BEFORE THE BOARD OF PHARMACY DEPARTMENT OF CONSUMER AFFAIRS STATE OF CALIFORNIA

In the Matter of the Accusation Against:

SHILOH FAMILY PHARMACY, INC. DBA SHILOH FAMILY PHARMACY, DIANA ARONSON and NATALIA VOYTOVA, OWNERS PIC ALAN BROWN

Pharmacy Permit No. PHY 51776

and

ALAN BROWN, Pharmacist License No. RPH 22146

Respondents.

Case No. 5813

OAH No. 2017071103

DECISION AND ORDER

The attached Proposed Decision of the Administrative Law Judge is hereby adopted by

the Board of Pharmacy, Department of Consumer Affairs, as its Decision in this matter

This Decision shall become effective at 5:00 p.m. on May 24, 2018.

It is so ORDERED on April 24, 2018.

BOARD OF PHARMACY DEPARTMENT OF CONSUMER AFFAIRS STATE OF CALIFORNIA

NC

By

Amy Gutierrez, Pharm.D. Board President

BEFORE THE BOARD OF PHARMACY DEPARTMENT OF CONSUMER AFFAIRS STATE OF CALIFORNIA

In the Matter of the Accusation Against:

SHILOH FAMILY PHARMACY, INC. DBA SHILOH FAMILY PHARMACY, DIANA ARONSON and NATALIA VOYTOVA, OWNERS PIC ALAN BROWN No. 5813

OAH No. 2017071103

Pharmacy Permit No. PHY 51776

and

ALAN BROWN, Pharmacist License No. RPH 22146

Respondents.

PROPOSED DECISION

Ji-Lan Zang, Administrative Law Judge, Office of Administrative Hearings, State of California, heard this matter on December 20, 21, and 22, 2018, in Los Angeles, California.

Nancy A. Kaiser, Deputy Attorney General, represented Virginia Herold (complainant), Executive Officer, Board of Pharmacy (Board), Department of Consumer Affairs.

Herbert L. Weinberg, Attorney at Law, represented Shiloh Family Pharmacy Inc., doing business as Shiloh Family Pharmacy, with owners Diana Aronson (respondent Aronson), who appeared, and Natalia Voytova (respondent Voytova), who did not appear.

On October 30, 2017, Alan Brown, Pharmacist-In-Charge (PIC), submitted a Stipulated Surrender of License to the Board. Pending the Board's decision and order regarding this Stipulated Surrender of License, the Accusation against Alan Brown was taken off calendar, and the matter proceeded against Shiloh Family Pharmacy and respondents Aronson and Voytova only. Oral and documentary evidence was received. The record was held open until January 26, 2018, for both parties to submit closing briefs regarding the purpose and meaning of misbranding laws, and until February 9, 2018, for both parties to submit reply briefs, if any. The parties timely filed closing briefs, which were marked for identification and lodged as Exhibit 17 (complainant's closing brief) and Exhibit J (Shiloh Family Pharmacy's closing Brief). On February 9, 2018, complainant filed and served its reply brief, which was marked and lodged as Exhibit 18. No reply brief was received from Shiloh Family Pharmacy. The record was closed and the matter was submitted for decision on February 9, 2018.

FACTUAL FINDINGS

Parties and Jurisdiction

1. A. On February 28, 2014, the Board issued Pharmacy Permit Number PHY 51776 to Shiloh Pharmacy. This permit was valid at all times relevant to this matter, and was scheduled to expire on February 1, 2018,¹ unless renewed.

B. During all relevant times herein, respondents Aronson and Voytova each owned 50 percent of the stock of Shiloh Family Pharmacy. Respondent Aronson is the President and Chief Executive Officer of Shiloh Family Pharmacy, while respondent Voytova serves as its Secretary.

C. From February 28, 2014, to May 29, 2014, Shiloh Family Pharmacy's PIC was Alan Brown (PIC Brown).

2. On March 18, 2017, complainant filed the Accusation in her official capacity. Shiloh Family Pharmacy timely filed a Notice of Defense and a Request for Hearing. Thereafter, this hearing ensued.

Background

3. Shiloh Family Pharmacy is a pharmacy located in the City of Los Angeles. In early 2014, on a date not established by the record, respondents Aronson and Voytova purchased the pharmacy from its previous owner. Shiloh Family Pharmacy received its pharmacy permit on February 28, 2014, and it became operational on March 4, 2014.

4. The physical layout of Shiloh Family Pharmacy consists of two areas: the retail area where over-the-counter drugs are sold and customers wait for their prescriptions to be filled, and the pharmacy area where prescription drugs, including controlled substances,

¹ Despite the expiration of the license, the Board retains its jurisdiction to proceed with this disciplinary proceeding against Shiloh Family Pharmacy or to render a decision suspending or revoking the license pursuant to Business and Professions Code section 4300.1.

are stored, prepared, and dispensed. The retail area is partitioned from the pharmacy area by a wall. Pharmacy staff members enter the pharmacy area through a door which is locked at all times. Only PIC Brown retains the key to the door. Next to the door is a large sliding glass window through which customers may interact with pharmacy staff members as they work in the pharmacy area.

Events Leading to the June 2, 2014 Inspection

5. On May 20, 2014, Shiloh Family Pharmacy submitted to the Drug Enforcement Agency (DEA) a Report of Theft or Loss of Controlled Substances (DEA report). The DEA Report indicated that controlled substances with a purchase value of approximately \$1,722 had been lost at the pharmacy.

6. On May 26, 2014, Shiloh Family Pharmacy's counsel submitted a letter to the Board, indicating that the following controlled substances were unaccounted for: 800 tablets of Vicodin² 5/300mg; 4,000 tablets of zolpidem³ 10mg; 450 tablets of hydrocodone/ acetaminophen⁴ 7.5/325mg; 600 tablets of hydrocodone/acetaminophen 5/325mg; and 2,700 tablets of hydrocodone/acetaminophen 10/325mg. A total of 8,550 tablets of controlled substances were reported lost.

7. On May 29, 2014, the Board received a tip from "Mitchell Brown" who alleged that Shiloh Family Pharmacy's pharmacy technician, Susanna Gabrielova (Gabrielova), was stealing bottles of narcotics and that Gabrielova was going to open the pharmacy on June 2, 2014, at 9 a.m. without a pharmacist present.

8. Based on this information, Board Inspector Sarah Bayley (Inspector Bayley) was assigned to investigate the drug loss reported by Shiloh Family Pharmacy and the allegations that the pharmacy was going to open for business without a pharmacist. After receiving her assignment, Inspector Bayley attempted to contact "Mitchell Brown" at the phone number listed on his complaint, but found that the number was invalid. She also searched for "Mitchell Brown's" address by using Google Maps, but found that the address was invalid as well.

² Vicodin is a Schedule II controlled substance pursuant to Health and Safety Code section 11055, subdivision (b)(1)(I). Vicodin is a trade name for a combination of hydrocodone or dihydrocodone and acetaminophen. In October 2014, hydrocodone combination products were rescheduled from Schedule III to Schedule II.

 3 Zolpidem is a Schedule IV controlled substance pursuant to Health and Safety Code section 11057, subdivision (d) (32). It is sold under the brand name Ambien, among others, and is a sedative used to treat insomnia.

⁴ Hydrocodone is a Schedule II controlled substance pursuant to Health and Safety Code section 11055, subdivision (b)(1)(I).

The June 2, 2014 Inspection

9. On June 2, 2014, the Board and the DEA conducted a joint inspection of Shiloh Family Pharmacy.

UNAUTHORIZED ACCESS INTO THE PHARMACY AREA

10. On the day of the inspection, Inspector Bayley had planned to arrive at Shiloh Family Pharmacy by 9 a.m. However, on route to the pharmacy, she got lost and arrived on the scene at 9:30 a.m. When Inspector Bayley arrived, the DEA agents were already staked out near the front and back doors of Shiloh Family Pharmacy. Inspector Bayley spoke to one of the DEA agents, who informed her that a female was observed to have climbed through the large sliding glass window to gain entry into the pharmacy area.

11. After they conferred, Inspector Bayley and the DEA agents entered Shiloh Family Pharmacy. Upon entry, Inspector Bayley saw respondent Aronson and Gabrielova in the pharmacy area. No pharmacist was present. When Inspector Bayley asked respondent Aronson about her presence in the pharmacy area without a pharmacist, respondent Aronson stated that she entered the pharmacy area through the sliding glass window because one of her employees, Crystal Pratt (Pratt), a typist, had recently quit and respondent Aronson needed to prepare for a busy day due to Pratt's absence. Respondent Aronson insisted that she had not touched any medication stored in the area and that she only worked on the computer. She also asserted that this was the first time she had entered the pharmacy area without a pharmacist present.

12. Approximately 15 to 20 minutes later, at approximately 9:45 a.m. or 9:50 a.m., PIC Brown arrived at the pharmacy.

MISBRANDED DRUGS

13. Inspector Bayley continued with her inspection and found that the following drugs appeared to be misbranded:

A. One stock bottle⁵ of $Crestor^6$ 10 mg was overfilled, in that the manufacturer's label indicated that it should contain 90 tablets, but the bottle, in fact, contained 150 tablets. Additionally, some of the tablets in the stock bottle were chipped.

⁵ Pharmacists purchase large quantities of drugs from wholesalers in stock bottles, which are stored on shelves in the pharmacy area. Tablets are dispensed from the stock bottles into amber vials for individual prescriptions.

⁶ Crestor is a statin drug used to prevent cardiovascular disease. It is available only by prescription.

B. One stock bottle of Crestor 20 mg contained some tablets which were chipped. Other tablets had variations in the imprinting. Specifically, the imprint of the drug name, "Crestor," on some tablets appeared shallower than others.

C. One stock bottle of Celebrex⁷ 200 mg contained capsules with variations in imprinting. Specifically, the imprinted yellow bands on some of the capsules were lighter in hue than others.

D. One stock bottle of Seroquel⁸ 25 mg was overfilled, in that the manufacturer's label indicated that it should contain 100 tablets, but the bottle, in fact, contained 383 tablets.

14. Inspector Bayley took several photographs of the stock bottles and their contents and secured them into evidence.

15. To perform a rough audit of these drugs, Inspector Bayley obtained the drugs' dispensing history, and PIC Brown performed a stock-on-hand inventory. This rough audit revealed that the pharmacy's acquisition and disposition records could not account for 90 tablets of Crestor 10 mg, 285 tablets of Celebrex 200 mg, and 383 tablets of Seroquel 25 mg in its possession. Moreover, the pharmacy had dispensed 360 more tablets of Crestor 20mg than it had purchased, but it could not account for the source of the dispensed tablets. When Inspector Bayley asked respondent Aronson about the source of these drugs, respondent Aronson stated that the additional Seroquel tablets were part of the inventory transfer when she purchased Shiloh Family Pharmacy from its previous owner. No explanation was provided regarding the additional tablets of Crestor and Celebrex that were unaccounted for.

16. In an Investigation Report dated February 24, 2016, Inspector Bayley wrote the following comments regarding the condition of these medications:

Variation in the appearance of the tablets (imprints on the tablets)-Celebrex & Crestor 20mg

Variation in the imprints possibly indicates counterfeit drugs, or pills from different lot numbers or manufacturers. In this case, Celebrex showed variation on appearance of imprint on the capsules.

Contained more tablets or capsules than the actual package size (overfill)-Seroquel and Crestor 10mg

⁸ Seroquel is an anti-psychotic drug available only by prescription.

⁷ Celebrex is a nonsteroidal anti-inflammatory drug used to relieve pain and swelling. It is available only by prescription.

This evidence indicated misbranded drugs: drugs were from different lot number or manufacturers, drugs were from a non FDA approved source.

Tablet's outer coating layers were chipped off or damaged-Crestor 20mg

This evidence showed possible mishandling of drugs due to beyond expiry date, over handling, exposure to extreme weather temperatures (freezing or heat). As a normal pharmacy practice, the dispensing pharmacist should examine the appearance of medications as a part of pharmaceutical care for patients.

(Ex. 4, p. 58.)(Italics in original.)

CONTROLLED SUBSTANCE LOSS

17. In order to audit the reported loss of Vicodin, Zolpidem, and hydrocodone/ acetaminophen, Inspector Bayley obtained the dispensing history for these drugs while PIC Brown performed a stock-on-hand inventory. Inspector Bayley requested that Shiloh Family Pharmacy perform another audit related to the loss and submit supporting documents. Additionally, she requested written statements from PIC Brown and respondent Aronson regarding the drug loss and the overfilled medications. All documents were to be returned to Inspector Bayley within 72 hours.

THE INSPECTION REPORT

18. At the end of the June 2, 2014 inspection, Inspector Bayley gave a written inspection report to respondent Aronson and PIC Brown. In this inspection report, Inspector Bayley summarized respondent Aronson's admissions regarding her entry into the pharmacy area without the presence of a pharmacist, as detailed above. She documented the drugs that were overfilled, chipped, or showed variations in imprinting or color. She also noted her requests for audit results for the lost Vicodin, zolpidem, and hydrocodone/acetaminophen and the written statements from respondent Aronson and PIC Brown. Inspector Bayley orally reviewed the report with respondent Aronson and PIC Brown, both of whom signed the inspection report.

Shiloh Family Pharmacy's June 6, 2014 Letter to the Board

19. A. On June 6, 2014, counsel for Shiloh Family Pharmacy wrote a letter to the Board in response to the June 2, 2014 inspection.

B. With reference to respondent Aronson's entry into the pharmacy area without a pharmacist present, counsel explained in this letter that on June 2, 2014, Shiloh Family Pharmacy's computer, which was stored in the pharmacy area, experienced problems. However, the pharmacy employee who services the computer had recently quit. Consequently, respondent Aronson believed the computer issues to be an emergency which warranted her entry into the pharmacy area in order to ensure that the pharmacy would be operational on that day.

C. With reference to Inspector Bayley's finding that certain bottles of medication were overfilled, counsel wrote, "I am advised by our client that the overfilled containers resulted when bottles of drugs were combined with other full or partial bottles, and that such a practice was employed only when the lot numbers and expiration dates of the combined containers were the same. Shiloh [Family Pharmacy] has since ceased this practice." (Ex. 13, p. 127.)

D. With reference to the controlled substances loss, counsel stated that Shiloh Family Pharmacy's initial audit was rushed and an error had occurred. He submitted a revised audit result based on an audit performed by PIC Brown and respondent Aronson. The revised audit results indicated that 1,031 tablets of Vicodin 5/300mg; 4,240 tablets of zolpidem 10mg; 511 tablets of hydrocodone/acetaminophen 7.5/325mg; 591 tablets of hydrocodone/acetaminophen 7.3/25mg were unaccounted for. A total of 9,234 tablets of controlled substances were reported as lost in this revised audit.

Inspector Bayley's Final Audit Results of Controlled Substance Loss

20. Inspector Bayley compared Shiloh Family Pharmacy's revised audit results with the supporting documents and found a few discrepancies. Using records provided by the pharmacy for the period from March 4, 2014, to June 2, 2014, her final audit result showed that 1,022 tablets of Vicodin 5/300 mg; 4,110 tablets of zolpidem 10 mg; 711 tablets of hydrocodone/ acetaminophen 7.5/325 mg; 691 tablets of hydrocodone/acetaminophen 5/325 mg; and 3,141 tablets of hydrocodone/acetaminophen 10/325 mg were unaccounted for. Thus, a total of 9,675 tablets of controlled substances were lost. Respondent Aronson did not dispute the results of this final audit.

PIC Brown's Statements to the Board

21. On May 29, 2014, PIC Brown resigned as Shiloh Family Pharmacy's PIC. However, he remained as the pharmacy's staff pharmacist until June 11, 2014, when a new PIC was hired.

22. On June 3, 2014, PIC Brown submitted a statement to the Board regarding the overfilled stock bottles. He wrote:

While performing my duties as Pharmacist-In-Charge and prior to my recent resignation in May, I had a strict policy prohibiting the return of any unused medications being returned or replaced to its respective original container. This policy is firm and my staff was informed and aware that this was not only my mandate, but also a violation of pharmacy law.

7

 $[\P] \dots [\P]$

As to the overfilled Crestor: I hereby declare that I did not personally restore any tablets to the container and considering my admonition to my immediate staff (as outlined above), I am certain that the overfilling did not occur on my watch.

(Ex. 13, p. 142.)

23. On June 4, 2014, PIC Brown submitted another statement to the Board regarding the controlled substances loss. In this statement, he asserted his suspicions that Gabrielova was responsible for the drug loss, based on the fact that she was in charge of placing drug orders with Shiloh Family Pharmacy's primary wholesaler. Additionally, PIC Brown recounted an incident during which Gabrielova took three bottles of Norco⁹ from the pharmacy shelf. When confronted by management, Gabrielova explained that she hid the Norco in order to conduct her own private investigation about the drug loss at the pharmacy.

Respondent Aronson's Statement to the Board

24. On Feburary16, 2016, respondent Aronson submitted her statement to the Board. Regarding the loss of controlled substances, she wrote:

As soon as I began my review [of the loss of controlled substances], Susanna Gabrielova, a pharmacy technician, asked if I was searching for misplaced controlled substances, specifically Norco. She told me, in front of our entire staff, that she had moved some bottles of Norco to a shelf where it normally would not be stocked because, the day before, she noticed that some Ambien was missing, and she wanted to see what she might learn by moving the Norco.

Later that day, I informed all employees that I am investigating the loss of controlled substances from the pharmacy, that I will report the loss to the Board of Pharmacy and DEA, and that I and all employees would be required to take a polygraph test...

All employees agreed to take the polygraph except Ms. Pratt [Shiloh Family Pharmacy's typist], who left the pharmacy on that day, and never returned.

(Ex. 14, p. 163.)

25. In her statement, respondent Aronson did not address the issue of the overfilled stock bottles, despite Inspector Bayley's request that she do so.

11

⁹ Norco is the brand name for a combination of hydrocodone and acetaminophen.

Testimony of Hasmik Hayrapetyan

26. Hasmik Hayrapetyan (Hayrapetyan), who has served as one of Shiloh Family Pharmacy's pharmacy technicians since 2014, testified at the hearing. Hayrapetyan's duties at the pharmacy include taking prescriptions from customers, giving prescriptions to the pharmacist, and inputting data into the computer to prepare labels for prescription bottles. She is familiar with the day-to-day operations of Shiloh Family Pharmacy.

27. Hayrapetayan testified that she was working at the pharmacy on the day that the DEA and the Board conducted their inspections. According to Hayrapetyan, on that day, she arrived at the pharmacy at 10 a.m. She asserted that the Board inspector did not arrive at the pharmacy until after 10 a.m., at which point respondent Aronson, Gabrielova, and PIC Brown were all present.

28. However, on cross-examination, Hayrapetayan could not remember the date that the inspection occurred. She remembered that it was on a Monday sometime in May 2014, when, in fact, the inspection occurred on June 2, 2014. Hayrapetayan did not recognize Inspector Bayley, who was present in the courtroom, as the Board inspector who conducted the inspection. She also could not recall how many Board investigators came to conduct the inspection. Hayrapetayan could only say that it was more than one and that they showed their badges, although she did not recall their names. Given these issues with Hayrapetyan's memory of the June 2, 2014 inspection, her testimony regarding the events of that day was given no weight.

29. During further questioning, Hayrapetyan was asked about the pharmacy's purported practice of combining tablets of the same lot and same expiration date into stock bottles. Hayrapetyan responded that the staff members at Shiloh Family Pharmacy never combined tablets in stock bottles at all, regardless of whether they were of the same lot and expiration date or not. Given PIC Brown's June 3, 2014 statement regarding the pharmacy's policy prohibiting any unused medications returned or poured back into the stock bottle, this portion of Hayrapetyan's testimony was deemed credible.¹⁰

Respondent Aronson's Testimony

30. Respondent Aronson testified at the hearing on her own behalf. Prior to becoming a co-owner of Shiloh Family Pharmacy in February 2014, respondent Aronson was a pharmacy manager at Kovacs' Pharmacy from 2006 to 2009. At Shiloh Family

¹⁰ The trier of fact may "accept part of the testimony of a witness and reject another part even though the latter contradicts the part accepted." (*Stevens v. Parke, Davis & Co.* (1973) 9 Cal.3d 51, 67.) The trier of fact may also "reject part of the testimony of a witness, though not directly contradicted, and combine the accepted portions with bits of testimony or inferences from the testimony of other witnesses thus weaving a cloth of truth out of selected material." (*Id.* at p. 67–68, quoting from *Nevarov v. Caldwell* (1958) 161 Cal.App.2d 762, 767.)

Pharmacy, respondent Aronson's duties include accounting and paying bills. She is not involved in any duties related to dispensing of prescription drugs.

31. Regarding the allegation that she entered the pharmacy area without a pharmacist present, respondent Aronson claimed that she had remained in the retail area. She denied entering the pharmacy area without PIC Brown being present. According to respondent Aronson, on June 2, 2014, she arrived at the pharmacy at approximately 9:25 a.m. to 9:35 a.m. She opened the pharmacy with Gabrielova, but she did not enter the pharmacy area. PIC Brown arrived at the pharmacy some 20 minutes later, at approximately 9:40 a.m. or 9:50 a.m. Indeed, Shiloh Family Pharmacy's dispensing records show that as of 9:51 a.m. on June 2, 2014, PIC Brown was filling prescriptions for customers. (Ex. C.) Respondent Aronson asserted that Inspector Bayley arrived on the scene sometime after 9:50 a.m., at which point PIC Brown was present at the pharmacy. Respondent Aronson further claimed that she is five foot five inches tall and weighs approximately 150 pounds and that someone of her physical size could not possibly have climbed through the sliding glass window in question.

32. A. Respondent Aronson's testimony on this issue was self-serving and not credible for the following reasons:

B. At the hearing, Inspector Bayley consistently and credibly testified that on June 2, 2014, she arrived at the pharmacy at approximately 9:30 a.m. and that she entered the pharmacy with three other DEA agents shortly after. Upon their entry into the pharmacy. Inspector Bayley observed respondent Aronson and Gabrielova in the pharmacy area, but PIC Brown was not present. Additionally, when inspector Bayley asked respondent Aronson about her presence in the pharmacy area without a pharmacist, respondent Aronson admitted that she had climbed through the sliding glass window in order to gain entry into the pharmacy area. Inspector Bayley's testimony on this subject is corroborated by her Inspection Report dated the same date, which documents the incident and respondent Aronson's admissions. This Inspection Report was also signed by respondent Aronson. (See Factual Findings 10, 11, 18.) During cross-examination, respondent Aronson was asked why she had signed the inspection report if she did not agree with its contents. Respondent Aronson testified that she did not review the document before signing it. However, this claim was rebutted by Inspector Bayley's testimony that she wrote the Inspection Report on site, printed it out with a portable printer she brought along with her, and orally reviewed the report with respondent Aronson before obtaining her signature.

C. On June 6, 2014, in a letter written by her counsel, respondent Aronson admitted that she had entered the pharmacy area purportedly to remedy a problem with the pharmacy's computer. (See Factual Finding 19B.) When asked at the hearing about the contents of this letter, respondent Aronson could not offer an explanation as to why, four days after the June 2, 2014 inspection, her attorney's letter contained such an admission.

D. A photograph of the sliding glass window in question was submitted into evidence as Exhibit H. The photograph shows that, when compared to the doorway into the

pharmacy area, the opening of the sliding glass window is approximately one-third of the length and one-third of the width of the doorway. Given these dimensions, it is not implausible for a woman of respondent Aronson's physical size to be able to climb through the window.

33. Regarding the controlled substance loss, respondent Aronson testified that she learned of the drug loss from PIC Brown on May 10, 2014. On the same date, she reportedly held a meeting with her staff members and informed them of the drug loss and that she would be reporting the loss to the Board and the DEA. Approximately 10 days later, she reportedly held a second meeting during which she informed her staff members that she would require each individual to undergo a polygraph test in order to uncover the perpetrator responsible for the loss. Following this meeting, Pratt, who was Shiloh Family Pharmacy's typist, quit and left the pharmacy. Based on that, respondent Aronson assumed that Pratt was responsible for the drug loss and concluded her internal investigation without conducting any polygraph tests. On May 10, 2014, respondent Aronson reported the drug loss to the DEA, and on May 24, 2014, she reported the loss to the Board through her counsel. Respondent Aronson asserted that she attempted to file a police report about the drug loss at the local police station, but claimed that the police refused to take the case and did not provide an incident report to her.

34. During cross-examination, respondent Aronson admitted that she was aware of the incident during which Gabrielova hid three bottles of Norco purportedly to conduct her own private investigation of the drug loss. Despite the dubious nature of this story, respondent Aronson did not find it to be suspicious. She acknowledged that PIC Brown and Gabrielova were the only two individuals who ordered controlled substances at the pharmacy. However, respondent Aronson maintained that she did not suspect either PIC Brown or Gabrielova of diverting the drugs. When asked why she did not conduct a more thorough investigation of the drug loss, respondent Aronson said, in her own words, "I'm not an investigator. I do what I can to the best of my knowledge." When asked whether the person who is responsible for the drug loss still could be in her employ, respondent Aronson admitted that it was possible. She stated, "It could be anybody. It could be me. It could be Gabrielova."

35. A. Moreover, during cross-examination, respondent Aronson was queried about her response to question 17 of the DEA Report, which asked what security measures have been taken to prevent future theft/losses. Respondent Aronson wrote, "All C3 [Schedule III] substances are now under lock and key cabinet. New security cameras will be installed. All employees will undergo a polygraph test. Controlled substance inventory will be done every 90 days. Contacted pharmacist attorney." (Ex. 8, p. 72.)

B. To demonstrate Shiloh Family Pharmacy's change in policy regarding the security of controlled substances, respondent Aronson submitted a document entitled "Shiloh Family Pharmacy's Policy and Procedure to Prevent the Internal Diversion of Controlled Substances" (Shiloh Policy and Procedure). Section 1a of the Shiloh Policy and Procedure provides that "Shiloh Family Pharmacy does not stock or fill prescriptions for Schedule II

controlled substances." (Ex. A.) Section 1b provides that "Shiloh Family Pharmacy stores all Schedule III-V controlled substances in a securely locked, substantially constructed cabinet, which is locked at all times." (*Id.*) Respondent Aronson claimed that the Shiloh Policy and Procedure was in effect as of July or August 2014. However, during further questioning, she admitted that she never provided the document to Inspector Bayley, despite the inspector's request for statements relating to the drug loss. Indeed, respondent Aronson did not provide this document to complainant's counsel until December 12, 2017, eight days before the hearing on this matter, despite an April 4, 2017 discovery request which required all documents intended to be admitted at hearing to be exchanged within 30 days. When asked why she didn't provide the document to complainant's counsel, respondent Aronson stated, "I'm not an attorney. I don't work in law." Furthermore, respondent Aronson provided little evidence, such as testimony from her current employees or photographs of the pharmacy area, to establish that the security changes contained in the Shiloh Policy and Procedure have actually been implemented.

C. With reference to the security cameras, respondent Aronson stated that Shiloh had two cameras, one of which was directed at the front door, the other was directed at the back door. There was no video camera directed at the pharmacy area. Consequently, video footage of any internal diversion of controlled substances was not captured. Respondent Aronson did not present any evidence at the hearing that new security cameras have been installed.

D. With reference to the polygraph test, respondent Aronson testified that polygraph tests were not administered to Shiloh Family Pharmacy's staff because she believed the internal investigation regarding the drug loss had resolved after Pratt quit her job.

E. With reference to taking inventory of controlled substances every 90 days, respondent Aronson admitted that this preventive measure has not been implemented. According to respondent Aronson, Shiloh Family Pharmacy had a number of pharmacists-in-charge after PIC Brown's resignation, but none of them purportedly agreed to conduct the inventory of controlled substances.

F. When asked how she could reassure the Board that a similar drug loss would not recur, given that she has not implemented any of the security measures, respondent Aronson stated, "I did everything that I could. I can't guarantee that the bank won't be robbed tomorrow."

Expert Testimony Regarding Misbranding

INSPECTOR BAYLEY'S TESTIMONY

36. Inspector Bayley testified as an expert witness for complainant. She received her doctor of pharmacy degree from the University of Southern California Pharmacy School. Inspector Bayley has been a licensed pharmacist in California since 1994, and she has served

as an inspector for the Board since 2000. Prior to working for the Board, Inspector Bayley worked as a pharmacist at Sav-On Drugs and at a long-term care facility.

37. Inspector Bayley defined misbranding as a drug that does not match its labeled description. Variations in the quantity of the drugs in the bottle from that indicated on the label, variations in color or appearance, and chipped or damaged pills are all examples of misbranding. According to Inspector Bayley, pharmacy laws prohibit misbranding because misbranded drugs may not be from the regular supply chain and pose a risk to the public in that they may be adulterated. Inspector Bayley explained that manufacturers make drugs in batches. Each batch is identified by a unique batch number. Drugs from the same batch use the same raw materials and should be similar in appearance, although variations in color or other minimal discrepancies may appear from batch to batch. Lot numbers are assigned to a specific portion of a batch. In the event of a drug recall, lot numbers are used to trace the drug back to its batch, and the only way to identify consumers who received drugs subject to the recall is through the lot number. Thus, misbranding laws are intended, in part, to effectuate drug recalls.

38. Inspector Bayley opined that drugs with different lot numbers and expiration dates may have been combined in the overfilled stock bottles of Crestor 10mg and Seroquel 25 mg. Some of the drugs may have come from a source not approved by the Food and Drug Administration, or the drugs may have been counterfeit. She further opined that the chipped tablets found in the bottles of Crestor 10mg and Crestor 20mg indicated that the quality of the tablets had been compromised, either through exposure to extreme temperature changes or through problems in shipping and handling. Also, the drugs could be counterfeit.

Additionally, Inspector Bayley testified that it is not the industry standard to 39. combine two stock bottles or to pour the contents of an unused prescription bottle back into the stock bottle. Inspector Bayley stated that the standard practice for a pharmacist is to count out the pills from a stock bottle in accordance with the prescription and put it into an amber vial. The prescription bottle is then placed on a will-call shelf. If the patient does not want the medication or fails to pick it up, the medication is left in the will-call area for a set amount of time, usually for approximately two weeks. After that set time period, the pharmacist will pull the medication from the will-call area and reverse the claim with the manufacturer, after erasing the patient's name from the bottle for confidentiality purposes. It is appropriate to pour the contents of the amber vial back into a stock bottle only when the contents match perfectly. For example, if a stock bottle is supposed to contain 90 Crestor tablets, and the amber vial contains 90 Crestor tablets of the same lot and expiration number. then it is acceptable to pour the contents back into the stock bottle. If the contents of the amber vial and the stock bottle are not a perfect match, then the medication should not be put back into the manufacturer's vial because it increases the possibility of error because different drugs could be combined.

40. A. During cross-examination, when asked whether an underfilled stock bottle of drugs constitute misbranding, Inspector Bayley opined that only overfilled stock bottles constitute misbranding. She testified that an underfilled stock bottle only indicates that the

medication has been dispensed and there is little possibility that different medications could have been combined. An overfilled stock bottle, however, is an obvious indication that different medications have been combined, and the lot numbers and the expiration dates of the drugs can no longer be ascertained.

B. Inspector Bayley acknowledged that there are instances in which a pharmacist may mix two drugs with different lot numbers. For example, if a prescription called for 60 tablets of a certain medication, the pharmacists may combine 35 tablets from one stock bottle and 25 tablets from another stock bottle with a different lot number in order to fill the prescription.

C. Moreover, inspector Bayley admitted that it is customary for the pharmacist to determine the expiration date on the prescription bottle. Some pharmacists choose a default expiration date of one year.

D. Inspector Bayley also agreed, under cross-examination, that pills from a single lot may have some variations in hues.

TESTIMONY OF FRED G. WEISSMAN

41. Fred G. Weissman (Weissman), Associate Professor of Clinical Pharmacy at the University of Southern California, testified as an expert witness for Shiloh Family Pharmacy. He received his doctor of pharmacy degree from the University of Southern California in 1963. He also obtained a juris doctorate degree from Loyola Law School in 1989. From 1965 to 1970, Weissman served as a staff pharmacist at various hospitals and retail pharmacies. After 1970, Weissman primarily worked as an instructor in clinical pharmacy for universities.

42. Weissman defined misbranding as having a bottle containing a substance that does not comply with the description on the label. Weissman initially opined that Health and Safety Code section 111440 (discussed below), which prohibits the holding of misbranded drugs, does not apply to stock bottles on a pharmacist's shelf because the bottles are sitting on the shelf. However, he later stated that "technically" (his words) having a stock bottle on the pharmacy shelf containing more pills than what is indicated on the label could be a violation of Health and Safety Code section 111440.

43. With regard to the issue of combining drugs with different lot numbers, Weissman asserted that this was a common occurrence in the pharmacy industry. He cited to the use of automated pill counters as an instance where a pharmacist may combine drugs with different lot numbers. To use an automated pill counter, the pharmacist pours stock bottles of medications into the machine, and the machine counts the pills, without making any distinctions between lot numbers or expiration dates.

44. With regard to overfilled stock bottles, Weissman initially stated that a stock bottle overfilled with the same drug does not present a problem. However, upon further

questioning about the typical protocol to be followed when prescription drugs are not picked up by patients, Weissman responded that the common practice is to leave the prescription bottle on the will-call shelf for a set period of time, typically for 30 days. If the bottle is not picked up within the set time limit, then the same prescription bottle is placed back onto the pharmacy shelf, with the patient's name redacted. Weissman stated that it is not a common practice to pour the contents of the prescription bottle back into the stock bottle. Nevertheless, he opined that one method was not safer than the other and that either method was appropriate. Later on during cross-examination, however, Weissman changed his opinion and stated that it is "not a good idea to mix the pills in the same bottle, unless there's a good reason to do that." However, he did not explain what good reason, if any, exists for a pharmacist to overfill a stock bottle.

45. With regard to chipped tablets, Weissman opined that bottles that contain chipped tablets may constitute misbranding. He testified that chipped tablets should not be dispensed to patients because any chip on a tablet would suggest that it may not possess the full dose strength indicated on the bottle.

Additional Testimony Regarding Misbranding

46. Jeffrey David Marcus (Marcus), a California licensed pharmacist since 1990, testified as a witness for Shiloh Family Pharmacy. He obtained his doctor of pharmacy degree from Long Island University in New York. Marcus is currently a PIC at an independent pharmacy in Los Angeles.

47. Marcus testified that in his experience as a pharmacist finding tablets of different hues in a single bottle is a normal occurrence. Marcus stated that he receives his drugs directly from the manufacturer and has not had any reason to suspect that pills with variations in hues are counterfeit. He has never called a manufacturer upon finding variations in hues in a single bottle.

48. During cross-examination, Marcus testified that he works in a pharmacy that fills 100 to 200 prescriptions per day. Since the beginning of his career as a pharmacist in 1990, he has found variations in hues in the pills that he obtains from the manufacturer at least 12 times. Marcus also acknowledged that he dispenses chipped tablets, which he believes are a common result of shaking during shipping. He has no concerns about dispensing chipped tablets if they are from a sealed bottle from a reliable manufacturer. Marcus stated that he would "lose hundreds or thousands" of tablets if he stopped dispensing chipped tablets. However, when asked whether or not chipped tablets would affect the dosage strength, Marcus asserted that chipping would affect the dosage strength of coated, time-released tablets and that he determines, on a case-by-case basis depending on the size of the chip, whether or not to dispense chipped tablets.

Evidence of Mitigation/Rehabilitation

49. Respondent Aronson submitted two character reference letters, which are described, in part, below.

50. In a letter dated November 2, 2017, Greta Ashbel (Ashbel), who was an owner of Kovac's Pharmacy where respondent Aronson worked from 2006 to 2009, described respondent Aronson as a "detailed oriented, self-motivated, and hard-working individual." (Ex. D.) Ashbel wrote:

I can attest that [respondent Aronson] is honest, [with a] strong moral character, which [*sic*] has always been focused on her job. There has never been any question as to her professionalism, work ethic, or managerial techniques. She is a manager to whom [*sic*] I would blindly trust to run a pharmacy, fully knowing that she will do all that is in her power for the good of the business.

(Ibid.)

51. In a letter dated November 15, 2017, Eugenia Simonyants, a customer of Shiloh Family Pharmacy wrote:

My husband, Garegin Simonyants, and I, Eugenia Simonyants, have been customers of Shiloh Family Pharmacy almost 4 years now. Not only are we satisfied with our services at the pharmacy, but we are thrilled and pleased to know [respondent Aronson] throughout all these years. She treats her patients as family, and her main priority is patient care. We have experienced the outstanding customer service from [respondent Aronson] and her team at the pharmacy, where they go out of their way to deliver medications. During our years with the pharmacy, I can personally vouch for [respondent Aronson's] character as a highly ethical and responsible individual. Shiloh Family Pharmacy provides top quality services under [respondent Aronson's] management, where she displays the greatest professionalism, honesty, compassion, and dedication to her patients and to her business.

(Ex. E.)

Cost Recovery

52. Complainant submitted evidence of the costs of investigation and enforcement of this matter, summarized as follows: 66 hours of legal services at rates ranging from \$120 to \$170 per hour for a subtotal of \$11,182.50; and 126.5 hours of investigative services at rates ranging from \$102 to \$121 per hour for a subtotal of \$14,608.25. The total costs of investigation and enforcement of this matter are \$25,790.75. These costs are reasonable.

11

LEGAL CONCLUSIONS

1. Shiloh Family Pharmacy's pharmacy permit is a nonprofessional license because it does require the extensive educational, training, or testing requirements as does a professional license. (See Mann v. Department of Motor Vehicles (1999) 76 Cal.App.4th 312, 319; San Benito Foods v. Veneman (1996) 50 Cal.App.4th 1889, 1894.) An applicant for a pharmacy permit need not be a pharmacist; instead, the applicant must designate a PIC with the requisite education, training, and licensure. (Bus. & Prof. Code, §§ 4110, subd. (a), 4113, subd. (a).) Therefore, the standard of proof in this case is a preponderance of the evidence, which is a lower standard of proof than clear and convincing evidence. (Imports Performance v. Department of Consumer Affairs, Bureau of Automotive Repair (2011) 201 Cal.App.4th 911, 916-917; Evid. Code, §115.) "Preponderance of the evidence means evidence that has more convincing force than that opposed to it.' [citations omitted] The sole focus of the legal definition of 'preponderance' in the phrase 'preponderance of the evidence' is on the quality of the evidence. The quantity of evidence presented by each side is irrelevant." (Glage v. Hawes Firearms Co. (1990) 226 Cal.App.3d 314, 324-325.) (Emphasis in original.)

First Cause for Discipline

2. Shiloh Family Pharmacy is subject to disciplinary action, pursuant to Business and Professions Code section 4301, subdivision (o), in conjunction with California Code of Regulations, title 16, section 1714, subdivisions (b) and (d), for unprofessional conduct by failing to maintain operational security to prevent the loss of controlled substances.

3. California Code of Regulations, title 16, section 1714, states in pertinent part:

(b) Each pharmacy licensed by the board shall maintain its facilities, space, fixtures, and equipment so that drugs are safely and properly prepared, maintained, secured and distributed. The pharmacy shall be of sufficient size and unobstructed area to accommodate the safe practice of pharmacy.

 $[1] \dots [1]$

(d) Each pharmacist while on duty shall be responsible for the security of the prescription department, including provisions for effective control against theft or diversion of dangerous drugs and devices, and records for such drugs and devices. Possession of a key to the pharmacy where dangerous drugs and controlled substances are stored shall be restricted to a pharmacist.

4. The pharmacy's "fixtures" and "equipment" to secure drugs (Cal. Code Regs., tit. 16, § 1714, subd. (b)) included surveillance cameras, but the cameras were aimed at the front and rear doors, not at the pharmacy area. (Factual Finding 35C.) Had there been

surveillance cameras in place in the pharmacy area, the recordings could have revealed the perpetrator responsible for the controlled substance loss. The "security of the prescription department" was compromised in multiple ways, leading to the loss of controlled substances. (Cal. Code Regs., tit. 16, § 1714, subd. (d).) Shiloh Family Pharmacy did not have accurate records for the controlled substances, in that both its initial audit of the drug loss reported to the Board on May 29, 2014, and its subsequent audit reported by its counsel on June 5, 2014, underreported the amount of the loss. Only Inspector Bayley's final audit revealed that over a brief period of three months, the pharmacy had actually lost 9,675 tablets of controlled substances. (Factual Findings 6, 19D, and 20.) Additionally, respondent Aronson failed to thoroughly investigate the drug loss. After discovering the loss, she demanded that all employees submit to a polygraph test, but the polygraph test was never administered based on respondent Aronson's assumption that Pratt was the perpetrator because Pratt had refused the polygraph test and quit. She did not investigate Gabrielova, who is responsible for ordering the drugs and told a rather dubious story about hiding some drugs in order to conduct her own investigation. Nor did she investigate PIC Brown, who was also responsible for ordering controlled substances. (Factual Findings 33 and 34.)

5. Accordingly, the Board may take disciplinary action against Shiloh Family Pharmacy for unprofessional conduct based on the violations. (Bus. & Prof. Code, § 4301, subd. (o).) Although California Code of Regulations, title 16, section 1714, subdivision (d) is directed towards the pharmacist, as a corporation, Shiloh Family Pharmacy's permit is subject to discipline for the violations of its agents or employees. (*Arenstein v. California State Bd. of Pharmacy* (1968) 265 Cal.App.2d 179, 192–93, overruled on another point as stated in *Barber v. Long Beach Civil Service Com.* (1996) 45 Cal.App.4th 652, 658.); see also *California Assn. of Health Facilities v. Department of Health Services* (1997) 16 Cal.4th 284, 296 ["[A] licensee will be held liable for the acts of its agents"].)

Second Cause for Discipline

6. Shiloh Family Pharmacy is subject to disciplinary action, pursuant to Business and Professions Code section 4301, subdivision (o), in conjunction with Business and Professions Code section 4081 and California Code of Regulations, title 16, section 1718, for unprofessional conduct by failing to maintain a current inventory of dangerous drugs.

7. Business and Professions Code section 4081 provides in relevant part:

(a) All records of manufacture and of sale, acquisition, receipt, shipment, or disposition of dangerous drugs or dangerous devices shall be at all times during business hours open to inspection by authorized officers of the law, and shall be preserved for at least three years from the date of making. A current inventory shall be kept by every manufacturer, wholesaler, third-party logistics provider, pharmacy, veterinary food-animal drug retailer, outsourcing facility, physician, dentist, podiatrist, veterinarian, laboratory, clinic, hospital, institution, or establishment holding a currently valid and unrevoked certificate, license, permit, registration, or exemption under Division 2 (commencing with Section 1200) of the Health and Safety Code or under Part 4 (commencing with Section 16000) of Division 9 of the Welfare and Institutions Code who maintains a stock of dangerous drugs or dangerous devices.

(b) The owner, officer, and partner of a pharmacy, wholesaler, third-party logistics provider, or veterinary food-animal drug retailer shall be jointly responsible, with the pharmacist-in-charge, responsible manager, or designated representative-in-charge, for maintaining the records and inventory described in this section....

8. California Code of Regulations, title 16, section 1718 defines "current inventory" as "complete accountability for all dangerous drugs handled by every licensee enumerated in [Business and Professions Code sections] 4081 and 4332."

9. In a recent decision, *Sternberg v. California State Board of Pharmacy* (2015) 239 Cal.App.4th 1159, 1168, the appellate court found that a pharmacy's inability to account for the loss of controlled substances was a result of inaccurate and incomplete inventory records and thus constituted a violation of Business and Professions Code section 4801. The PIC was held strictly liable for the violation, despite the fact that he was unaware of the improper conduct which led to the loss of controlled substances. (*Ibid.*) Under Business and Professions Code section 4801, subdivision (b), the owner of the pharmacy is jointly responsible with the PIC for accurate and complete records and inventory of controlled substances at the pharmacy. Therefore, PIC Brown and respondent Aronson are jointly and strictly liable for failing to maintain and preserve all records of acquisition, disposition, and current inventory of controlled substances which resulted in the pharmacy's inability to account for the loss of 9,675 tablets of controlled substances.

Third Cause for Discipline

10. Shiloh Family Pharmacy is subject to disciplinary action, pursuant to Business and Professions Code section 4301, subdivision (o), in conjunction with Health and Safety Code section 111440, for unprofessional conduct by holding misbranded drugs.

11. A. Health and Safety Code section 111440 states: "It is unlawful for any person to manufacture, sell, deliver, hold, or offer for sale any drug or device that is misbranded."

B. Health and Safety Code section 111330, subdivision (c), states: "Any drug or device is misbranded if its labeling is false or misleading in any particular."

D. California Code of Regulations, title 16, section 1718.1 states that "All prescription drugs not bearing a manufacturer's expiration date pursuant to Title 21, Code of Federal Regulations, section 211.137 are deemed to have expired and may not be manufactured, distributed, held for sale, or dispensed by any manufacturer, distributor, pharmacist, pharmacy or other persons authorized to dispense such drugs in California."

E. Business and Professions Code section 4076, subdivision (a), states in pertinent part: "A pharmacist shall not dispense any prescription in a container that meets the requirements of state and federal law and is correctly labeled with all of the following: . . (9) The expiration date of the effectiveness of the drug dispensed."

12. Respondent Aronson contends in her closing brief that Health and Safety Code section 111440 is directed at drug manufacturers and does not apply to "a pharmacy stocking its products." (Ex. J, p. 2.) She further contends that because the term "hold" is not define in the statute, a "pharmacy that only sells some of the contents of a stock bottle to a patient cannot be accused of holding for sale a misbranded drug." (*Ibid.*) These arguments were not persuasive.

13. The fundamental rule in construing a statute is to determine the Legislature's intent. (*Delaney v. Superior Court* (1990) 50 Cal.3d 785, 798.) To determine that intent, "'The court turns first to the words themselves for the answer." (*Brown v. Kelly Broadcasting Co.* (1989) 48 Cal.3d 711, 724, quoting *People v. Knowles* (1950) 35 Cal.2d 175, 182.) Here, Health and Safety Code section 111440 prohibits any "person" from manufacturing, selling, delivering, holding, or offering for sale any misbranded drugs. Thus, the language of the statute is broad and is intended to encompass manufacturers, pharmacists, and any other individuals involved in the drug supply chain. Although the statute does not specifically define the term "hold," words in a statute should be given the meaning they bear in ordinary use. (*In re Rojas* (1979) 23 Cal.3d 152, 155.) The Merriam-Webster Dictionary defines the word, "hold," as "to have possession or ownership or to have at one's disposal." Given the foregoing, pharmacies clearly hold the contents of stock bottles on their shelves and offer them for sale to the public.

14. However, even if Health and Safety Code section 111440 applies to the contents of stock bottles held by pharmacies, the issue that remains is whether the mismatch between the contents of the stock bottles and their manufacturer's label found at Shiloh Family Pharmacy constitutes misbranding within the meaning of that statute. Specifically, during the June 2, 2014 inspection, Inspector Bayley found (1) one bottle of Crestor 10 mg that was overfilled with 150 tablets, some of which were chipped, when the manufacturer's label indicated that the bottle should have contained 90 tablets; (2) one bottle of Crestor 20 mg containing some tablets that were chipped and had variations in imprinting; (3) one bottle of Celebrex with variations in imprinting; and (4) one bottle of Seroquel that contained 383 tablets, when the manufacturer's label indicated that the bottle should have contained that the bottle should have contained 100 tablets.

15. Although expert and percipient testimony was proffered regarding whether stock bottles containing chipped tablets or tablets with variations in imprinting or coloring constitute misbranded drugs, it is not necessary to reach a conclusion on this issue.¹¹ It is sufficient, for the purpose of this analysis, to find that the overfilled stock bottles found at Shiloh Family Pharmacy constitute misbranded drugs. The overfilled stock bottles of Crestor and Seroquel are misbranded, not because, as complainant contends, the quantity of the medication found in the stock bottles are different from what is indicated on the manufacturer's label,¹² or because the lot numbers may have been mixed. (Ex. 17, p. 11-12.) If the misbranding were based on variation in the quantity of the medication in the stock bottle from the amount indicated on the manufacturer's label, then an underfilled stock bottle would also constitute misbranding. As Inspector Bayley testified, stock bottles in pharmacies are routinely underfilled because their contents have been dispensed. If the misbranding were based on mixing of the lot numbers, then a pharmacist who mixes lot numbers by using an automatic pill counter or by dispensing drugs from two separate stock bottles would be guilty of misbranding. As the testimonies of Inspector Bayley and Weissman demonstrated, both practices are acceptable within the drug industry. Additionally, it should be noted that lot numbers are not required to be denoted on a prescription bottle. (See Health & Saf. Code, § 111480; Bus. & Prof. Code, § 4076.)

A. More significantly, in this case, the overfilled stock bottles of Crestor and 16. Seroquel contain additional tablets of unknown expiration dates. Respondent Aronson claimed, through her counsel, in a June 5, 2015 letter that the pharmacy only combined tablets of the same lot number and same expiration dates in stock bottles. However, this claim is not credible for several reasons. PIC Brown wrote in his statement that he had a strict policy against combining drugs, and that the overfilled bottles could not have occurred on his watch. Hayrapetyan, Shiloh Family Pharmacy's pharmacy technician, corroborated PIC Brown's statement with her testimony that she never combined drugs in the stock bottle, regardless of whether they are the same lot number and expiration dates. Thus, both PIC Brown and Hayrapetyan contradicted respondent Aronson's assertions on this issue. In her inspection report of June 2, 2014, Inspector Bayley requested a written statement from respondent Aronson regarding the overfilled stock bottles. Respondent Aronson never addressed the issue of overfilled stock bottles after the June 5, 2014 letter. She did not offer evidence, either to Inspector Bayley or at the hearing, that the additional tablets found in the Crestor and Seroquel bottles were of the expiration date indicated on the manufacturer's bottle. Indeed, she could not even account for the additional Crestor and Seroquel that were found in her inventory.

¹¹Consequently, expert and percipient witness testimony regarding whether chipped tablets or tablets with variations in imprinting or imprinting constitute misbranded drug will not be addressed.

¹² Health and Safety Code section 111340 states: "Any drug or device is misbranded unless it bears a label containing all of the following information: . . . (b) An accurate statement of the quantity of the contents in terms of weight, measure, or numerical count."

B. Furthermore, the expert testimony presented at the hearing demonstrated that the practice of pouring the contents of a prescription bottle back into the stock bottle is highly unusual. Inspector Bayley testified that this practice increases the potential for error, and pharmacists usually reverse claims of any prescription bottles that are not picked up by patients. Weissman, respondent's expert witness, initially stated that stock bottles overfilled with the same drug do not present a problem. Upon further questioning, however, he agreed with Inspector Bayley that the practice of pouring unused drugs back into the stock bottle is uncommon. He later opined that this practice is not a good idea unless there a good reason for it, but he did not offer any explanation of the circumstances under which there may be a good reason to combine drugs in a stock bottle.

C. Given the foregoing, it was established that Shiloh Family Pharmacy poured tablets of an unknown expiration date into the overfilled stock bottles of Crestor and Seroquel bottles. Thus, the expiration date of the additional tablets found in the overfilled Crestor and Seroquel bottles did not match the expiration of the medication as indicated on the manufacturer's label.

17. The expiration date of a drug is critical to determining whether the product is safe and effective. Thus, the expiration date is required to be displayed on the prescription drug label. (Bus. & Prof. Code, § 4076, subd. (a); Health & Saf. Code, § 111480, subd. (i)) Moreover, under California law, all prescription drugs not bearing a manufacturer's expiration date are deemed to have expired and may not be held for sale, or dispensed by any pharmacy. (Cal. Code Regs., tit. 16, § 1718.1.) During the hearing, respondent Aronson cited to the use of the automatic pill counter and the pharmacists' common practice of using one year as the default expiration date on prescription bottles to suggest that the expiration date of a drug is irrelevant to that issue of misbranding. However, regardless of whether a pharmacist uses an automatic pill counter, and regardless of whether a pharmacist indicates a default one-year expiration date on the prescription label, so long as the pharmacist commingles tablets with unknown expiration dates with other tablets, it is unlawful and constitutes misbranding.

18. In the case at hand, the overfilled stock bottles of Crestor and Seroquel bottles found at Shiloh Family Pharmacy contained tablets of unknown expiration dates. Because the contents of those bottles do not bear the manufacturer's expiration dates, the entire contents of the bottles are deemed to be expired, and the drugs are misbranded pursuant Health and Safety Code section 111330, subdivision (c), in that their labeling is false or misleading as to the expiration date.

Fourth Cause for Discipline

19. Shiloh Family Pharmacy is subject to disciplinary action, pursuant to Business and Professions Code section 4301, subdivision (j), in conjunction with Business and Professions Code section 4116, subdivision (a), for unprofessional conduct, in that personnel was allowed to enter the pharmacy without a pharmacist present.

11

20. Business and Professions Code section 4116, subdivision (a) states in pertinent

part:

No person other than a pharmacist, an intern pharmacist, an authorized officer of the law, or a person authorized to prescribe shall be permitted in that area, place, or premises described in the license issued by the board wherein controlled substances or dangerous drugs or dangerous devices are stored, possessed, prepared, manufactured, derived, compounded, dispensed, or repackaged....

21. The Accusation alleges that during the Board Inspection of June 2, 2014, respondent Aronson was in Shiloh Family Pharmacy's pharmacy area without the presence of a pharmacist. Respondent Aronson offered the testimony of Hayrapetyan to show that when Inspector Bayley arrived at the pharmacy on the day of the Board inspection, PIC Brown was already present in the pharmacy. However, Hayrapetyan's testimony on this issue is discounted entirely due to her inability to recall some basic facts of that day. Respondent Aronson denied at the hearing that she entered the pharmacy area without the presence of PIC Brown. Notwithstanding this denial, Inspector Bayley credibly testified that upon her entry into the pharmacy, she saw respondent Aronson and Gabrielova in the pharmacy area, but PIC Brown was not present. Respondent Aronson admitted to Inspector Bayley that she had climbed through the sliding glass window in order to gain entry into the pharmacy area, and this admission was documented in Inspector Bayley's inspection report dated that day. Additionally, in a letter dated June 5, 2014, respondent Aronson admitted, through her counsel, that she had entered the pharmacy area to remedy a computer problem. Based on the foregoing, it was established that respondent Aronson entered Shiloh Family Pharmacy's pharmacy area where dangerous drugs are stored and dispensed without the presence of a pharmacist. (Factual Findings 27, 28, 31, and 32.)

The Degree of Discipline

22. The Board's Disciplinary Guidelines (Rev. 10/2007) (Guidelines) set forth categories of violations and recommended penalties. Violations of Business and Professions Code section 4301, subdivisions (j) and (o), constituting unprofessional conduct that involves serious potential harm or greater disregard for pharmacy law and public safety, are Category II violations. The minimum penalty is revocation stayed and three years' probation. The maximum penalty is revocation.

23. The Guidelines specify that, in determining whether the minimum, maximum or an intermediate penalty is to be imposed in a given case, the following factors should be considered: (1) actual or potential harm to the public; (2) actual or potential harm to any consumer; (3) prior disciplinary record; (4) prior warnings; (5) number and or variety of current violations; (6) the nature and severity of the act(s) or offense(s), or crime(s); (7) aggravating evidence; (8) mitigating evidence; (9) rehabilitation evidence; (10) compliance with terms of any criminal sentence, parole, or probation; (11) overall criminal record; (12) if

applicable, evidence of dismissal proceedings pursuant to section 1203.4 of the Penal Code; (13) the time that has elapsed since commission of the act(s) or offenses(s); (14) whether the conduct was intentional or negligent; and (15) financial benefit to the respondent from the misconduct. (Guidelines, p. 3.)

24. Here, although there was no evidence of actual harm, the potential harm to the public and to Shiloh Family Pharmacy's consumers flowing from the violations was immense. Shiloh Family Pharmacy lost 9,675 tablets of controlled substances. These controlled substances were diverted and could have been sold on the black market. Shiloh Family Pharmacy also held misbranded bottles of Crestor and Seroquel containing tablets of unknown expiration dates which could have been dispensed to consumers. Although Shiloh Family Pharmacy has no prior history of discipline, the controlled substance loss and the violations found during the Board's June 2, 2014 inspection occurred within the first three months of its operation. The nature of the misconduct in this case, therefore, is serious, and the variety of the violations also includes failure to account for controlled substances and respondent Aronson's unauthorized access to the pharmacy area.

25. Most significantly, respondent Aronson presented scant evidence of rehabilitation. She failed to take full responsibility for the failures in security that led to the controlled substance loss at Shiloh Family Pharmacy. When asked why she did not administer the polygraph tests to her employees and conduct a more thorough investigation of the controlled substance loss, respondent Aronson stated that she was not an investigator. When asked why she did not provide Shiloh Family Pharmacy's Policy and Procedure prohibiting the sale of Schedule II controlled substances to either Inspector Bayley or complainant's counsel prior to December 12, 2017, she stated that she was not an attorney. These excuses are particularly troubling in light of respondent Aronson's previous experience as a pharmacy manager at Kovac's pharmacy for three years. Respondent Aronson also presented little evidence of any changes in Shiloh Family Pharmacy's security measures. Specifically, there was no evidence that surveillance cameras directed at the pharmacy area have been installed, that controlled substances are locked away in a cabinet, or that an inventory of controlled substances has been conducted every 90 days.

26. Furthermore, respondent Aronson was less than candid in her testimony at the hearing. Given the lack of evidence establishing any effort to prevent future drug loss and respondent Aronson's propensity for dishonesty, Shiloh Family Pharmacy cannot be relied upon to comply with reasonable terms or conditions that would be imposed if it were allowed to operate under a probationary license. As a result, protection of the public health, safety and welfare requires the revocation of Shiloh Family Pharmacy's pharmacy permit.

27. Because the discipline imposed is revocation, pursuant to Business and Professions Code section 4307, respondents Aronson and Voytova, as individual licensed owners, shall be prohibited from serving as a managers, administrators, owners, members, officers, directors, associates, or partners of a Board licensee, until the pharmacy permit is reinstated.

Costs

28. Under Business and Professions Code section 125.3, the Board may recover costs "not to exceed the reasonable costs of the investigation and enforcement" of this matter. As set forth in Factual Finding 52, the costs claimed are \$25,790.75. These costs are reasonable, and Shiloh Family Pharmacy did not present any evidence to warrant a reduction in costs.

29. Given the nature of the order below, it would be unnecessarily punitive to require Shiloh Family Pharmacy to pay the Board's costs at this time. However, it is reasonable to require Shiloh Family Pharmacy to pay the Board's costs if its pharmacy permit is ever reinstated.

ORDER

1. Pharmacy Permit Number PHY 51776, issued to Shiloh Family Pharmacy, Inc., doing business as Shiloh Family Pharmacy, is revoked. Respondents Diana Aronson and Natalia Voytova, owners of Shiloh Family Pharmacy, shall, by the effective date of this decision, arrange for the destruction of, the transfer to, sale of, or storage in a facility licensed by the board of all controlled substances and dangerous drugs and devices. Respondents Aronson and Voytova shall provide written proof of such disposition, submit a completed Discontinuance of Business form and return the wall and renewal licenses to the board within five days of disposition.

2. Respondents Aronson and Voytova are prohibited from serving as managers, administers, owners, members, officers, associates or partners of a licensee until Pharmacy Permit PHY 517756 is reinstated.

3. As a condition precedent to reinstatement of Shiloh Family Pharmacy's pharmacy permit, Shiloh Family Pharmacy shall reimburse the board for its costs of investigation and prosecution in the amount of \$25,790.75. Said amount shall be paid in full prior to the reapplication or reinstatement of Shiloh Family Pharmacy's pharmacy permit, unless otherwise ordered by the Board.

DATED: March 9, 2018

-DocuSigned by: Ji-lan Eans

JI-LAN®ZANG Administrative Law Judge Office of Administrative Hearings

1 2 3	XAVIER BECERRA Attorney General of California ARMANDO ZAMBRANO Supervising Deputy Attorney General NANCY A. KAISER Deputy Attorney General State Bar No. 192083	
4	300 So. Spring Street, Suite 1702 Los Angeles, CA 90013	
5	Telephone: (213) 897-5794 Facsimile: (213) 897-2804	
6	Attorneys for Complainant	
7		RE THE PHARMACY
. 8	DEPARTMENT OF C	CONSUMER AFFAIRS
9		CALIFORNIA
10	In the Matter of the Accusation Against:	Case No. 5813
11	SHILOH FAMILY PHARMACY INC.	
12	DBA SHILOH FAMILY PHARMACY, DIANA ARONSON and NATALIA	ACCUSATION
13	VOYTOVA, OWNERS PIC ALAN BROWN (2/28/14-5/29/14)	
14	5551 Hollywood Blvd., Space A	
15	Los Angeles, CA 90028	
16	Pharmacy Permit No. PHY 51776 and	
17 18	ALAN BROWN 202 118 th Avenue SE, #C11 Bellevue, WA 98005	
19	Pharmacist License No. RPH 22146	
20	Respondents.	
21		
22 23	Complainant alleges:	
23		TIES
25	1. Virginia Herold (Complainant) bring	s this Accusation solely in her official capacity
26	as the Executive Officer of the Board of Pharma	
27		Board of Pharmacy issued Pharmacy Permit
28	_Number_PHY 51776 to Shiloh Family Pharmacy	Inc. dba Shiloh Family-Pharmacy (Respondent-
		· · · · · · · · · · · · · · · · · · ·
	(SHILOH FAM	ILY PHARMACY and ALAN BROWN) ACCUSATION

1	Pharmacy). Diana Aronson and Natalia Voytova have been the owners (each own 50% of the
2	stock in Respondent Pharmacy) of Respondent Pharmacy since February 28, 2014. Diana
3	Aronson has been the President and Chief Executive Officer and Natalia Voytova has been the
4	Secretary since February 28, 2014. The Pharmacy Permit was in full force and effect at all times
5	relevant to the charges brought herein and will expire on February 1, 2018, unless renewed.
6	3. On or about August 10, 1961, the Board of Pharmacy issued Pharmacist License
. 7	Number RPH 22146 to Respondent Alan Brown (Respondent Brown). Respondent Alan Brown
.8	(RPH 22146) was the Pharmacist-in-Charge (PIC) of Respondent Pharmacy from February 28,
9	2014, to May 29, 2014. Respondent Brown worked at Respondent Pharmacy as a staff
10	pharmacist from May 30, 2014, through June 11, 2014. The Pharmacist License was in full force
11	and effect at all times relevant to the charges brought herein and expired on February 8, 2017, and
12	has not been renewed. The Pharmacist License is retired.
13	JURISDICTION
14	4. This Accusation is brought before the Board of Pharmacy (Board), Department of
15	Consumer Affairs, under the authority of the following laws. All section references are to the
16	Business and Professions Code (Code), unless otherwise indicated.
17	STATUTORY PROVISIONS
18	5. Section 4300 of the Code provides in pertinent part, that every license issued by the
19	Board is subject to discipline, including suspension or revocation.
20	6. Section 4300.1 of the Code states:
21	"The expiration, cancellation, forfeiture, or suspension of a board-issued license by
22	operation of law or by order or decision of the board or a court of law, the placement of a license
23	on a retired status, or the voluntary surrender of a license by a licensee shall not deprive the board
24	of jurisdiction to commence or proceed with any investigation of, or action or disciplinary
25	proceeding against, the licensee or to render a decision suspending or revoking the license."
26	
27	
	2
	(SHILOH FAMILY PHARMACY and ALAN BROWN) ACCUSATION

(SHILOH FAMILY PHARMACY and ALAN BROWN) ACCUSATION

7. Section 4301 of the Code states, in part:

"The board shall take action against any holder of a license who is guilty of unprofessional conduct or whose license has been procured by fraud or misrepresentation or issued by mistake. Unprofessional conduct shall include, but is not limited to, any of the following:

"(j) The violation of any of the statutes of this state, of any other state, or of the United States regulating controlled substances and dangerous drugs.

"(o) Violating or attempting to violate, directly or indirectly, or assisting in or abetting the violation of or conspiring to violate any provision or term of this chapter or of the applicable federal and state laws and regulations governing pharmacy, including regulations established by the board or by any other state or federal regulatory agency."

12

8.

1

2

3

4

5

6

7

8

9

10

11

13

14

15

16

17

18

19

20

21

22

23

24

25

26

27

 28°

Section 4302 of the Code states:

"The board may deny, suspend, or revoke any license of a corporation where conditions exist in relation to any person holding 10 percent or more of the corporate stock of the corporation, or where conditions exist in relation to any officer or director of the corporation that would constitute grounds for disciplinary action against a licensee."

9. Section 4113 of the Code states, in part:

"(b) The pharmacist-in-charge shall be responsible for a pharmacy's compliance with all state and federal laws and regulations pertaining to the practice of pharmacy."

10. Section 4115, subdivision (h), states that "[t]he pharmacist on duty shall be directly responsible for the conduct of a pharmacy technician supervised by that pharmacist."

11. Section 4116 of the Code states, in pertinent part:

"(a) No person other than a pharmacist, an intern pharmacist, an authorized officer of the law, or a person authorized to prescribe shall be permitted in that area, place, or premises described in the license issued by the board wherein controlled substances or dangerous drugs or dangerous devices are stored, possessed, prepared, manufactured, derived, compounded, dispensed, or repackaged. However, a pharmacist shall be responsible for any individual who –enters-the pharmacy for the purposes of receiving consultation from the pharmacist or performing

3

clerical, inventory control, housekeeping, delivery, maintenance, or similar functions relating to the pharmacy if the pharmacist remains present in the pharmacy during all times as the authorized individual is present."

4

1

2

3

5

6

7

8

9

10

11

12

13

12. Section 4307, subdivision (a), of the Code states, in pertinent part:

"Any person who has been denied a license or whose license has been revoked or is under suspension, or who has failed to renew his or her license while it was under suspension, or who has been a manager, administrator, owner, member, officer, director, associate, or partner of any partnership, corporation, firm, or association whose application for a license has been denied or revoked, is under suspension or has been placed on probation, and while acting as the manager, administrator, owner, member, officer, director, associate, or partner had knowledge of or knowingly participated in any conduct for which the license was denied, revoked, suspended, or placed on probation, shall be prohibited from serving as a manager, administrator, owner, member, officer, director, associate, or partner of a license as follows:

(1) Where a probationary license is issued or where an existing license is placed on
probation, this prohibition shall remain in effect for a period not to exceed five years.

(2) Where the license is denied or revoked, the prohibition shall continue until the license is issued or reinstated."

18

19

20

21

22

23

24

25

26

27

28

16

17

13. Section 4081 of the Code states, in pertinent part:

"(a) All records of manufacture and of sale, acquisition, receipt, shipment, or disposition of dangerous drugs or dangerous devices shall be at all times during business hours open to inspection by authorized officers of the law, and shall be preserved for at least three years from the date of making. A current inventory shall be kept by every manufacturer, wholesaler, third-party logistics provider, pharmacy, veterinary food-animal drug retailer, outsourcing facility, physician, dentist, podiatrist, veterinarian, laboratory, clinic, hospital, institution, or establishment holding a currently valid and unrevoked certificate, license, permit, registration, or exemption under Division 2 (commencing with Section 1200) of the Health and Safety Code or under Part 4 (commencing with Section 16000) of Division 9 of the Welfare and Institutions Code who maintains a stock of dangerous drugs or dangerous devices.

"(b) The owner, officer, and partner of a pharmacy, wholesaler, third-party logistics provider, or veterinary food-animal drug retailer shall be jointly responsible, with the pharmacistin-charge, responsible manager, or designated representative-in-charge, for maintaining the records and inventory described in this section."

13. Health and Safety Code Section 111440 states: "It is unlawful for any person to manufacture, sell, deliver, hold, or offer for sale any drug or device that is misbranded."

REGULATORY PROVISIONS

1

2

3

4

5

6

7

8

14. California Code of Regulations, title 16, section 1770, states:

9 "For the purpose of denial, suspension, or revocation of a personal or facility license
10 pursuant to Division 1.5 (commencing with Section 475) of the Business and Professions Code, a
11 crime or act shall be considered substantially related to the qualifications, functions or duties of a
12 licensee or registrant if to a substantial degree it evidences present or potential unfitness of a
13 licensee or registrant to perform the functions authorized by his license or registration in a manner
14 consistent with the public health, safety, or welfare."

15

16

17

18

19

20

21

22

23

24

15. California Code of Regulations, title 16, section 1714 states, in part:

"(b) Each pharmacy licensed by the board shall maintain its facilities, space, fixtures, and equipment so that drugs are safely and properly prepared, maintained, secured and distributed.The pharmacy shall be of sufficient size and unobstructed area to accommodate the safe practice of pharmacy."

"(d) Each pharmacist while on duty shall be responsible for the security of the prescription department, including provisions for effective control against theft or diversion of dangerous drugs and devices, and records for such drugs and devices. Possession of a key to the pharmacy where dangerous drugs and controlled substances are stored shall be restricted to a pharmacist."

25

26

27

28

16. California Code of Regulations, title 16, section 1718 states:

"Current Inventory' as used in Sections 4081 and 4332 of the Business and Professions Code shall be considered to include complete accountability for all dangerous drugs handled by every licensee enumerated in Sections 4081 and 4332.

5

(SHILOH FAMILY PHARMACY and ALAN BROWN) ACCUSATION

	- -					
1	"The controlled substances inventories required by Title 21, CFR, Section 1304 shall be					
2	available for inspection upon request for at least 3 years after the date of the inventory."					
. 3	COST RECOVERY					
4	17. Section 125.3 of the Code provides, in pertinent part, that the Board may request the					
5	administrative law judge to direct a licentiate found to have committed a violation or violations of					
6	the licensing act to pay a sum not to exceed the reasonable costs of the investigation and					
7	enforcement of the case, with failure of the licentiate to comply subjecting the license to not being					
8	renewed or reinstated. If a case settles, recovery of investigation and enforcement costs may be					
9	included in a stipulated settlement.					
10	18. <u>DRUC</u>	CLASSIFICATION	<u>S</u>			
11 12 13	Brand Name(s)	Generic Name	Dangerous Drug Per Bus. & Prof. Code § 4022	Scheduled Drug per Health & Safety Code (HSC)	Indications For Use	
14	Ambien	zolnidem tartrate	Ves	Schedule IV per	Insomnia	

Brand Name(s)	Generic Name	Dangerous Drug Per	Scheduled Drug per Health &	Indications For Use
		Bus. & Prof. Code § 4022	Safety Code (HSC)	
Ambien	zolpidem tartrate	Yes	Schedule IV per HSC § 11057(d)(32)	Insomnia
Lortab 7.25/325mg, Norco 10/325mg, Vicodin 5/300mg	hydrocodone/ acetaminophen (APAP)	Yes	Schedule III per HSC § 11056(e)(4) and Schedule II per 21 CFR 1308 (as of 10/6/14)	Moderate to Severe Pain
Celebrex 200mg	celecoxib	Yes	Not scheduled	Pain, Arthritis
Crestor 10mg/20mg	rosuvastatin calcium	Yes	Not scheduled	Cholesterol
Seroquel 25mg	quetiapine fumarate	Yes	Not scheduled	Schizophrenia, bipolar disorder, and depression.
///				
///	······	6	 - · · · · · · ·	·····

	FIRST CAUSE FOR DISCIPLINE					
(Failure to Maintain Operational Standards and Security)						
19. Respondents are subject to disciplinary action under section 4301, subdivision (o), of						
the Code, on the gro	ounds of unpro	fessional conduct	, for violating C	alifornia Code	of Regulations	
title 16, section 171	4, subdivisions	s (b) and (d), in th	at they failed to	secure the pha	rmacy to	
prevent loss of cont	rolled substanc	es. Specifically,	a Board audit of	the pharmacy	's controlled	
substances for the p	eriod of March	14, 2014, through	u June 2, 2014, w	hile Responde	ent Brown was	
the Pharmacist-in-C	harge, reveale	d that 9,675 table	ts of controlled s	substances wer	e unaccounted	
for, as follows:						
		TABLE (ONE			
	BEGINNING INVENTORY	TOTAL PURCHASED	TOTAL DISPENSED	ON STOCK	TOTAL DRUG LOSS (TABLET)	
Vicodin 5/300mg	91	2,400	1320	149	1,022	
Zolpidem 10mg	0	10,000	4,875	1,015	4,110	
Hydrocodone/ acetaminophen 7.5/325mg	100	1,700	990	99	711	
Hydrocodone/ acetaminophen 5/325mg	100	3,500	2,662	247	691	
Hydrocodone/ acetaminophen 10/325mg	280	4,200	1,230	109	3,141	
TOTAL LOSS					9,675	
		· · · ·		•	<u> </u>	
		ECOND CAUSE				
	,	re to Account for		,		
20. Respon	dents are subje	et to disciplinary	action under sec	tion 4301, sub	division (o), o	
the Code, on the gro	ounds of unpro	fessional conduct	t, for violating se	ection 4081 of	the Code and	
California Code of	Regulations, ti	tle 16, section 17	18, by failing to	maintain a "cu	rrent	
inventory", in that Respondents were unable to account for 9,675 tablets of controlled subs					lled substance	

Complainant re	Complainant refers to, and by this reference incorporates, the allegations set forth above in					
paragraph 19, as though set forth in full herein.						
	THIR	D CAUSE FOR	<u>DISCIPLINE</u>			
	(H	olding Misbrand	led Drugs)			
21. Respondents are subject to disciplinary action under section 4301, subdivision (j), of						
the Code, on th	e grounds of unprofe	ssional conduct, f	for violating He	alth and Safety Code sect		
111440, by hol	ding misbranded drug	gs. Specifically, o	on or about June	2, 2014, during a Board		
inspection of R	espondent Pharmacy	's facility, located	l at 5551 Hollyv	vood Blvd., Space A, Los		
- Angeles, Califo	rnia, misbranded dar	igerous drugs (Cr	estor 10 and 20	ng, Celebrex 200mg, and		
- · ·				macy's active inventory.		
follows:	1	9				
DRUG NAME	MANUFACTUR	TABLE TW LOT NO.	<u>VO</u> TOTAL	COMMENTS		
AND STRENGTH	ER AND PACKAGE SIZE	AND EXPIRATION DATE	QUANTITY FOUND			
Crestor 10mg	AstraZeneca 1 container (90 tablets)	CF0004 (12/2016)	150 tablets	Overfilled packaging ¹ Chipped tablets ²		
Crestor 20mg	AstraZeneca 1 container (90 tablets)	CF0002 (11/2016)	90 tablets	Chipped tablets. Variation on appearance of imprints Missing temper evidence seal		
			2.5 1	Variation on		
Celebrex 200mg	Pfizer 1 container (100 capsules)	H67410 (09/2016)	35 capsules	appearance of imprint		
	1 container		35 capsules 383 tablets	appearance of imprint on the capsules (lighte		
200mg Seroquel 25mg 1 Overfi numbers or ma ² Chipp date, over hand ³ Variat	1 container (100 capsules) AstraZeneca 1 container (100 tablets) Iled packages may innufacturers, or the drawn damaged table ling, and/or exposure	(09/2016) AN0021 (02/19/15) dicate that the dr ugs were from a r ets may indicate r to extreme weath nay indicate coun	383 tablets 383 tablets ugs in the packa on-FDA appro- nishandling of c her temperature terfeit drugs or	appearance of imprin on the capsules (light vs. darker hue) Overfilled packaging uge were from different ved source. trugs due to beyond exp s (freezing or heat) pills from different lot		

(SHILOH FAMILY PHARMACY and ALAN BROWN) ACCUSATION

ą.

FOURTH CAUSE FOR DISCIPLINE

(Unauthorized Access to Pharmacy)

22. Respondent Pharmacy is subject to disciplinary action under section 4301, subdivision (o), of the Code, on the grounds of unprofessional conduct, for violating section 4116, subdivision (a), of the Code, by allowing personnel into the pharmacy without a pharmacist present. Specifically, on or about June 2, 2014, U.S. Drug Enforcement Administration (DEA) agents observed Diana Aronson (unlicensed) and a pharmacy technician, S.G., enter the pharmacy area of Respondent Pharmacy's facility, located at 5551 Hollywood Blvd., Space A, Los Angeles, California, without a pharmacist present.

OTHER MATTERS

23. Pursuant to section 4307 of the Code, if discipline is imposed on Pharmacy Permit Number PHY 51776 issued to Shiloh Family Pharmacy Inc. dba Shiloh Family Pharmacy, Shiloh Family Pharmacy Inc. shall be prohibited from serving as a manager, administrator, owner, member, officer, director, associate, or partner of a licensee for five years if Pharmacy Permit Number PHY 51776 is placed on probation or until Pharmacy Permit Number PHY 51776 is reinstated if it is revoked.

24. Pursuant to section 4307 of the Code, if discipline is imposed on Pharmacy Permit Number PHY 51776 issued to Shiloh Family Pharmacy Inc. dba Shiloh Family Pharmacy while Diana Aronson and Natalia Voytova have been an officer and owner and had knowledge of or knowingly participated in any conduct for which the licensee was disciplined, Diana Aronson and Natalia Voytova shall be prohibited from serving as a manager, administrator, owner, member, officer, director, associate, or partner of a licensee for five years if Pharmacy Permit Number PHY 51776 is placed on probation or until Pharmacy Permit Number PHY 51776 is reinstated if it is revoked.

9

///

|||

1

 2°

3

4

5

6

7

8

9

10

11

12

13

14

15

16

17

18

19

20

21

22

23

24

25

26

27

28

(SHILOH FAMILY PHARMACY and ALAN BROWN) ACCUSATION

1	DISCIPLINE CONSIDERATIONS					
2	25. To determine the degree of discipline, if any, to be imposed on Respondent Brown,					
3	Complainant alleges that in or about 2001, in a prior action, the Board of Pharmacy issued					
4	Citation Number CI 2001 23242 to Respondent Brown, for violating sections 4301					
5	(unprofessional conduct), 4301, subdivision (o) (violation of laws or regulations governing					
6	pharmacy), and 4076 (inaccurate label), of the Code, and California Code of Regulations, title 16,					
7	section 1716 (prescription deviation). That Citation is now final and is incorporated by reference					
8	as if fully set forth.					
9	///					
10						
11						
12						
13	///					
14	/// · · · · · · · · · · · · · · · · · ·					
15						
16						
17	///					
18	///					
19	///					
20						
21	///					
22	/// · · · · · · · · · · · · · · · · · ·					
23	///					
24						
25	///					
26	///					
27	///					
28	///					

(SHILOH FAMILY PHARMACY and ALAN BROWN) ACCUSATION

PRAYER 1 WHEREFORE, Complainant requests that a hearing be held on the matters herein alleged, 2 and that following the hearing, the Board of Pharmacy issue a decision: 3 1. Revoking or suspending Pharmacy Permit Number PHY 51776, issued to Shiloh 4 Family Pharmacy Inc. dba Shiloh Family Pharmacy, 5 2. Revoking or suspending Pharmacy License Number 22146 issued to Alan Brown. 6 3. Prohibiting Diana Aronson from serving as a manager, administrator, owner, 7 member, officer, director, associate, or partner of a licensee for five years if Pharmacy Permit 8 Number PHY 51776 is placed on probation or until Pharmacy Permit Number PHY 51776 is 9 reinstated if Pharmacy Permit Number PHY 51776 issued to Shiloh Family Pharmacy Inc. dba 10 Shiloh Family Pharmacy is revoked; 11 4. Prohibiting Natalia Voytova from serving as a manager, administrator, owner, 12 member, officer, director, associate, or partner of a licensee for five years if Pharmacy Permit 13 Number PHY 51776 is placed on probation or until Pharmacy Permit Number PHY 51776 is 14 reinstated if Pharmacy Permit Number 51776 issued to Shiloh Family Pharmacy Inc. dba Shiloh 15 Family Pharmacy is revoked; 16 Ordering Respondent Pharmacy, Respondent Brown, Diana Aronson and Natalia 5. 17 Voytova to pay the Board of Pharmacy the reasonable costs of the investigation and enforcement 18 of this case, pursuant to Business and Professions Code section 125.3; 19 6. Taking such other and further action as deemed necessary and proper. 20 21 22 23 3/18/17 24 DATED: VIRGINIA HEROLD 25 Executive Officer Board of Pharmacy 26 Department of Consumer Affairs State of California .27

(SHILOH FAMILY PHARMACY and ALAN BROWN) ACCUSATION

28

LA2016600987 52075871 2.doc

Complainant

11