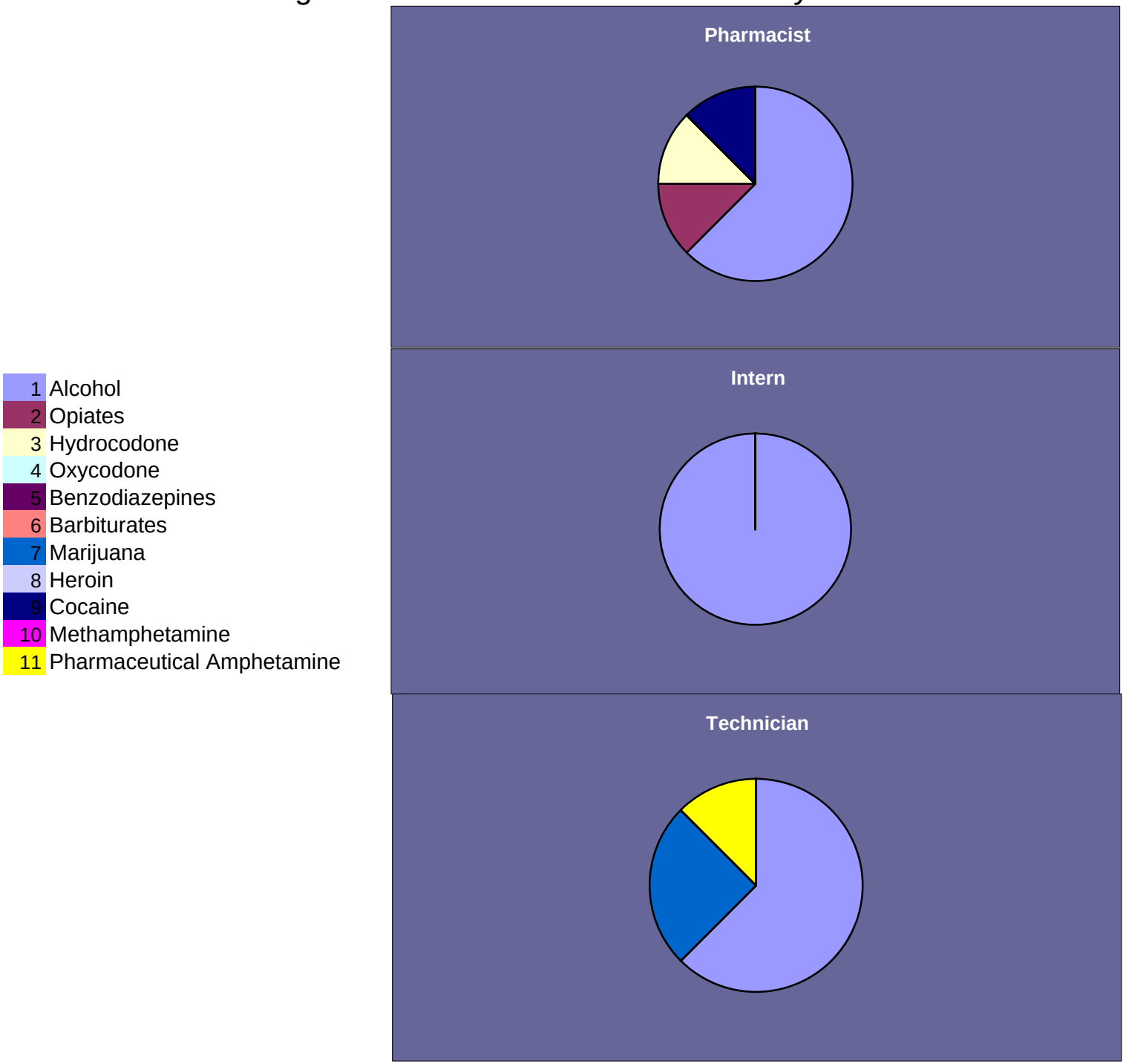
Board of Pharmacy	July -Sep	Oct – Dec	Jan-Mar	Apr-Jun	Total 15/16
PRP Intakes					
PRP Self-Referrals	1	1			2
PRP Board Referrals	1	2	2		5
PRP Under Investigation	3	1	1		5
PRP In Lieu Of			1		1
Total Number of PRP Intakes	5	4	4		13
New Probationers					
Pharmacists	3	4	5		12
Interns		1			1
Technicians	3	2	1		6
Total New Probationers	6	7	6		19
PRP Participants and Contracts					
Total PRP Participants	66	63	60		N/A
Contracts Reviewed	61	60	64		185
Probationers and Inspections					
Total Probationers	82	85	83		N/A
Inspections Completed	106	139	83		328
PRP Referrals to Treatment					
Referrals to Treatment	6	5	3		14
Drug Tests					
Drug Test Ordered	1006	874	525		2405
Drug Tests Conducted	974	857	516		2347
Relapse					
Relapsed	3	7	6		16
Major Violation Actions					
Cease Practice/Suspension	7	11	14		32
Termination - PRP	1	1			2
Referral for Discipline		1	2		3
Exit from PRP or Probation					
Successful Completion	5	3	7		15
Termination - Probation		1			1
Voluntary Surrender	4		5		9
Surrender as a result of PTR		1			1
Public Risk	1	1	2		4
Non-compliance	8	14	12		34
Other	4	1	1		6
Patients Harmed					
Number of Patients Harmed	None	None	None	None	None

SB 1441 – Program Statistics

Licensees with substance abuse problems who are either on board probation and/or participating in the Pharmacist Recovery Program (PRP)

Board of Pharmacy	July -Sep	Oct – Dec	Jan-Mar	Apr-Jun	Total 15/16
Drug of Choice at PRP Intake or Probation					
Pharmacists	**July-Sep**	**Oct-Dec**	**Jan-Mar**	**Apr-Jun**	**Total 15/16**
Alcohol	2	2	1		5
Ambien		1			1
Opiates		1			1
Hydrocodone					
Oxycodone					
Morphine					
Benzodiazepines					
Barbiturates					
Marijuana			1		1
Heroin					
Cocaine					
Methamphetamine					
Pharmaceutical Amphetamine					
Phentermine					
Methadone					
Zolpidem Tartrate					
Hydromorphone					
Clonazepam					
Tramadol					
Carisprodol					
Phendimetrazine					
Promethazine w/Codeine					
Intern Pharmacists	**July-Sep**	**Oct-Dec**	**Jan-Mar**	**Apr-Jun**	**Total 15/16**
Alcohol		1			1
Opiates					
Hydrocodone					
Oxycodone					
Benzodiazepines					
Barbiturates					
Marijuana					
Heroin					
Cocaine					
Methamphetamine					
Pharmaceutical Amphetamine					
Phentermine					
Methadone					
Zolpidem Tartrate					
Hydromorphone					
Clonazepam					
Tramadol					
Carisprodol					
Phendimetrazine					
Promethazine w/Codeine					
Pharmacy Technicians	**July-Sep**	**Oct-Dec**	**Jan-Mar**	**Apr-Jun**	**Total 15/16**
Alcohol	3	1	1		5
Opiates					
Hydrocodone					
Oxycodone					
Benzodiazepines					
Barbiturates					
Marijuana	1	1			2
Heroin					
Cocaine					
Methamphetamine					
Pharmaceutical Amphetamine		1			1
Phentermine					
Methadone					
Zolpidem Tartrate					
Hydromorphone					
Clonazepam					
Tramadol					
Carisprodol					
Phendimetrazine					
Promethazine w/Codeine					

Drug Of Choice - Data entered from July 2014 to June 2015



Printed on 4/13/2016

Board of Pharmacy Citation and Fine Statistics
July 1, 2015 - March 31, 2016

Citation Breakdown by License Type

Total Issued	RPH with Fine	RPH no Fine	PHY with Fine	PHY no Fine	PIC with Fine**	PIC no Fine**	TCH with Fine	TCH no Fine
1446	538	59	261	184	267	101	255	1

Citation Breakdown by Miscellaneous License Type

Wholesalers	Exemptee's	Clinics	Drug Room	Exempt Hosp.	Hosp. Pharmacy	Misc.*	Unlicensed Premises	Unlicensed person
15	16	4	1	6	8	70	27	1

*Intern Pharmacist, Licensed Correctional Facilities, Exempt Pharmacies, Non-Resident Pharmacies, and Vet Retailers

**These numbers are also represented in the RPH columns, but reflect how many RPHs were cited as PICs

Top Ten Violations by License Type
July 1, 2015 - March 31, 2016

Pharmacists	%	Pharmacies	%	Pharmacists In Charge	%
1716 - Variation from prescription	44%	**1716** - Variation from prescription	46%	**1714(d)** - Operational Standards and Security; Pharmacist responsible for pharmacy security	29%
1714(d) - Operational Standards and Security; Pharmacist responsible for pharmacy security	13%	**1714(b)** - Operational Standards and Security; pharmacy responsible for pharmacy security	20%	**1716** - Variation from prescription	28%
1764/56.10(a) - Unauthorized disclosure of prescription and medical information	8%	**1764/56.10(a)** - Unauthorized disclosure of prescription and medical information	8%	**1764/56.10(a)** - Unauthorized disclosure of prescription and medical information	8%
1707.2(b)(1)(A) - In addition to the obligation to consult…a pharmacist shall provide oral consultation to his or her patients…whenever the prescription drug has not previously been dispensed to a patient…	6%	**1707.3** - Duty to review drug therapy	5%	**1714(b)** - Operational Standards and Security; pharmacy responsible for pharmacy security	7%
1707.3 - Duty to review drug therapy	5%	**1707.2(b)(1)(A)** - In addition to the obligation to consult…a pharmacist shall provide oral consultation to his or her patients…whenever the prescription drug has not previously been dispensed to a patient	4%	**4081(a)** - Records of Dangerous Drugs and Devices Kept Open for Inspection; Maintenance of Records, Current Inventory	7%
1714(b) - Operational Standards and Security; pharmacy responsible for pharmacy security	5%	**4113(d)** - Every pharmacy shall notify the board in writing within 30 days of the date of a change in pharmacist-in-charge	4%	**1707.2(b)(1)(A)** - In addition to the obligation to consult…a pharmacist shall provide oral consultation to his or her patients…whenever the prescription drug has not previously been dispensed to a patient	5%
4301(h) - Unprofessional Conduct – The administering to oneself, of any controlled substance, or the use of any dangerous drug or of alcoholic beverages to the extent or in a manner as to be dangerous	4%	**4081(a)** - Records of Dangerous Drugs and Devices Kept Open for Inspection; Maintenance of Records, Current Inventory	4%	**1735.2(j)** - Compounding Requirements- Pharmacist-in-Charge shall complete a compounding self-assessment prior to any sterile injectable compounding is performed in pharmacy and must be completed before July 1st of each odd numbered year	4%
4301(g) - Unprofessional Conduct - Knowingly making or signing any certificate or other document that falsely represents the existence or nonexistence of a state of facts	4%	**4113(a)** - Pharmacist-in-Charge: Notification to Board; Responsibilities; Every pharmacy shall designate a pharmacist-in-charge within 30 days in writing of the identity and license number of that pharmacist and the date he or she was designated	3%	**1707.3** - Duty to review drug therapy	4%
4231(d)/1732.5 - Failure to provide documentation substantiating completion of continuing education/Renewal Requirements for Pharmacist	4%	**1735.2(j)** - Compounding Requirements- Pharmacist-in-Charge shall complete a compounding self-assessment prior to any sterile injectable compounding is performed in pharmacy and must be completed before July 1st of each odd numbered year...	3%	**1711(d)** - Quality assurance program finding shall be used to develop systems to prevent medication errors…	3%
4301(l) - Unprofessional Conduct - Conviction of a crime substantially related to the practice of pharmacy	4%	**1711(d)** - Quality assurance program finding shall be used to develop systems to prevent medication errors…	3%	**1735.5(b)** - Policy and Procedure Manual shall be reviewed on an annual basis by the pharmacist-in-charge and shall be updated whenever changes in processes are implemented	3%

Attachment 4

Alternative Sterility Testing of Compounded Sterile Preparations

Presentation to the California Board of Pharmacy
March 2, 2016

californiapharmacistsassociation

Presenters

Introduction

Brian Warren
California Pharmacists Association

Technical Review

Tony Cundell, Ph. D.

Microbiological Consulting, LLC, Scarsdale, NY

& Member of the USP Microbiology Expert Committee

californiapharmacistsassociation

Questions & Answers

- **Question:** What are “alternative sterility testing methods”?
- **Answer:** They are methods for testing the sterility of a drug, biologic product or compounded preparation that differ from the compendial sterility test described in USP <71> that met the validation requirements as found in USP <1223>.

Questions & Answers

- **Question:** Why should the California Board of Pharmacy regulations governing sterile compounding pharmacies allow for use of alternative sterility tests? What are the advantages of using an alternative method to the USP <71> Sterility Test?
- **Answer:** The compendial sterility test being a growth-based test using microbiological culture media has an incubation time of at least 14 days. This incubation period is often incompatible with the beyond use dating, shipping, and inventory control of CSPs. We believe that the availability of a real time sterility test is in the interest of public health and safety.

Questions & Answers

- **Question:** What are the other limitations of the USP <71> sterility test?
- **Answer:** The selection of the media, i.e., Fluid Thioglycollate Medium and Soybean-Casein Digest Media, incubation temperature and incubation time were a compromise, not all microorganisms will grow under these conditions, and over 30% of the sterility failures occur between 7 and 14 days of incubation. Scoring growth in the media in form of turbidity, pellicle formation, precipitation and floccular growth is subjective.

Questions & Answers

- **Question:** What technologies are the most commonly use as alternative rapid microbial methods to test pharmaceutical products?
- **Answer:** These methods are usually based on the detection of various aspects of microbial physiology (ATP bioluminescence, CO_2 production, nucleic acid amplification, fluorescence of viable organisms, etc.), not the visualization of microbial growth in terms of turbidity or colony formation.

Questions & Answers

- **Question:** Are there alternative sterility test methods available that can test CSPs in less than 14 days?
- **Answer:** Yes. A number of microbiology instrument companies sell sterility testing technologies which reduce the time to result of a sterility test to 7 days or less. Today, only a system based on Solid Phase Laser Scanning Cytometry can detect viable organism(s) without requiring growth and conduct a sterility test in less than 4 hours.

Questions & Answers

- **Question:** Does the USP allow for alternative sterility test methods?
- **Answer:** Yes. According to General Notice 6.30, alternative methods and/or procedures may be used if they provide advantages in terms of accuracy, sensitivity, precision, selectivity, or adaptability to automation or computerized data reduction, or in other special circumstances. Such alternative procedures and methods shall be **validated as described in the general chapter *Validation of Compendial Procedures* <1225> and must be shown to give equivalent or better results.**

Questions & Answers

- **Question:** Does the USP explicitly support alternative sterility tests for Compounded Sterile Preparations?
- **Answer:** Yes. USP <797> *Pharmaceutical Compounding – Sterile Preparations* states that high-risk compounded sterile preparations shall meet the sterility test (see Sterility Tests <71>) before they are dispensed or administered. The chapter states that a method not described in the USP **may be used if verified results demonstrate that the alternative is as least as effective and reliable as the <71> test**.

Questions & Answers

- **Question:** Does the FDA support the use of alternative sterility tests?
- **Answer:** Yes. The 2004 FDA Aseptic Processing Guidance for Industry states that other suitable microbiological test methods (e.g., rapid test methods) can be considered for environmental monitoring, in-process control testing, and finished product release testing after it is demonstrated that the methods are equivalent or better than traditional methods (e.g., USP methods).

Questions & Answers

- **Question:** Does the current FDA Strategic Plan address alternative microbiological test methods?

- **Answer:** Yes. The strategic plan acknowledges that analytical technologies are rapidly changing and leading to dramatic improvements in sensitivity, resolution, and precision in the detection of contaminants. In order to better reduce the risk of microbial contamination of products, the following needs will be addressed:
  Develop sensitive, rapid, high-throughput methods to detect, identify, and enumerate microbial contaminants and validate their utility in assessing product sterility.

Questions & Answers

- **Question:** Does the FDA specifically approve alternative methods to the USP <71> Sterility Tests for drug products?

- **Answer:** No. The FDA approves **regulatory filings** for manufactured pharmaceutical products **including their specifications and analytical methods for the release of a drug product** to the market. *However, CSPs are exempt from New Drug Applications (NDA).*
  Sterile compounding facilities, working with the instrument company, are responsible for the validation of alternative methods. **Documentation associated with the qualification of the method for each CSP is reviewed during regulatory inspections as part of the 503B registration process**.

Questions & Answers

- **Question:** Do FDA podium presentations at technical meetings and publications support alternative microbial test methods?
- **Answer:** Yes. During the 2007 PDA Annual Global Conference on Pharmaceutical Microbiology Dr. Brenda Uratani, consumer safety officer for the Center for Drug Evaluation and Research (CDER), described the benefits of using a RMM, and these included: automating the testing process, electronic capture of test data and information creation, the ability to initiate investigations earlier as compared with conventional methods, the reduction of risk associated with microbial contamination, and the use of the data as a continuum for process improvement.

Questions & Answers

- **Question:** Do FDA technical publications support alternative microbial test methods?
- **Answer**: Yes. Dr. Bryan Riley, CDER New Drug Microbiology Staff, published a 2004 paper *Rapid Microbiology Methods in the Pharmaceutical Industry.* He wrote, "The use of rapid microbiology methods by the pharmaceutical industry should offer many advantages. Receiving microbiology test results sooner will provide for better control and understanding of the manufacturing process via faster feedback."

  "Appropriate validation of rapid microbiology methods is necessary to ensure that the test is suitable for its intended purpose."

Questions & Answers

- **Question:** Do FDA publications support alternative microbial test methods?
- **Answer:** Yes, in 2006, Drs. Hussong and Mello, in the CDER paper *Alternative Microbiology Methods and Pharmaceutical Quality Control* stated: "New microbiology methods can offer advantages of speed and precision for solving microbiological problems associated with materials or environmental influences. Neither corporate economics nor regulatory attitudes should be a barrier to the use of new testing technologies or different measurement parameters"

Questions & Answers

- **Question:** Do FDA technical presentations support alternative microbial test methods?
- **Answer:** Yes, Erika Pfeiler (FDA) gave the Agency's position on alternative microbiology methods (AMMs) at the 2015 USP <1223> Workshop. She reviewed FDA's policies and stated that CDER has approved AMMs for water testing, environmental monitoring, bioburden testing, microbial limits (for release and stability) and sterility testing (for release and stability). She stated that FDA welcomes submissions for the use of AMMs, they are routinely approving around 5 AMMs annually, different approaches to validation are acceptable and validation studies should depend on your product and process.

Questions & Answers

- **Question:** Has the FDA position on alternative sterility testing extended to the GMP regulations?

- **Answer:** Yes. In May 2012, the FDA amended the 21 CFR 610.12 sterility test requirements for biological products in their Final Rule, *Amendments to Sterility Test Requirements for Biological Products*. The Final Rule provides specific guidance when it comes to RMMs, especially as they relate to validation. For example, a novel method is required to be validated in accordance with an established protocol to demonstrate that the test is capable of consistently detecting the presence of viable microorganisms.

Questions & Answers

- **Question:** Is it likely the use of alternative sterility tests will be included in GMP regulations for Section 503B outsourcing sterile compounding facilities?

- **Answer:** Yes. In *G. Release Testing* the interim GMPs state that USP <71> "Sterility Tests" is the principal source used for sterility testing methods, and requires that the number of samples for batches of parenteral drug products containing less than 100 containers be 10% or 4 containers, whichever is greater. This implies that according to the USP General Notices alternative methods, if validated, could be used in place of USP <71>.

Questions & Answers

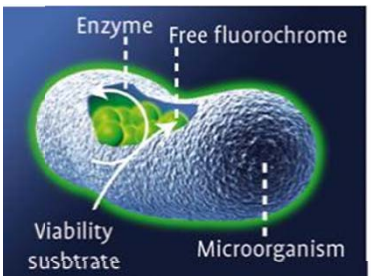
- **Question:** How is the Solid Phase Laser Scanning Cytometry instrument used to conduct a sterility test?

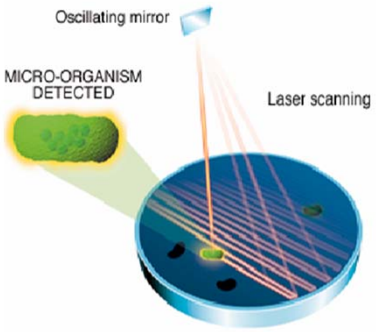
- **Answer:** The number of units and the quantity of the CSP as specified in Tables 2 and 3 of USP <71> is filtered using a sterile filtration unit to trap microorganisms which are then treated with reagents to determine their viability. Only viable organisms are capable of enzymatically cleaving the non-fluorescent substrate and retaining the fluorescent end-products. The appearance of fluorescence (a fluorescent event) is determined by a solid phase cytometer system. Confirmation of the fluorescent event being due to a microorganism is carried out by microscopic examination.

Solid Phase LASER Scanning Cytometry

Solid Phase LASER Scanning Cytometry

Criteria of Viability
- Enzymatic activity
- Membrane activity





Questions & Answers

- **Question**: How would a sterile compounding pharmacy go about validating an alternative sterility test using Solid Phase LASER Scanning Cytometry?

- **Answer:** The validation requirements for sterility test as outlined in USP <1223> are accuracy, specificity, limit of detection, robustness, ruggedness and method suitability. bioMerieux has demonstrated and documented the equivalence or superiority of their the *ScanRDI®* System to USP <71> following these requirements with the exception of method suitability that would need to be demonstrated for each CSP by the compounding pharmacy. bioMerieux provides all documentation, training and on site support to allow the compounding pharmacy to successfully conduct method suitability on their CSPs.

Questions & Answers

- Question: Can a 503A sterile compounding pharmacy use a contract testing laboratory to run sterility tests on their CSPs? If so, whom is responsible for the method qualification?

- Answer: Yes, a compounding pharmacy can use a contract lab to conduct the <71> sterility test provided specified number of unit and quantities per media and the method suitability requirements are met. If an alternative sterility test method is used it must meet the validation requirements found in USP <1223> and the method suitability testing found in USP <71>. It is the pharmacy's responsibility to confirm that all these requirements are met.

Questions & Answers

- **Question:** Is this validation strategy acceptable to the FDA and has it been successfully implement by any compounding pharmacy?
- **Answer:** Yes. Representatives from bioMerieux presented the details of their Solid Phase LASER Scanning Cytometry System (*ScanRDI®*), its application for CSP sterility testing and the division of responsibility in method validation to a large FDA audience on September 22, 2014 at the FDA headquarters in Silver Spring, MD. Based on an extensive question period after the presentation, we concluded that the FDA was comfortable with the path forward to the implementation of the technology for sterility testing at sterile compounding pharmacies.

Questions & Answers

- **Question:** Given the limited technical resources available to the CABOP, can the sterile compounding industry assist with the training of the CABOP management, technical staff and auditors on CSP alternative sterility testing?
- **Answer:** Definitely, the CPhA would be willing to sponsor training programs for both compounding pharmacists and state regulators on the selection, validation, and implementation of alternative sterility tests for compounded sterile preparations.

Conclusions

- Alternative sterility testing methods for compounded sterile preparations, when properly validated, are supported by both the FDA and USP and their use will promote the safety compounded products and benefit public health.
- We encourage the Enforcement and Compounding Committee to continue to investigate this issue and include authority to use alternative sterility testing methods in future regulations according to USP and FDA requirements.

Attachment 5

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

BUSINESS, CONSUMER SERVICES AND HOUSING AGENCY
DEPARTMENT OF CONSUMER AFFAIRS
GOVERNOR EDMUND G. BROWN JR.

STATE BOARD OF PHARMACY
DEPARTMENT OF CONSUMER AFFAIRS
ENFORCEMENT AND COMPOUNDING COMMITTEE
MEETING MINUTES

DATE: March 2, 2016

LOCATION: DCA Headquarters, Building Two
1747 North Market Blvd., Room 186
Sacramento, CA 95834

COMMITTEE MEMBERS PRESENT:
Amy Gutierrez, PharmD, Chair, Professional Member
Greg Lippe, Public Member, Vice Chair
Stan Weisser, Professional Member
Allen Schaad, Professional Member

COMMITTEE MEMBERS NOT PRESENT:
Greg Murphy, Public Member

STAFF PRESENT:
Virginia Herold, Executive Officer
Anne Sodergren, Assistant Executive Officer
Janice Dang, PharmD, Supervising Inspector
Christine Acosta, PharmD, Supervising Inspector
Laura Freedman, DCA Staff Counsel
Susan Cappello, Enforcement Manager
Kelli Williams, Complaint Unit Manager
Debbie Damoth, Administration Unit Manger

Call to Order

Dr. Gutierrez, chair of the committee, called the meeting to order at 10:16 a.m.

Dr. Gutierrez welcomed those in attendance. Roll call of the board members present was taken and a quorum of the committee was established.

I. PUBLIC COMMENT FOR ITEMS NOT ON THE AGENDA/AGENDA ITEMS FOR FUTURE MEETINGS

Note: The committee may not discuss or take action on any matter raised during this public comment section that is not included on this agenda, except to recommend whether to place the matter on the agenda of a future meeting. [Government Code Sections 11125, 11125.7(a)]

No public comments were received.

II. ENFORCEMENT MATTERS

a. Update by the University of California, San Diego on Its Pilot Program to Permit Patients to Access Medication from an Automated Storage Device not Immediately Adjacent to a Pharmacy

Background

At the Board of Pharmacy's April 2015 Board Meeting, the board approved an 18-month pilot study under the auspices of the UCSD School of Pharmacy involving use of an automated storage device for prescription medication for which staff of Sharp Hospital in San Diego and their families, who opt in, may pick up their outpatient medications from this device which is located in a hospital, instead of having to go to the community pharmacy. Consultation will be provided via telephone before medication is dispensed to a patient.

This study was planned to start in June or July, 2015; however, at the September 9, 2015 Enforcement Committee meeting, Dr. Jan Hirsch, BS Pharm, PhD, spoke via telephone and anticipated the pilot study would not begin until December.

At the December 14, 2015 Enforcement Committee Meeting, Dr. Jan Hirsch, BS Pharm, PhD, reported that they would launch the device, enroll patients and refine data collection tools and processes during the first quarter of 2016. During the third quarter of 2016, they will collect and review the data and report back to the board with their results.

Also at the December Enforcement Committee meeting the committee recommended that the board ask UCSD to collect drug classification data as part of the study.

At the Board of Pharmacy's February 2016 Board Meeting, the board approved this recommendation.

Discussion and Comment

At this meeting, via telephone, Dr. Hirsch delivered a presentation on the progress of the implementation and reported that the program launched on January 20, 2016. Dr. Hirsh indicated that there are about 120 patients enrolled that want to use the ScriptCenter kiosk and confirmed that the device was located in the secured, ground floor employee entrance at Sharp Memorial Hospital.

Dr. Hirsch also indicated that the kiosk is getting some activity during the morning hours but most of the activity is during pharmacy hours with a little activity on the weekends when the pharmacy is closed.

Mr. Weisser asked for information on consultations and how often consultations are requested and provided. Mr. Weisser was advised that if it was a new prescription, consultation was delivered. No information was available at the time detailing how many prescriptions were new versus refills.

Mr. Weisser also asked how many potential users there could be and if the 120 that were enrolled so far was what was expected. Mr. Weisser further asked how Sharp felt about the current results. Dr. Hirsch indicated that she'd have to report back on the number of potential users but indicated that Sharp was pleased so far with the results.

Dr. Hirsch was advised that the board approved the recommendation to include the drug classification data in the study. Dr. Hirsch indicated that she would submit the Institutional Review Board (IRB) amendment.

Steve Gray, representing Kaiser, congratulated UCSD and Sharp Memorial for implementing this study.

Dr. Gray sought clarification on whether "delivery" meant "picked up" and was advised that it did. Dr. Gray further asked for the ratio of employees and the overall number of employees on duty or finishing duty after hours versus those finishing duty during regular pharmacy hours to better understand how and when employees are utilizing the kiosk.

Laura Freedman, legal counsel, clarified that a member of the public requested that the number of employees be reported as part of the study. Ms. Freedman further stated that the committee would need to request that information from UCSD for it to be reported as part of the study and that committee could make a recommendation to the full board.

Committee Recommendation:
Motion: Recommend that the board ask UCSD for the number employees and work hours of those who utilize the kiosk as part of the study.

M/S: Lippe/Weisser
Support: 4 Oppose: 0 Abstain: 0

There were no questions or comments.

A copy of this presentation can be found at the end of this document.

Reports on this study will be provided at each quarterly Enforcement and Compounding Committee meeting while the study is underway.

b. Update on the CURES 2.0 Prescription Monitoring Program

Background

The Department of Justice (DOJ) recently announced another milestone in its conversion to CURES 2.0. Specifically, the DOJ announced that beginning January 8, 2016, the upgraded prescription drug monitoring program is available. As part of this transition, on or after January 8, 2016, all current registrants are required to update their registration in the new 2.0 environment to ensure access to the system. This can be done electronically.

According to the DOJ, CURES 2.0 will be available to all registrants that use Microsoft Internet Explorer Version 11.0 or greater, Mozilla FireFox, Google Chrome, or Safari when accessing the system. Registrants that do not currently have access to one of those specified internet browsers will be able to continue to access the prior version of CURES until the legacy system's retirement, at that time the updated browser must be used.

The board is working with the DOJ to develop "Frequently Asked Questions" to assist registrants with understanding CURES 2.0. The board will send out updates via its subscriber alert system as it learns additional information from the DOJ. Questions regarding these changes should be directed to cures@doj.ca.gov .

On February 8, 2016, the board sent post cards to all licensed California pharmacists as a reminder that California law requires that all individuals holding an active California pharmacist license must register with CURES by July 1, 2016. Another post card will be sent by the board in May 2016.

It has been reported that 25,132 pharmacists have registered for CURES 2.0. Additionally, over 344,000 patient activity reports (PARs) were run in the last 30 days.

Discussion and Comment

At this meeting, Ms. Herold, who sits on the DOJ/DCA Change Control Board for CURES, provided an update on CURES 2.0 program. Ms. Herold stated that DOJ indicated that there are 23,168 pharmacists currently registered in the old system, CURES 1.0, and there are 3,678 pharmacist currently registered in new system, CURES 2.0.

Ms. Herold also reported that users registered in CURES 1.0 will be able to log into 2.0 but will have to go through the first time profile update. Ms. Herold also indicated that online registration is the only method by which to register as paper registration is no longer available.

Mr. Lippe stated that everyone was required to register in CURES 2.0 but not required to access it.

Ms. Herold further stated that DOJ does not have staff to answer phone inquiries and indicated that pharmacy board would do everything it could to help the licensees get registered.

It was also noted that not being registered in CURES 2.0 would not hold up licensure renewal.

Dr. Gray commented that the enrollment process is difficult when someone has a license as a pharmacist and as a prescriber and encouraged the board to seek help from DOJ to help facilitate this process.

Dr. Gutierrez requested that the board send subscriber alerts out that include the percentage of registered users so that licensees could monitor the progress.

There were no further questions or comments.

c. Discussion and Update to the Board's Procedures to Waive Requirements During a Declared Emergency Pursuant to Business and Professions Code section 4062

Background

On September 15, 2015, the board held an Emergency Board meeting in response to the wildfires in Lake and Napa counties. In light of the recent use of the policy it was brought to the board for evaluation and assessment to determine if changes to the policy are necessary.

At the October 28-29, 2015 board meeting, this item was referred to the enforcement committee for discussion.

At the December 15, 2015, Enforcement Committee meeting, the committee recommended that the board modify the policy to delegate its authority pursuant to Business and Professions Code section 4062 to the board president for a period of 30 days.

At the February 25, 2016 Board Meeting, the board approved the modified language. The new language will read as:

> In the event that the board is not able to convene a public meeting on regular notice or pursuant to the emergency meeting provisions of the Open Meetings Act, the board president may, on behalf of the board, exercise the powers delegated to full board pursuant to Business and Professions Code section 4062 for a period of 30 days.

Discussion and Comment

At this meeting, Dr. Gutierrez reported that the board modified the policy language. Ms. Freedman clarified the board's intent with the policy language and indicated that the policy should read as:

> In the event that the board is not able to convene a public meeting on regular notice or pursuant to the emergency meeting provisions of the Open Meetings Act, the board president may, on behalf of the board, exercise the powers pursuant to Business and Professions Code section 4062 for a period of 30 days.

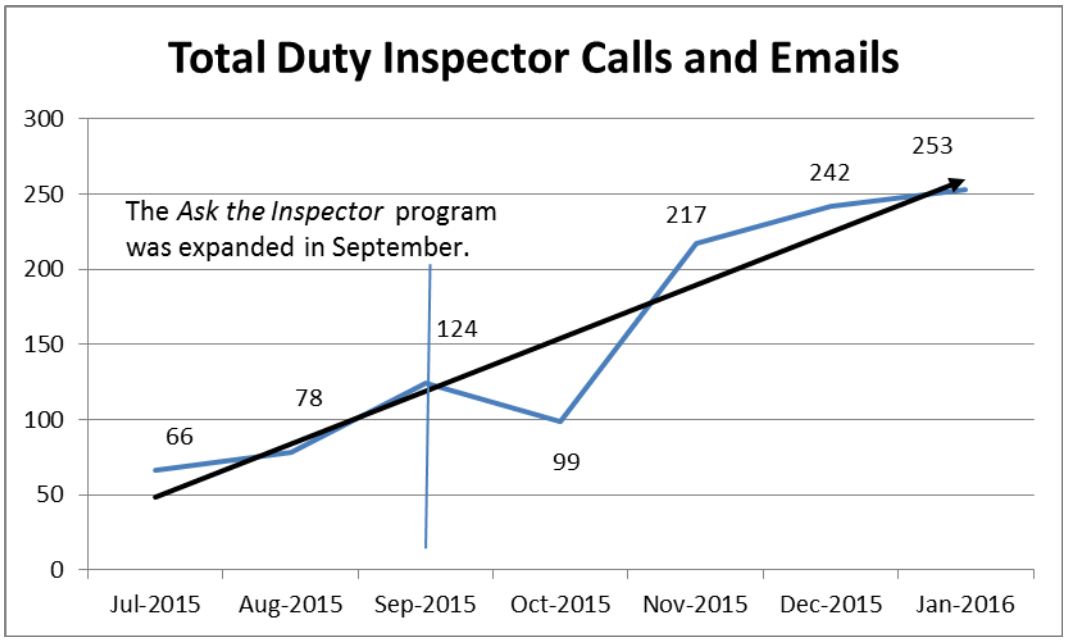
There were no questions or comments.

d. Data Describing Duty Inspector Activities

Background

From July 2015 through January 2016, the Complaint Unit resolved 166 *Ask the Inspector* inquiries. This is an average of 23 resolutions per month, with July being the lowest with 7 resolutions and January the highest with 40 resolutions. In addition, the Complaint Unit has screened 916 *Ask the Inspector* inquiries before escalating them to the weekly duty inspector for a response. This is an average of 130 inquiries per month.

Chart 1: *Ask the Inspector* Inquiries, by Month



Note: This graph includes inquiries resolved by the analyst as well as inquiries screened by the analyst and transferred to the weekly duty inspector for resolution.

The trend line shows the steady increase in calls and emails, an overall increase of 283%, from July 2015. The expansion of the *Ask the Inspector* service has caused a significant spike in activity for the Pharmacy board.

The board will continue to provide these statistics at future meetings.

Discussion and Comment

At this meeting, Dr. Gutierrez asked about the turnaround time for inspectors to respond to inquiries and was advised that responses are usually provided within the same week of receiving the inquiry.

Dr. Acosta stated that the board is receiving a lot of complex questions, legal questions and questions that could have been found in the law book by the caller.

Dr. Gutierrez asked if the board was compiling these questions into an FAQ document to be posted on the board's website and was advised that the board has compiled the top five questions received from pharmacists and the top five received from the public. Dr. Gutierrez was also told that the FAQs would be posted to the board's website in the next few months.

There were no questions or comments.

e. Automated Dispensing Machines – Available Drug Diversion Tools, Assessing Features Available, Training Provided to Pharmacy and Health Facility Staff. Presentations by:

1. **Kaiser Permanente**
2. **BD CareFusion/Pyxis & Rx Auditor**
3. **Omnicell/Aesyent**
4. **Cerner Automated Cabinets**
5. **Talyst**

Background

At the September 9, 2015, Enforcement Committee meeting, staff suggested that a simple registration be established for pharmacies that operate each of these machines that identify their locations as a beneficial step in board oversight and enforcement. The list could be updated as needed via form submission to the board by a pharmacy adding, moving or removing a machine. This registration could operate much like the off-site storage waivers for records waivers. Then at annual renewal of the pharmacy, the pharmacy would update or confirm the list of machines it operates and where each is located. Staff has drafted proposed language for requiring every pharmacy that owns or provides dangerous drugs dispensed through an automated drug delivery system to provide the board, in writing, the location of each device.

Presentations

These presentations provided information on the secured log on features as well as the various types of reports that are available with each device. It was also noted that training and consultation is provided initially and over time.

1. Kaiser Permanente

   Representatives from Kaiser Permanente provided an overview of their business operations and indicated the following as it relates to the automated delivery devices in their facilities which is only available in Kaiser facilities:

   - Currently there are 2,388 Pyxis machines enterprise wide
   - Able to create their own reports in addition to what comes standard with the Pyxis/Pandora reports
   - Kaiser uses biometrics to log on to the system in addition to being able use a password
   - Automated reports are delivered daily to the inpatient pharmacy director in the north and south
   - Able to perform trending reports

   Kaiser's National Special Investigations Unit (NSIU) investigates all suspicious behavior. The NSIU looks for signs of potential diversion such as poor job performance, appearance, behavior, complaints, and medication centered problems.

Discussion and Comment

Mr. Schaad asked if there was a way to reconcile the medication taken out of Pyxis machine and given to the patient. He was advised that Kaiser figured out a way to marry the removal to the Electronic Medication Administration Record (eMAR).

Dr. Gutierrez asked if Kaiser begins the tracking of the drug when it's placed in the machine and was advised that the tracking starts once it's placed in the machine.

Mr. Lippe asked if the nurses know that Kaiser has the capability to detect diversion activity and was advised that they did.

Comments included whether the devices had the capability to detect diversion activity as well as track the drugs from the time they are placed in the device to the time when they're dispensed to the patient and it was confirmed that it could.

It was also noted that processes are needed to ensure analytics are available for criteria-based best practices, understating behaviors and controlling the processes.

Dr. Gutierrez recessed for a break at 12:03 p.m.
The meeting reconvened at 12:18 p.m.

2. BD Carefusion
   Crystal Woodward, RPh, of BD/Carefusion provided an overview of the Pyxis MiniDrawer system, Pyxis Cubie pockets and medication management options available with the Pyxis machines. The options included the types of reports available, tracking, training, continuing education, consultation services and security features.

   Each cubie has a computer chip to track from when it leaves the pharmacy to be placed in the machine. The Pyxis machine uses biometrics (fingertip access) and scanning of a bar code from the employee's identification badge if the fingerprint doesn't work.

   Also available is a Pyxis CIISafe system that manages controlled substances for the pharmacy when receiving medications from manufacturers, and restocking of the Pyxis machines at the nurse's station.

Dr. Gutierrez recessed for lunch at 12:55 p.m.
The meeting reconvened at 1:16 p.m.

3. CUBEX
   Karen Nishi of Cubex Solutions provided an overview of the Pyxis hardware and Cubex software that included the automated technology available, security features, and reports.

4. Omnicell
   Representatives from Omnicell provided an overview of the automated dispensing cabinet's security features, including hardware, software, reporting capabilities, training and analytic options.

5. Cerner
   Steve Ward of Cerner provided an overview of the drug diversion strategies which included physical security and access control, including, software, reporting capabilities, analytics, and training.

6. Talyst
   Representatives of Talyst provided an overview of the technology, medication dispensing and administration, safeguards to ensure accuracy and security, reports and the training available.

f. Discussion on Technology Available to Detect Drug Diversion within Automated Cabinets

Discussion for this item can be found in the previous section.

g. Discussion on the Proposed Reconciliation and Inventory Report of Controlled Substances Regulation, Proposal to Add Title 16 California Code of Regulations Section 1715.65

This topic was not discussed at the committee meeting due to lack of time.

III. COMPOUNDING MATTERS

a. Update on the Status of the Sterile Compounding Regulations, Title 16 California Code of Regulations Sections 1735 et seq., and 1751 et seq.

Discussion and Comment
At this meeting, Ms. Herold stated that board staff is compiling all the responses received and putting together the rulemaking file to be submitted for DCA legal review by mid-March. The board has set January 1, 2017 as the date for implementation.

Ms. Herold indicated that one USP 797 has been released and that the committee will review those comments.

Rita Shane, Cedars Sinai, brought to the committee's attention that CSHP released comments to USP 797.

There were no further questions or comments.

b. Presentation on FDA-Approved Alternative Testing Technologies to Assess Sterility and Potency In Compounded Medications in use by Drug Manufacturers

Discussion and Comment
At this meeting, the committee heard a presentation by Dr. Tony Cundell on the Alternative Sterility Testing of Compounding Sterile Preparations.

A copy of this presentation can be found at the end of this document.

c. Discussion Regarding The Pew Charitable Trust Reports: "Best Practices For State Oversight of Drug Compounding" and "National Assessment of State Overnight of Sterile Drug Compounding"

The goal of these reports is to establish a baseline describing state policies today, and promote best practices in order to ensure that patients are safeguarded regardless of the state in which they receive treatment.

- ***Best Practices for State Oversight of Drug Compounding*** proposes best practices that are most meaningful to patient safety and the most achievable -- while recognizing that state funding may place limits on oversight systems
- ***National Assessment of State Oversight of Sterile Drug Compounding*** looks at the compounding landscape across the states to see how regulation and oversight vary in a number of categories (e.g., inspection, tracking, licensing).

A complete copy of these reports and more information regarding The Pew Charitable Trust organization can be found at: http://www.pewtrusts.org/en/projects/drug-safety-project.

This topic was not discussed at the committee meeting due to lack of time.

d. Overview of Compounding Inspections Performed and Violations Noted

This topic was not discussed at the committee meeting due to lack of time.

IV. MEETING DATES FOR 2016

The Enforcement Committee will meet on the following dates during 2016:

- June 1, 2016
- August 31, 2016