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

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STATE BOARD OF PHARMACY DEPARTMENT OF CONSUMER AFFAIRS PUBLIC BOARD MEETING MINUTES

| DATE: | March 9, 2015 |
|-------------------------------|---|
| LOCATION: | Department of Consumer Affairs 1 st Floor Hearing Room 1625 North Market Blvd Sacramento, CA 95834 |
| BOARD MEMBERS | |
| PRESENT: | Stanley C. Weisser, President Amy Gutierrez, PharmD, Vice President Greg Lippe, Public Member Gregory Murphy, Public Member Victor Law, RPh Allen Schaad, RPh Ricardo Sanchez, Public Member |
| BOARD MEMBERS NOT PRESENT: | Ramon Castellblanch, Public Member Lavanza Butler, RPh Deborah Veale, RPh, Treasurer Albert Wong, PharmD Rosalyn Hackworth, Public Member Ryan Brooks, Public Member |
| STAFF | |
| PRESENT: | Virginia Herold, Executive Officer Anne Sodergren, Assistant Executive Officer Michael Santiago, DCA Staff Counsel Janice Dang, Supervising Inspector Desiree Kellogg, Deputy Attorney General Liz McCaman, Researcher Laura Hendricks, Staff Analyst |

Monday, March 9, 2015

Call to Order

I. Call to Order, Establishment of Quorum and General Announcements

President Weisser called the meeting to order at 10:00 a.m. President Weisser noted that there was not a quorum of the board present due to flight delays for two of the board members. Board members present: Stanley Weisser, Allen Schaad, Amy Gutierrez, Victor Law, Ricardo Sanchez and Greg Lippe. Note: Gregory Murphy arrived at 10:35 a.m., creating a quorum.

II. Public Comments on Items Not on the Agenda/Agenda Items for Future Meetings

There were no comments from the board or from the public.

IV. <u>Legislative Proposal to Establish a Separate Licensure Category for Outsourcing</u> <u>Facilities</u>

President Weisser reported that at the January Board Meeting, the board voted to sponsor legislation to license outsourcing facilities. Currently the board's bill is ontained in a spot bill, which has been introduced as SB 619. President Weisser noted that Senator Morrell is lead author and Senator Jeff Stone is a co-author on this bill.

President Weisser explained that outsourcing facilities were created in November 2013 by enactment of the federal Drug Quality Security Act, the law that also preempted California's e-pedigree requirements. Outsourcing facilities compound large quantities of medication at one time, usually without a patient-specific prescription (which is typical of pharmacy compounding). The FDA has stated that they will use current good manufacturing practices as the standards to which outsourcing facilities will be held. President Weisser noted that there are currently about 59 outsourcing facilities registered with the FDA to do business in the US.

President Weisser stated that in early 2013, the board sponsored legislation (SB 294, Emmerson) that strengthened requirements for pharmacies that perform sterile compounding of products for California. This legislation was enacted nearly three months before the federal legislation. President Weisser reported that there are approximately 1,000 in state and non-resident sterile compounding pharmacies licensed in California.

President Weisser reported that in the short span of just over one year, most states are now either grappling with or have established separate requirements to regulate

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outsourcing facilities as a different group than pharmacies.

President Weisser explained that the licensure of outsourcing facilities by California would harmonize California's regulation of entities that compound large quantities of non-patient specific sterile medications with federal requirements that permit such compounding. President Weisser stressed that it would allow differentiation of these entities from compounding pharmacies, and focus manufacturing-like requirements on outsourcing facilities while for sterile compounding pharmacies, continuing to foster the patient-pharmacist relationships of pharmacy.

President Weisser reported that specific provisions will be developed to establish licensure requirements for in state and out-of-state outsourcing facilities that will be added into SB 619.

Dr. Gutierrez and President Weisser expressed their support of the legislation.

VI. <u>Discussion and Possible Action to Add Title 16, California Code of Regulations, Section</u> <u>1730 Regarding Requirements for Advanced Practice Pharmacists</u>

President Weisser explained that the item was inadvertently agendized incorrectly and would not be discussed at the meeting. President Weisser stated that it would be added to the agenda for the April board meeting.

VIII. <u>Opportunity to Provide Comments on U.S. Food and Drug Administration Draft Guidance</u> <u>Documents</u>

President Weisser reported that the FDA recently released five guidance documents on various aspects of sterile compounding by pharmacies and the production of medication by outsourcing facilities. President Weisser explained that each of these guidance documents (listed below) has been agendized so the board may discuss and take action on any of them. He noted that the comments are due in about 70 days (90 days from the date they were initially released). President Weisser explained that this time frame would permit the board to direct staff to develop comments and have the board president approve and sign them, or the board can ask that the draft comments be returned to the full board in April to review them at our next board meeting.

- a. Draft Guidance: For Entities Considering Whether to Register As Outsourcing Facilities under Section 503B of the Federal Food, Drug, and Cosmetic Act
- b. Draft Guidance for Industry: Repackaging of Certain Human Drug Products by Pharmacies and Outsourcing Facilities
- c. Draft Guidance for Industry: Mixing, Diluting, or Repackaging Biological Products Outside the Scope of an Approved Biologics License Application (BLA)

- d. Draft Guidance for Industry: Adverse Event Reporting for Outsourcing Facilities under Section 503B of the Federal Food, Drug, and Cosmetic Act
- e. Draft Memorandum of Understanding Between A State and the U.S. Food and Drug Administration Addressing Certain Distributions of Compounded Human Drug Products

President Weisser stated that in mid-March, the board's executive officer will be attending a 50-state meeting convened by the FDA to discuss these guidance documents, and the continued development of the federal outsourcing facility licensing provisions and sterile compounding by pharmacies. He added that Ms. Herold would report back to the board in April on the outcome of the FDA meeting.

Ms. Herold reported that at this time the guidance documents are not final requirements. She noted that the guidance documents make it clear where the FDA is going on outsourcing facilities and that the board needs to keep them in mind so that they do not create contradictory requirements.

Dr. Gutierrez asked how the federal government views prescriber office use. Ms. Herold responded that it is the opinion of the board's attorneys that the California law seems to not allow physicians to compound. Desiree Kellogg added that if the board decided to enter into the MOU it would need to modify the language to exclude reference to physicians compounding and joint investigations with the Medical Board.

President Weisser read an excerpt from the draft memorandum of understanding between a state and the U.S. Food and Drug Administration addressing certain distributions of compounded human drug products as follows:

"This Memorandum of Understanding (MOU) establishes an agreement between the State of [insert State] and the U.S. Food and Drug Administration (FDA) regarding the distribution of inordinate amounts of compounded human drug products interstate and the appropriate investigation by the State of [insert State] of complaints relating to compounded human drug products distributed outside the state. This is the MOU provided for by section 503A(b)(3)(B)(i) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C 353a), and does not apply to drugs that are compounded by registered outsourcing facilities."

President Weisser explained that if the state entered into the MOU, then the MOU:

- Requires the home state to investigate issues arising from the interstate distribution of compounded drugs by a pharmacy, identify the root cause of the problem, and take response to the action
- Requires the state to review compounding records during the inspections of compounding pharmacies to ensure the compounding pharmacy has not

distributed an inordinate amount of compounded drug product interstate.

• Defines an inordinate amount as not more than 30 percent of the total number of compounded and non-compounded drug products distributed or dispensed (both in-state and interstate).

President Weisser stated that once the MOU's parameters are finalized, the board will need to determine whether it wishes to enter into such an agreement with the FDA.

Mr. Lippe asked if the FDA drafted this guidance in response to drug shortages. Ms. Herold responded that this was one factor and noted that another factor was the high cost of manufactured drugs.

President Weisser asked if this MOU was something that the board should seriously consider. Ms. Kellogg responded that she would encourage the board to consider it. She added that the signatory will likely need to be vetted by the Governor's Office and another the Business, Consumer Services and Housing Agency.

Christine Versicle from Dynalabs noted that many of the testing samples that they receive are directly related to drug shortages. She noted that 70 percent of the registered FDA outsourcing facilities have been inspected and there have been 5 warning letters issued.

William Blair from McGuff Compounding Pharmacy noted that if the board decides not to enter into the MOU with the FDA, the cut-off for shipping into California will default to 5 percent. Dr. Gutierrez asked when the board would have to sign the MOU in order to avoid the 5 percent default. Ms. Herold responded that at this time there is nothing to sign as these are only guidance documents provided so that stakeholders can offer feedback.

President Weisser asked if the board should be working with the Governor's Office to prepare them for this MOU. Ms. Kellogg responded that this would be wise, and added that Ms. Herold would have more information on the timing after her meeting with the FDA in mid-March.

William Stuart, a compounding pharmacist, stated that even if the board elects to enter into the MOU, he feels that the 30 percent cut-off for shipping into California is still a restraint of trade.

Tony Park from CPHA encouraged the board to consider how entering into the MOU, or not entering into the MOU, will affect the board's jurisdiction over pharmacies. Ms. Herold responded that she would seek clarification during the FDA meeting.

Dr. Gutierrez asked why the FDA is placing a limit on the percent of drugs that can be shipped into California. Ms. Herold responded that the FDA is attempting to create a

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William Stuart again expressed his concern with the 30 percent limit.

Joe Gracella from University Compounding Pharmacy stated that the different limits for in-state and out-of-state pharmacies is prejudicial.

Ms. Herold noted that the FDA's goal it to protect the public from pharmacies that are actually acting functioning as a manufacturers and should thus be held to manufacturing standards.

Note: Gregory Murphy arrived at the meeting at 10:35 a.m. and established a quorum of the board.

III. Discussion and Possible Action to Make Changes in Response to Comments Received During the 15-Day Comment Period, or to Adopt or Amend Proposed Text at Title 16, California Code of Regulations, Section 1735, et seq., and 1751, et seq., Relating to Pharmacy Compounding

President Weisser reported that at the October 2013 Board Meeting, the board moved to initiate the notice of proposed changes in the California's compounding regulations (located in 16 California Code of Regulations Sections1735 et seq. and 1751 et seq). President Weisser provided a timeline of the regulation which included multiple comment periods and revisions to the language.

President Weisser stated that at the January 2015 Board Meeting, the board adopted revised language incorporating many of the comments submitted during the 45-day comment period, and voted to notice the revised language for the required 15-day comment period. President Weisser added that the 15-day comment period ran from February 6, 2015 to February 20, 2015.

The current version of the draft regulation language, and compilation of the comments received, including board response to each comment, were provided in the meeting materials.

President Weisser thanked the multiple stakeholders for their input on the language and noted that the language being presented is the result of much time and detailed review.

President Weisser explained that the board will have the opportunity to discuss the regulation and the comments received and determine what course of action it wishes to pursue. Among its options:

1. Adopt the regulation as noticed following the 15-day comment period.

- 2. Amend the regulation in some way(s) to address concerns expressed in the comments.
- 3. Provide general guidance to the Enforcement and Compounding Committee to do more work on the regulation and bring it back to the board.

Dr. Gutierrez commented that many of the changes to the language revolve around veterinary compounding. She added that some of the definitions had also been changed for clarity.

Mr. Law thanked Dr. Gutierrez and Mr. Schaad for their work on responding to each comment. Dr. Gutierrez also thanked Lori Martinez, Christine Acosta and Joshua Room for their work on the regulation.

Brian Warren with the California Pharmacists Association stated that 1751.7 subdivision e should be changed to require end product sterility testing only for batches of 25 or more. He added that there are no allowances in the language for the release of a product from quarantine in an emergency situation. Mr. Warren concluded that these requirements will cause an increase in the price of compounded drugs. Dr. Gutierrez explained that because a batch is defined as two or more, in an emergency a pharmacy could make one compounded drug product without needing to quarantine it.

Marie Cottman from Pacific Compounding Pharmacy provided examples of the challenges pertaining to compounding emergency eye drops for patients. Dr. Gutierrez directed her to the section of the language that would address her concerns with the need for emergency compounding for eye drops. Dr. Gutierrez asked Ms. Cottman to submit any additional comments during the 15-day comment period.

William Blair from McGuff Compounding Pharmacy stated that the self-assessment forms are now outdated and asked if they could be revised at the same time as the compounding regulation. Ms. Herold responded that the forms would be updated once the regulations have been put into effect.

Tom Bone, representing Pharmedium Services, noted that many comments were submitted on section 1735.1 regarding potency, and the board's response was that the comments were out-of-scope. Ms. Herold confirmed that this section was not open for comments (out-of-scope) and the board had already reviewed this section and chose not to make any amendments.

Grant Miller from the California Veterinary Medical Association thanked the board for considering their comments. He asked that when the board creates a guidance document they have a section specific to veterinary compounding.

Motion: Adopt the revised language to the modified text that was noticed for a 15-day

Board Meeting Minutes – March 9, 2015 Page **7** of **15** comment period Feb. 6 - 20, 2015, and to notice this revised language for an additional 15-day comment period. Delegate authority to the executive officer to adopt this modified text and to make any non-substantive or technical changes at the conclusion of the second 15-day comment period if no adverse public comments are received during this comment period, and proceed with the rulemaking.

M/S: Lippe/Law

| Support: 7 | Oppo | se: 0 Abstain: 0 |) | | |
|---------------|------|------------------|--------|---------|-------------|
| Name | | Support | Oppose | Abstain | Not Present |
| Brooks | | | | | х |
| Butler | | | | | х |
| Castellblanch | | | | | х |
| Gutierrez | | х | | | |
| Hackworth | | | | | х |
| Law | | х | | | |
| Lippe | | х | | | |
| Murphy | | х | | | |
| Sanchez | | х | | | |
| Schaad | | х | | | |
| Veale | | | | | х |
| Weisser | | х | | | |
| Wong | | | | | х |

V. Discussion and Possible Action to Initiate a Rulemaking to Add Title 16, California Code of Regulations, Section 1746.1 Regarding Requirements for Pharmacists Who Furnish Self- Administered Hormonal Contraceptives

President Weisser reported that at the January Board Meeting, the board approved the proposed protocol for self-administered hormonal contraception. The board also moved to initiate the regulation of the approved protocol if the Medical Board of California approved the protocol during its meeting on January 30.

President Weisser stated that during its January 30th meeting, the Medical Board did approve the protocol, but with a small change. A copy of the approved protocol with the Medical Board's-suggested change indicated (in underscore) was provided in the meeting materials.

President Weisser explained that the American Congress of Obstetricians and Gynecologists (ACOG), who under provisions in SB 493 is a group with whom the board is required to consult in developing the protocol, appeared at the Medical Board meeting to request changes in the protocol. The Medical Board did not incorporate ACOG's recommendations into the protocol when it modified and approved the protocol.

President Weisser noted that the February SB 493 Implementation Committee agenda

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was crafted so that an ACOG representative could provide its comments to the committee. A representative of ACOG did attend the committee meeting and provided verbal comments about the protocol. The changes involved whether:

- 1. On Depo-injection: ACOG recommended removal of this form of selfadministered birth control because pharmacists may not know how to advise patients how to self-administer medications, and patients may be fearful of selfadministration of an injectable medication.
- 2. ACOG recommended removal from the protocol (on page 1) the requirement that the pharmacist obtain the patient's blood pressure, and instead suggested asking the patient what her blood pressure is. The requirement as specified in the regulation is provided below:
 - "Measure and record the patient's seated blood pressure if combined hormonal contraceptives are requested or recommended.

President Weisser reported that the committee discussed each comment and declined to accept either modification.

Liz McCaman added that ACOG was also concerned with the format of the self-screening tool. Ms. McCaman clarified that a pharmacy can modify the format of self-screening tool to make it more user friendly.

Scott Clark, from the California Medical Association, asked if as part of the patient training required in the protocol, the first depo-injection will be observed by the pharmacist. The board noted that other subcutaneous injections are dispensed by pharmacists, and while the training is provided by the pharmacist, the first injection is administered by the patient at home. Dr. Gutierrez stated that she would expect the pharmacist to use his or her professional judgment to determine during the training if the patient may have difficulty administering their first injection.

Dr. Clark asked if the one hour training course required for the pharmacists is being developed. Ms. Herold responded that schools of pharmacy have taught hormonal contraception and additional training programs for pharmacists are being developed. Ms. Herold added that in order to administer an injection the pharmacist must first complete 20 hours of training.

Dr. Steve Grey, speaking as an individual, noted that the main goal of SB 493 was to increase patient access, especially to those seeking hormonal contraception.

Motion: Adopt the Medical Board's modifications to the protocol. Direct the board staff to initiate the rulemaking process to adopt section 1746.1.

M/S: Law/Lippe

| Name | Support | Oppose | Abstain | Not Present |
|---------------|---------|--------|---------|-------------|
| Brooks | | | | х |
| Butler | | | | х |
| Castellblanch | | | | х |
| Gutierrez | x | | | |
| Hackworth | | | | х |
| Law | х | | | |
| Lippe | х | | | |
| Murphy | x | | | |
| Sanchez | х | | | |
| Schaad | х | | | |
| Veale | | | | х |
| Weisser | х | | | |
| Wong | | | | х |

Support: 7 Oppose: 0 Abstain: 0

The board recessed for a break at 11:28 a.m. and returned at 11:38 a.m.

VII. <u>Title 16, California Code of Regulations, Section 1746.3: Protocol for Pharmacists Who</u> <u>Furnish Naloxone – Update and Next Steps</u>

President Weisser reported that at the January Board Meeting, the board approved the proposed protocol for pharmacists to provide naloxone. The board directed staff to initiate an emergency rulemaking as the authorizing legislation provides, provided the Medical Board of California approved the protocol during its meeting on January 30.

President Weisser stated that the Medical Board did approve the protocol during its January 30 meeting. A copy of the approved protocol was provided in the meeting materials.

President Weisser explained that earlier in the week DCA Director Awet Kidane and Business, Consumer Services and Housing Secretary Anna Caballero both approved the protocol, the final steps before the board can file the emergency rulemaking with the Office of Administrative Law. As an emergency adoption, the protocol will go into effect upon approval and filing with the Office of Administrative Law. President Weisser reported that this filing will occur following this board meeting.

President Weisser reported that at the SB 493 Implementation Committee Meeting, the committee approved a fact sheet that will be available to pharmacists to provide to the public. A copy of this fact sheet was provided in the meeting materials.

President Weisser noted that there were two items for board discussion and possible action:

1. One point of clarification for board discussion: the approved protocol contains the directions for use for each of the three forms of naloxone administration.

Board Meeting Minutes – March 9, 2015 Page **10** of **15** However, as a prescription drug dispensed by a pharmacy, the container will need to be labeled by the pharmacy. As such, all elements of prescription container labeling will be required. This will require a patient name. As such staff recommends that the board develop a short guidance document to explain that the patient name on the container should be that of the individual who secures the naloxone from the pharmacy.

2. At the April board meeting, staff will provide an update on the implementation of the protocol. The board will also be asked to review the protocol for possible changes and to refer the existing protocol to the Medical Board for its review and approval. The goal would be to initiate a formal rulemaking to adopt the protocol after the Medical Board's May board meeting. It typically will take at least 180 days (the initial length of the emergency adoption period) to secure the formal adoption of a regulation.

Ms. McCaman explained that the some states allow the prescription to be issued to the person purchasing the naloxone (perhaps on behalf of someone else) while other states require the prescription to be issued to the person who will be receiving the naloxone. Ms. McCaman noted that the committee drafted the language to allow the prescription to be issued and labeled to a third party.

Dr. Gutierrez stated that the kit labeling is incorrect for the intranasal administration; the active ingredient should be listed first.

Dr. Gutierrez noted that the auto injector currently costs approximately \$200 per dose. President Weisser asked if there would be a problem for patients being reimbursed by insurance companies if the naloxone was issued to someone else.

Dr. Gutierrez asked how Rhode Island handles the labeling of naloxone (person purchasing the naloxone vs. the person receiving the naloxone). Ms. McCaman reported that Rhode Island specifically wrote their regulations to define patient, for purposes of naloxone distribution, as either the person at risk or a third-party. Dr. Gutierrez felt that this was a good definition as it allowed flexibility for the pharmacist and patient.

Ms. Herold noted that if the board elects to make this change it would need to be approved by the Medical Board at their May board meeting. President Weisser expressed his concern with delaying the emergency rulemaking in order to make this change. Ms. Herold added that the board still must go through the 180-day comment period during the regular rulemaking process, and at that time the board could modify the definition of patient.

Dr. Gutierrez asked if the change to the kit labeling would need to be reapproved by the Medical Board. Laura Freedman responded that this would be a non-substantive change and would not require approval by the Medical Board.

Board Meeting Minutes – March 9, 2015 Page **11** of **15** Amy Swartz from Kaleo Pharm (a manufacturer of the naloxone auto injector) commented that the good samaritans law would protect the person administering the naloxone to someone who is overdosing. Ms. Swartz added that Kaleo Pharm has worked with many insurance companies and currently about 80 percent of the companies will cover naloxone. Dr. Gray added that there will be numerous ways in which insurance companies handle reimbursement.

Ms. Swartz asked who approves the one hour continuing education course required in the regulation. Ms. McCaman responded that ACPE is an approver of continuing education.

Motion: Direct the board staff to initiate the formal rulemaking process to adopt section 1746.3.

Ms. Freedman asked if the board wanted to make any changes to the language regarding who the prescription is issued to as part of the motion to initiate the formal rulemaking process. Dr. Gutierrez and President Weisser responded that the board was not going to make any changes to that section at this time.

| Support: 7 | Oppo | se: 0 Abstain: 0 | | | |
|---------------|------|------------------|--------|---------|-------------|
| Name | | Support | Oppose | Abstain | Not Present |
| Brooks | | | | | х |
| Butler | | | | | х |
| Castellblanch | | | | | х |
| Gutierrez | | х | | | |
| Hackworth | | | | | х |
| Law | | х | | | |
| Lippe | | х | | | |
| Murphy | | х | | | |
| Sanchez | | х | | | |
| Schaad | | х | | | |
| Veale | | | | | х |
| Weisser | | х | | | |
| Wong | | | | | x |

M/S: Lippe

Motion: Modify the emergency rulemaking language to state the name of the drug first for the kit labeling of intranasal naloxone.

M/S: Gutierrez/Lippe

Prior to the vote Ms. Freedman asked the board if they agreed with her assessment that this change would be non-substantive. The board agreed that it would be non-substantive. Ms. Freedman advised the board to modify the motion to state: "Assuming no

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Motion: Assuming no stakeholders object, modify the emergency rulemaking language to state the name of the drug first for the kit labeling of intranasal naloxone.

| Support: 7 | Орро | se: 0 Abstain: (| 0 | | |
|---------------|------|------------------|--------|---------|-------------|
| Name | | Support | Oppose | Abstain | Not Present |
| Brooks | | | | | х |
| Butler | | | | | х |
| Castellblanch | | | | | х |
| Gutierrez | | х | | | |
| Hackworth | | | | | x |
| Law | | х | | | |
| Lippe | | х | | | |
| Murphy | | х | | | |
| Sanchez | | х | | | |
| Schaad | | х | | | |
| Veale | | | | | х |
| Weisser | | х | | | |
| Wong | | | | | x |

M/S: Gutierrez/Lippe

IX. Organizational Development Committee

a. New Legal DCA Counsel

President Weisser reported that in mid-February, board staff was advised that new DCA legal counsel was assigned to the board. President Weisser welcomed Laura Freedman as the new counsel. President Weisser noted that Ms. Freedman has worked for the department for a number of years and has significant experience working with other healing arts boards and highlighted her resume that was provided in the meeting materials.

President Weisser stated that Michael Santiago will continue to serve as a resource for the board during the transition period. President Weisser thanked Michael Santiago for his work with the board.

b. Fee Audit Update

President Weisser stated that as discussed at previous meetings, the board may need to pursue a fee increase to sustain operations. He added that as a precursor to making such a determination the board pursued a contract for completion of an independent fee audit. The board secured a contract with Macias Consulting Group to complete this independent audit for the board.

President Weisser reported that he and board staff met with the auditors to gain a thorough understanding of the audit process and based on the preliminary findings of the auditors, it is clear that the board will need to increase fees.

Anne Sodergren reported that board staff is reviewing the contractor's current findings and the methodology used. Board staff is working with the department's Budget Office to address concerns. Ms. Sodergren concluded that staff anticipates that this should be resolved in advance of the April Board Meeting.

President Weisser explained that legislation will be necessary to facilitate any fee increase as all of the board's current fees are at their statutory maximum levels.

Mr. Law asked when the staff anticipated the fee increase would take place. Ms. Sodergren responded that the board had hoped to introduce the legislation this year however because of the staff's concerns with the audit methodology, this may need to be delayed.

c. Update of BreEZe, DCA's New Application and Licensing Computer System

Ms. Sodergren explained that for a number of years the department has worked to replace its legacy licensing and enforcement tracking systems. The system selected was framed around a commercial off the shelf product (COTS), and will become known as BreEZe.

Ms. Sodergren reported that the first release of the system occurred on October 8, 2013. At that time the board was scheduled to deploy in the second release. However, as reported at the January 2015 Board Meeting, the board was removed from the second deployment primarily due to the absence of critical functionality that was not detailed in the original contractual requirements.

Ms. Sodergren stated that on February 12, 2015 the California State Auditor released an audit report concerning how the Department of Consumer Affairs planned, developed, and implemented the BreEZe system. She noted that the executive summary of the audit was provided in the meeting materials and the full audit can be accessed using the following link - - <u>https://www.auditor.ca.gov/pdfs/reports/2014-116.pdf</u>

Ms. Sodergren explained that the audit report highlighted several problems with implementation of the new system. She noted that many of the audit findings were not new information to either the department or board staff, but highlighted several of the challenges involved in implementing this information technology project.

Ms. Sodergren reported that subsequent to the release of the audit report, on February 25, 2015, the Joint Legislative Budget Committee denied a request from the

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Ms. Sodergen stated that with these recent events, there is more uncertainty about how and when the board will resume its transition to the new system.

Mr. Law asked if the board will continue to use its current systems. Ms. Sodergren confirmed that the department would still support the legacy systems.

President Weisser thanked Ms. Sodergren for her work on the BreEZe project.

Mr. Law stated that he is disappointed with the amount of money and time the board has put into a system that will not even work. Ms. Sodergren clarified that she believes that ultimately the board will join the BreEZe system, it is just a question of the timing. Mr. Lippe noted that most major IT projects in the state have similar problems.

d. Procedures for Evaluation of the Performance of the Board's Executive Officer President Weisser explained that it is time for the annual performance review of the Executive Officer. He added that the evaluations will be provided to each board member and a summary of the evaluations will be compiled and provided to the Ms. Herold at the April 2015 Board Meeting.

XI. <u>Closed Session</u>

Pursuant to Government Code Section 11126(c)(3), the board convenes in closed session to deliberate on disciplinary matters. President Weisser convened closed session at 12:30 p.m.

XII. <u>Reconvene Open Session</u> President Weisser reconvened open session at 12:55 p.m.

XIII. Adjournment

President Weisser adjourned the meeting at 12:56 p.m.