

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

**In the Matter of the First Amended Accusation Against:**

**PATHWAY PHARMACEUTICALS INC., dba  
FIRESIDE PHARMACY,**

**Pharmacy Permit No. PHY 47407, and**

**Sterile Compounding Pharmacy License No. LSC 99523;**

**and**

**ADEYEMI AKINTUNDE OMILANA,**

**Pharmacist License No. RPH 46012,**

**Respondents**

**Agency Case No. 6470**

## 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 27, 2020.

It is so ORDERED on April 27, 2020.

BOARD OF PHARMACY  
DEPARTMENT OF CONSUMER AFFAIRS  
STATE OF CALIFORNIA

A handwritten signature in black ink, appearing to read "Greg M. Lippe", written in a cursive style.

By

Greg Lippe  
Board President

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

**In the Matter of the First Amended Accusation Against:**

**PATHWAY PHARMACEUTICALS, INC. dba FIRESIDE  
PHARMACY, Respondent**

**Pharmacy Permit No. PHY 47407**

**Sterile Compounding Pharmacy License No. LSC 99523**

**and**

**ADEYEMI AKINTUNDE OMILANA, Respondent**

**Pharmacist License No. RPH 46012**

**Agency Case No. 6470**

**OAH No. 2019090058**

**PROPOSED DECISION**

Kimberly J. Belvedere, Administrative Law Judge, Office of Administrative  
Hearings, State of California, heard this matter on January 6 and 7, 2020.

Theodore S. Drcar, Deputy Attorney General, appeared on behalf of complainant, Ann Sodergren, Executive Officer,<sup>1</sup> Board of Pharmacy, Department of Consumer Affairs, State of California (board).

Ronald S. Marks, Attorney at Law, appeared on behalf of respondents.

Oral and documentary evidence was received. The record was held open for closing briefs, which were timely submitted and considered. The record closed and the matter was submitted for decision on February 5, 2020.

## **FACTUAL FINDINGS**

### **Jurisdictional Matters**

1. On March 10, 1993, the board issued Pharmacist License Number RPH 46012 to respondent Adeyemi Omilana. Mr. Omilana's license was in full force and effect at all times relevant to his matter.

2. On February 16, 2006, the board issued Pharmacy Permit Number PHY 47407 to Pathway Pharmaceuticals, Inc., doing business as Fireside Pharmacy (Fireside), with Mr. Omilana listed as the pharmacist-in-charge.

3. On October 7, 2008, the board issued Sterile Compounding Pharmacy License Number LSC 99523 to Fireside.

---

<sup>1</sup> Ms. Sodergren, who was Interim Executive Officer at the time of the filing of the first amended accusation, has since been appointed Executive Officer.

4. There is no prior history of discipline against any of the licenses.<sup>2</sup>

5. On August 30, 2019, complainant, in her official capacity, filed the first amended accusation against respondents, alleging the following causes for discipline:

Causes for Discipline Related to Security and Recordkeeping: The following causes for discipline relate to security and controls in place at Fireside, and the transfer of compounded medications to Las Palmas Pharmacy, which is also owned and operated by Mr. Omilana:

First Cause for Discipline: Failure to Adhere to Operational Standards and Security, in violation of California Code of Regulations, title 15, section 1714, subdivisions (b) and (d). Complainant alleged respondents failed to maintain adequate security and control over the purchase, intake, and security of controlled substances, which resulted in a pharmacy technician being able to steal 5,000 Xanax<sup>3</sup> pills from the pharmacy, and the inability to account for an additional 22,285 Xanax pills.

---

<sup>2</sup> On February 13, 2015, the board issued a citation to Fireside and one to Mr. Omilana for having an intern pharmacist work at Fireside without a current intern pharmacist license from October 1, 2013, to December 27, 2013. On November 17, 2017, the board issued a citation to Mr. Omilana for the presence of expired medications at Fireside and dispensing of medications that had expired.

<sup>3</sup> Xanax is the trade name for Alprazolam, a benzodiazepine, which is classified as a schedule IV controlled substance and a dangerous drug. (Health & Saf. Code, § 11057, sub. (d); Bus. and Prof. Code, § 4022.)

Second Cause for Discipline: Failure to Maintain Records of Disposition of Dangerous Drugs, in violation of Business and Professions Code sections 4059, subdivisions (a) and (b), and 4081, subdivision (a). Complainant alleged respondents failed to maintain complete records for the transfer of controlled substances, among other things, from Fireside to Las Palmas Pharmacy, another pharmacy owned by Mr. Omilana. Complainant also alleged that during an inspection of Fireside on February 10, 2016, nine written orders for transfers of non-controlled substances were found, which did not include the name and address of the buyer and seller, as required. Mr. Omilana admitted that transfer records were only kept for controlled substances, and not for other dangerous drugs, bases, devices, filters, and non-bulk items.

Causes for Discipline Related to Incorrect Expiration Dates: Complainant alleged respondents dispensed compounded medications that were labeled with incorrect expiration dates (beyond use dates [BUDs]) that exceeded the BUD for one or more of the ingredients contained in the compounded medications, as follows:

Third Cause for Discipline: Dispensing Dangerous Drugs in Incorrectly Labeled Containers, in violation of Business and Professions Code sections 4076, subdivision (a)(9), and 4077, subdivision (a).

Fourth Cause for Discipline: Sales of Compounded Medications Lacking in Quality or Strength, in violation of Business and Professions Code sections 4301, subdivision (f), and 4342.

Fifth Cause for Discipline: Misbranding of Dangerous Drugs, in violation of Health and Safety Code section 111440.

6. Complainant seeks suspension or revocation of all licenses at issue and recovery of all investigation and enforcement costs.

## **Evidence Presented by Complainant**

### **THE BOARD'S FEBRUARY 10, 2016, INVESTIGATION**

7. Sejal Desai is an inspector with the board. Her testimony, and the report she completed regarding her investigation, are summarized as follows: Ms. Desai has been a licensed pharmacist in California since 2003, and is also licensed in two other states. As a pharmacist, Ms. Desai worked in large retail pharmacies and independent private pharmacies, as a pharmacist in charge, and also in quality assurance. Ms. Desai has investigated over 500 cases for the board for a variety of disciplinary offenses. Ms. Desai has also conducted many investigative audits, which involve looking for correct BUDs and ensuring compounded products do not have a BUD date beyond six months overall, or a shorter duration if any one substance in the compounded product has a shorter BUD date. The most concerning investigations are those involving controlled substances, because they are highly regulated and worth more "on the streets" than in the pharmacy.

The investigation in this case began when Mr. Omilana reported a theft of 5,000 Xanax (2mg)<sup>4</sup> pills that occurred at Fireside Pharmacy. The 2 mg Xanax pill is the highest potency of Xanax that exists. Xanax is used to treat anxiety. Xanax is sold on the black market and the 2mg pill is the highest demand of all the drugs in the benzodiazepine class. It sells between \$3 to \$5 per pill on the street. Users of Xanax can become physically dependent on Xanax. Mr. Omilana utilized the required DEA 106 form to make his report on December 28, 2015. At least one of Fireside's

---

<sup>4</sup> All further references to Xanax are to the 2mg dosage.

employees had stolen the Xanax, but it had been returned.<sup>5</sup> Mr. Omilana also reported that, since the theft, he had installed two more cameras, installed rolling locked shutters to lock up all Schedule III through V drugs, and changed the delivery receiving process so that all shipments had to be approved by Mr. Omilana or other authorized personnel.

Whenever the board gets notified regarding a theft or loss, the board sends out a letter of audit, which requests additional documents. In the case of Fireside Pharmacy, the audit period was June 26, 2015, through December 28, 2015. Mr. Omilana produced all documents required of him by the end of December 2015. The records included inventory counts at the beginning and end of the audit period; invoices; acquisition records; and dispensing records. The audit showed that, starting in June 2015, Fireside had 30 pills of Xanax. During the audit period, Fireside acquired 30,000 pills from its wholesaler, AmeriSource Bergen. At the end of the audit period, 600 pills remained. Aside from the 5,000 Xanax pills that were stolen but returned, an additional 22,285 Xanax pills were unaccounted for.<sup>6</sup>

---

<sup>5</sup> In a statement respondent wrote to the board on January 12, 2016 (incorrectly dated January 12, 2015), respondent noted that an employee, Susana Fernandez, confessed to taking the 5,000 Xanax pills. She signed a written statement admitting as much, which was also provided to the board. Although there were video cameras in Fireside, Mr. Omilana was unable to retrieve video of the theft. By Stipulated Surrender of License and Order effective August 28, 2018, Ms. Fernandez surrendered her pharmacy technician license.

<sup>6</sup> Specifically, Fireside had 30 Xanax pills starting in June 2016. During the audit period, 30,000 Xanax pills were ordered; 2,075 were sold through proper dispensing.



In looking at the dispensing records for Fireside, only 2,075 Xanax pills had actually been dispensed during the audit period. Thus, orders during the audit period for 30,000 Xanax pills were inconsistent with Fireside Pharmacies dispensing practices, and the large quantity ordered should have been a “red flag” to the pharmacist that something was awry.

On February 10, 2016, Ms. Desai conducted an inspection at Fireside and Las Palmas. Ms. Desai predominantly reviewed security measures for controlled substances, such as where they were stored, who had authority to order controlled substances, and compounding records. Mr. Omilana is the pharmacist in charge at both pharmacies. While only Mr. Omilana could order Schedule II controlled substances, anyone at Fireside was permitted to order any other substance from AmeriSource Bergen. It is not improper to delegate ordering authority to employees, However, a pharmacist who does so should verify every order prior to submission and conduct random audits. Fireside was not doing this.

Further, typical operational standards in pharmacy practice is to lock up controlled substances. Some pharmacies only lock up Schedule II controlled substances, but many have all schedules locked up with only a small amount of Schedule III through V controlled substances available on the shelves. Most pharmacies do not permit anyone to make orders, but if they do, at a minimum, the pharmacist should ensure when deliveries come in that they are correct or do random audits of invoices. Fireside did not have adequate controls because they allowed all

---

70 were returned for destruction. At the end of the audit period, only 600 Xanax pills remained.

employees to order drugs, had no random audits, did no verification of deliveries, and had nothing in place to notice if any orders were inappropriate.

Regarding compounding practices, all ingredients in a compounded medication must have an expiration or BUD date that is appropriate. In no event may a compounded medication have a BUD date that exceeds six months. In the event any one ingredient in a compounded medication has an expiration or BUD date shorter than six months, the compounded medication must contain a BUD date that reflects the shorter date. Compounded medications are medications that are made for a specific dosage that is needed by a patient. Not all pharmacies are compounding pharmacies. To become a compounding pharmacy, a separate license is required. Essentially, the BUD date is important because beyond that date, a manufacturer cannot guarantee safety or strength of the product. Some BUD dates are less than six months because of how the individual ingredients interact with each other. Sometimes, when compounded, certain ingredients are not stable and will lose potency or stability prior to six months. Further, there is a threat of harm to the public because if a product is expired or not stable it may be ineffective in treating the patient or may even cause an adverse reaction. The sale of medications beyond the BUD date also constitutes fraud because patients are falsely led to believe they are receiving proper medication.

During her records inspection, Ms. Desai found approximately 28 compounding worksheets for medications dispensed between February 1, 2016, and February 9, 2016, which contained incorrect BUD dates. Specifically, the BUD of the final compounded medications reflected six months, which exceeded the expiration or BUD date for at least one of the ingredients in each compounded medication. Ms. Desai found similar irregularities at Las Palmas.

Regarding transfer of medications and recordkeeping, Ms. Desai found nine transfer orders for either progesterone or testosterone, dated between October 25, 2014, and February 2, 2016, that did not include the name and address of the buyer and seller as required by law. The drugs were transferred to Las Palmas. Las Palmas had no records of the transfers. Respondent admitted to Ms. Desai that unless a medication is a controlled substance, transfer records are not usually kept.

Ms. Desai has not returned to Fireside since her February 10, 2016, inspection. Respondents produced six inspection reports regarding inspections conducted at Fireside since 2016, to show he has had no further issues at Fireside. Ms. Desai had no knowledge of the six inspections, but said they appeared to be official inspection reports.<sup>7</sup>

---

<sup>7</sup> Respondents did not produce the six inspection reports in discovery. In a letter to complainant dated December 18, 2019, respondents stated that they had “copies of inspection reports” for the “last few years” but did not specify which reports they intended to produce or provide copies of the reports to complainant. Complainant objected to the introduction of the inspection reports on the basis that they had not been produced in discovery. Complainant was given time off the record to review the inspection reports with Ms. Desai, who stated that they appeared to be board inspection reports, but that she had no participation or knowledge of those inspections. Respondents’ counsel requested official notice be taken of the reports under Government Code section 11515, but it was noted that while official notice can be taken of the existence of the reports, not the content, which constitutes hearsay. None of the individuals who completed the inspections were called to testify. Over objection, the inspection reports were admitted and classified as administrative

## **Evidence Presented by Respondents**

### **TESTIMONY OF MR. OMILANA**

8. Mr. Omilana's testimony, curriculum vitae, and documents he submitted to support his testimony are summarized as follows: He has been a licensed pharmacist since 1993. He obtained a degree in Pharmacy in 1987 from the University of Ife, Nigeria. He was on the fast track clinical pharmacy program. When respondent emigrated to California, he was permitted to take the pharmacy board exam because his degree was equivalent to a bachelor's degree. Mr. Omilana is a member of the Professional Compounding Centers of America, the International Academy of Compounding Pharmacies, the American Academy of Anti-Aging Medicine, the California Pharmacist Association, and the National Community Pharmacists Association. He is a fellow of the American College of Veterinary Pharmacists.

Mr. Omilana worked as a pharmacist in Nigeria from 1988 to 1992. After coming to California, he worked as an intern pharmacist at Thrifty from 1992 to 1993. Thereafter, he became the pharmacist at Thrifty and remained there until 1995. He became the pharmacy manager at Walmart in 1997, and then promoted to staff pharmacist in 2000. While working at Walmart, Mr. Omilana became a co-owner of Anza Valley Pharmacy. In 2002, he acquired Las Palmas. In 2005 he acquired Fireside. In 2013, he acquired La Quinta Pharmacy.

---

hearsay pursuant to Government Code section 11513, subdivision (d). In that respect, they can be used to supplement or explain other properly admitted testimony. Mr. Omilana testified about the inspection reports, so the reports supplement or explain his testimony.

In 2011, Mr. Omilana was awarded the Compounding Pharmacist of the Month Award from the Professional Compounding Centers of America. Mr. Omilana is very proud of his compounding abilities; he works with physicians from all over the Coachella Valley and sometimes beyond, because not all pharmacies can handle physician compounding requests.

Susana Fernandez was employed at Fireside and had worked for Mr. Omilana for approximately eight years before the December 2015 theft of Xanax pills. Her performance as an employee during those eight years was great. She was very productive, hard-working, and had good demeanor. Mr. Omilana had "no clue" that she would do something dishonest. Although he still does not know how she was able to steal the Xanax, he opined that because she knew the system, she may have ordered the Xanax from the wholesaler and diverted the pills at the time of delivery.

Typically, when Fireside orders Xanax, only one bottle is ordered. The amount stolen by Ms. Fernandez was the equivalent of 10 bottles. Mr. Omilana was surprised that such a deviation from the amount Fireside usually ordered was not identified and flagged by AmeriSource Bergen. He felt they should have notified Fireside of the unusual amount.

Prior to the theft, only employees who performed data entry had access to order non-Schedule II controlled substances from AmeriSource Bergen. Since the theft, Mr. Omilana has notified AmeriSource Bergen and had them create a unique username and password for any person authorized to make orders so that every single order can be tracked.

When Mr. Omilana was notified about the missing Xanax, he immediately went to Fireside. He contacted the IT employee and had him look at cameras and video to

see if they could find how the theft occurred. They were not able to find video of what occurred.

Mr. Omilana could not believe the pharmacy could be missing 10 bottles of Xanax. Before finding out who may have stolen the Xanax, Mr. Omilana was immediately concerned about securing the pharmacy. That same day, Mr. Omilana bought nine additional cameras to add to his system in addition to the four cameras that already existed. He ordered custom shutters with a lock for the cabinet that contains all Schedule III through V substances. Policies and procedures regarding Schedule II controlled substances were reviewed with all employees. All Schedule II controlled substances were already kept in a locked cabinet. After the theft, a safe was purchased and the key to the locked cabinet would be kept in the safe. Only pharmacists had the combination to the safe. Metal bars were installed on the windows. Fireside also invested in a machine that not only counts pills as they are being prepared, but it takes a picture of the count so the pills being counted can be identified. That picture is stored for later retrieval in case anything dispensed needs to be verified.

After the theft, Mr. Omilana filled out the required form and self-reported the theft to the board. Once the board requested documentation, he provided all that was asked of him. After the audit, when he was informed that over 20,000 Xanax pills were missing, he was "shocked."

Regarding the products with expired BUDs, respondent said that most of the dispensed medications contained testosterone. The testosterone used came from a large drum and was not expired. In order to make manipulation of medications easier, testosterone would be placed in a separate smaller bottle and compounded medications would be made from the testosterone in the smaller bottle. The smaller

bottles contained an expiration date that was shorter than the expiration date of the product in the drum. Thus, technically, the testosterone being used in the compounded medications was not expired. Mr. Omilana tried to explain to Ms. Desai that the testosterone drum he purchased was dated December 2015 – but feels she disregarded what he sent her. Mr. Omilana conceded that when the testosterone was transferred from the drum to the smaller containers, he should have changed the label. Although Fireside still engages in the same practice (of purchasing a big drum for certain medications), when these medications are transferred into a smaller container, the smaller container is properly labeled.

Regarding the issue of assigning the wrong BUDs, Mr. Omilana understood that the date is typically six months but must be labeled with a shorter BUD if any one ingredient had a BUD less than six months. Mr. Omilana admitted that the incorrect BUDs were “an oversight” on his part, but noted that most of the medications dispensed with the incorrect BUD were prescriptions to be used in 15 or 30 days. Thus, if properly used, they would have been used long before they expired. Fireside now ensures that every BUD is correct. On cross-examination, respondent became emotional when confronted with the records showing the wrong BUDs. Mr. Omilana cried, and asserted that it was never his intent to defraud anyone.

Since the December 2015 theft, Fireside has undergone six inspections and no new problems have been noted. Mr. Omilana was present during each and every one of the inspections and provided board inspection reports he received. Those inspection reports were dated May 30, 2017; December 29, 2017; February 27, 2018; April 24, 2018; December 19, 2018; and November 1, 2019. All of the inspection reports were signed (and thus authenticated) by Mr. Omilana. The inspection reports

do not indicate Mr. Omilana or Fireside has engaged in any violations of pharmacy law.

Regarding the transfer of progesterone and testosterone from Fireside to Las Palmas, Fireside only recorded transfers of controlled substances. Since progesterone and testosterone were not Schedule II controlled substances, there were no proper records. At present, Fireside has a sales book for transfers of any item – not just controlled substances. Las Palmas has a record of all requests. Further, all transfers have to be approved by Mr. Omilana.

If Fireside and/or Mr. Omilana are put on probation, economic harm will ensue because some suppliers will not supply to a probationary pharmacy. Mr. Omilana was sincere, contrite, and credible in his testimony.

### **CHARACTER WITNESSES**

9. Mr. Omilana called multiple character witnesses. Their testimony is summarized below.

10. Kristine Braunschweiger has lived in Palm Desert for 17 years. Ms. Braunschweiger utilizes Fireside Pharmacy for her needs. Ms. Braunschweiger has a medical condition that requires specially formulated medications and no pharmacy other than Fireside has been able to accommodate her pharmaceutical needs. Respondent is like a family friend. Respondent attends her church and also bible study, which is conducted in Ms. Braunschweiger's home. Respondent is honest and has integrity in the way he interacts with everyone in the community. Respondent has an amazing reputation.



11. Marshall Hankin has been a licensed pharmacist since 1966. His testimony is summarized as follows: Mr. Hankin ran his own pharmacy for many years and sold it to respondent. Mr. Hankin noted that when a pharmacist sells his pharmacy to someone, the seller gets a real idea of who the buyer is. Respondent had a wife and two kids, was not doing anything "shady," and was conducting himself in an open and "above-board" manner. Mr. Hankin appreciated that. Mr. Hankin has worked in other pharmacies since he sold his own. He began working at Fireside in 2015. He wanted to work there because he knew respondent to be an honest and ethical person. Mr. Hankin's duties at Fireside included supervising pharmacy technicians and clerks, performing consultations, taking phone calls, and checking the accuracy of prescriptions, among other things. As far as he knows, Fireside is the only compounding pharmacy in the area.

Security has changed since the incident that gave rise to this accusation. Schedule II controlled substances are now locked in a safe; schedule III through V substances are on the shelves in a locked area, although it is kept open during the day. The key to the shelves is kept in the safe. Metal bars have been placed throughout the building. There is an alarm system. The safe is only accessible by a pharmacist. Regarding compounding, the practice now is to check each compounding ingredient and make sure it is not outdated and that the product will not expire prior to the BUD. Recently, Fireside also purchased a special tray that ensures only the proper pill count for each medication is completed; it even has a sensor so that the tray can verify that the pills being sorted/counted match those being dispensed. In short, Mr. Hankin said Fireside is very cautious about mistakes. Finally, when employees come into the pharmacy, they bring their belongings in clear plastic bags so everyone one can see what is going in and out of the pharmacy. That way, Fireside can make sure employees do not leave the facility with something that does not belong to them.

Mr. Hankin described respondent as an ethical, honest, competent, and technically skilled pharmacist who constantly reads and updates his skills. Respondent is frequently contacted by other pharmacists and doctors to ask for his advice. Respondent puts customers first and is a humble man.

12. Alan Nyman has been a licensed pharmacist since 1959. He has worked at Fireside for five years. Mr. Nyman corroborated Mr. Hankin's testimony with respect to security procedures and controls at Fireside. Mr. Nyman has known Mr. Omilana for some time, having worked with Mr. Omilana before the latter's purchase of Fireside. Fireside has an excellent reputation in the community. Respondent works very hard and spends time with patients.

13. Sophie Lara is currently employed as an office assistant at Fireside. She has worked there for 10 years. Her duties include ordering supplies, assisting with payroll, invoicing, and data entry. She is supervised by Mr. Omilana and his wife. Mr. Omilana is almost always present.

14. Regarding the theft, Ms. Lara said that once it was discovered that there were 10 bottles of Xanax missing, everyone was looking for them. Nobody would have questioned "Susie Fernandez's" honesty; she was like the "lead compounder" at the time. She worked right behind Mr. Omilana and was quick and proficient. Her husband was a border patrol agent and she had two children. While everyone was looking for the missing bottles, Ms. Fernandez asked her if Mr. Omilana had figured out who took them. She then told Ms. Lara she was tired of waiting and told her to tell Mr. Omilana that she and another employee, Mariana Lopez, took the Xanax. That same night, Ms. Fernandez returned the 10 missing bottles in the presence of her and Mr. Omilana. Ms. Fernandez resigned on December 22, 2015. Ms. Lopez was also fired because she had confessed to stealing four bottles of Xanax from Las Palmas.

Ms. Lara corroborated Mr. Omilana's testimony with respect to reviewing the video cameras after discovery of the December 2015 Xanax theft. When it was discovered that the cameras either were not working properly or something was wrong with the system, Mr. Omilana immediately went to Costco and purchased more cameras. Now there are cameras that cover the lunch area, stairs, back room, storage area, the compounding room, and additional views of the register area. The new system also has more capabilities to store data. Ms. Lara was also the one charged with ordering custom shutters for the Schedule III through V controlled substances. That shuttered area is behind the pharmacist work station. Schedule II controlled substances are locked up and only the pharmacists have the PIN number to the safe that holds the key to unlock them.

Regarding the ordering of any drugs, following this incident, those responsible for ordering were given their own username and password so orders can be traced.

Regarding the transfer of substances between pharmacies, Ms. Lara was charged with creating a form to properly record transfers. She did so within a few days of the board investigation.

15. Robert Elsner is a former member of the board. He was appointed by Governor Pete Wilson to serve as a public member from 1998 to 2002. He served as president of the board in 2000. Mr. Elsner is a retired CEO of the California Medical Association. He has worked with physicians in some capacity for over 35 years. Mr. Elsner is heavily involved in the local community and has never heard anything bad about Mr. Omilana. Fireside is a good pharmacy and the staff are very professional. The service is great. Mr. Elsner understands that the primary duty of the board is to protect the public and while he understands that Fireside should have had tighter controls he would not think probation is appropriate. When he was on the board, he

saw “very bad apples.” Mr. Omilana, in contrast, is a good and dedicated pharmacist who was “duped and made a mistake.” Mr. Elsner admitted that he was only aware of the missing Xanax allegations; he did not know prior to his testimony about the allegations involving compounding and transfer problems.

16. Jeralyn Brossfield, M.D., is a doctor with a practice in the Coachella Valley. She has known Mr. Omilana for a very long time; she refers approximately 20 to 30 patients to him every month. Dr. Brossfield chooses Fireside because it is a compounding pharmacy, which is what many of her patients need. Mr. Omilana is very knowledgeable about drug interactions. For that reason, Dr. Brossfield seeks him out when she needs something special for the women she treats. Dr. Brossfield is aware that Mr. Omilana has sought out additional training for himself regarding interactions between supplements and pharmaceuticals. Dr. Brossfield has had Mr. Omilana act as a guest lecturer for her in 2010 and 2013, regarding gut health and women’s hormones. Compared to other pharmacists in the area, Dr. Brossfield sees Mr. Omilana as a “thought leader” in the community because of his skill. Mr. Omilana shows her a great deal of respect, which other pharmacists often fail to do. Some pharmacies have either changed her prescriptions or disparaged her recommendations to her patients, which Mr. Omilana does not do. Dr. Brossfield has confidence in Mr. Omilana’s skill because her patients have consistent blood levels when taking compounded medications from Fireside, whereas with other pharmacies, her patients’ blood levels are “all over the map.”

Dr. Brossfield testified that Ms. Omilana’s understanding regarding the BUDs is that it simply means a medication is expired but not unsafe. Even assuming the facts in the first amended accusation were true, it would not affect her opinion regarding Mr. Omilana’s character. If she ever received an expired medication, she would simply call

Fireside and report it. Dr. Brossfield explained that she would be concerned if medications were expired, but at the same time, she does not think the pharmacy profession is as fantastic as everyone seems to think it is. Dr. Brossfield said her senses are dulled to mistakes but, as professionals, she understands everyone tries to do their best.

17. Yetunde Omilana is Mr. Omilana's wife. They have been married for 27 years and have three adult children. Mrs. Omilana holds a Bachelor of Science in chemical engineering and a Master of Science in environmental engineering. Mrs. Omilana works in all three pharmacies owned by Mr. Omilana. Her duties include bookkeeping and human resources. Mrs. Omilana was very surprised when it was discovered that Ms. Fernandez stole the 10 bottles of Xanax. There were no signs that she was a dishonest person. Since Ms. Fernandez left, there have been no problems. Billing is now conducted on a bi-monthly basis. Mrs. Omilana checks all invoices twice per month, so she knows what is being ordered from the wholesalers. All three pharmacies have an excellent reputation in the community.

## **Costs**

18. Complainant requested cost recovery under Business and Professions Code section 125.3. A certification by the deputy attorney general contained information related to services provided by the Office of the Attorney General and included costs of prosecution in the amount of \$16,432.50.<sup>8</sup> The certification complied

---

<sup>8</sup> This amount omits an estimated 16 hours of hearing preparation for an additional \$3,520. The estimate failed to comply with the regulation as there was no explanation for the reason actual cost information was not available or declarations

with California Code of Regulations, title 1, section 1042, subdivision (b), and the requested costs were reasonable.

19. A certification of investigative costs in the amount of \$6,352.50 was also attached. The certification broke down the costs by hours, task, and hourly rate. The certification of investigative costs complied with California Code of Regulations, title 1, section 1042, subdivision (b), and the requested costs were reasonable.

20. The total costs are therefore \$22,785.

## **LEGAL CONCLUSIONS**

### **Applicable Law**

#### **STATUTES**

1. The board is authorized to enforce all aspects of Pharmacy Law contained in Business and Professions Code section 4000 et seq., regulations promulgated under the authority contained in Business and Professions Code section 4005, subdivision (a), and the Uniform Controlled Substances Act (Health and Safety Code.11000 et seq.). (Bus. & Prof Code, §§ 4000, 4011.)

2. Business and Professions Code section 4022, subdivision (a), provides that any prescription medication is considered a “dangerous drug.”

---

concerning actual time spent preparing for the hearing. (Cal. Code Regs., tit. 1, § 1042, subd. (b)(3).) These costs are therefore disallowed.

3. Business and Professions Code section 4300, subdivision (a), provides that every license issued by the board may be suspended or revoked.

4. Protection of the public shall be the highest priority for the board in exercising its licensing, regulatory, and disciplinary functions. Whenever the protection of the public is inconsistent with other interests sought to be promoted, the protection of the public shall be paramount. (Bus. & Prof. Code, § 4001.1.)

5. The standard of proof utilized in proceedings to impose discipline on a professional license is "clear and convincing evidence." (*Ettinger v. Board of Medical Quality Assurance* (1982) 135 Cal.App.3d 853.) The burden of proof is on complainant. (Evid. Code, § 500.)

6. Business and Professions Code section 4059, provides:

(a) A person may not furnish any dangerous drug, except upon the prescription of a physician, dentist, podiatrist, optometrist, veterinarian, or naturopathic doctor pursuant to Section 3640.7. A person may not furnish any dangerous device, except upon the prescription of a physician, dentist, podiatrist, optometrist, veterinarian, or naturopathic doctor pursuant to Section 3640.7.

(b) This section does not apply to the furnishing of any dangerous drug or dangerous device by a manufacturer, wholesaler, or pharmacy to each other or to a physician, dentist, podiatrist, optometrist, veterinarian, or naturopathic doctor pursuant to Section 3640.7, or to a laboratory under sales and purchase records that correctly give the date, the

names and addresses of the supplier and the buyer, the drug or device, and its quantity. This section does not apply to the furnishing of any dangerous device by a manufacturer, wholesaler, or pharmacy to a physical therapist acting within the scope of his or her license under sales and purchase records that correctly provide the date the device is provided, the names and addresses of the supplier and the buyer, a description of the device, and the quantity supplied. . . .

7. Business and Professions Code section 4060, provides:

A person shall not possess any controlled substance, except that furnished to a person upon the prescription of a physician, dentist, podiatrist, optometrist, veterinarian, or naturopathic doctor pursuant to Section 3640.7, or furnished pursuant to a drug order issued by a certified nurse-midwife pursuant to Section 2746.51, a nurse practitioner pursuant to Section 2836.1, a physician assistant pursuant to Section 3502.1, a naturopathic doctor pursuant to Section 3640.5, or a pharmacist pursuant to Section 4052.1, 4052.2, or 4052.6. This section does not apply to the possession of any controlled substance by a manufacturer, wholesaler, third-party logistics provider, pharmacy, pharmacist, physician, podiatrist, dentist, optometrist, veterinarian, naturopathic doctor, certified nurse-midwife, nurse practitioner, or physician assistant, if



in stock in containers correctly labeled with the name and address of the supplier or producer.

This section does not authorize a certified nurse-midwife, a nurse practitioner, a physician assistant, or a naturopathic doctor, to order his or her own stock of dangerous drugs and devices.

8. Business and Professions Code section 4076, subdivision (a), provides:

A pharmacist shall not dispense any prescription except 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.

9. Business and Professions Code section 4077 provides:

(a) Except as provided in subdivisions (b) and (c), no person shall dispense any dangerous drug upon prescription except in a container correctly labeled with the information required by Section 4076.

(b) Physicians, dentists, podiatrists, and veterinarians may personally furnish any dangerous drug prescribed by them to the patient for whom prescribed, provided that the drug

is properly labeled to show all information required in Section 4076 except the prescription number.

(c) Devices that bear the legend "Caution: federal law restricts this device to sale by or on the order of a\_\_\_\_," or words of similar meaning, are exempt from the requirements of Section 4076, and Section 111480 of the Health and Safety Code, when provided to patients in skilled nursing facilities or intermediate care facilities licensed pursuant to Chapter 2 (commencing with Section 1250) of Division 2 of the Health and Safety Code.

(d) The following notification shall be affixed to all quantities of dimethyl sulfoxide (DMSO) prescribed by a physician, or dispensed by a pharmacy pursuant to the order of a physician in California: "Warning: DMSO may be hazardous to your health. Follow the directions of the physician who prescribed the DMSO for you."

(e) The label of any retail package of DMSO shall include appropriate precautionary measures for proper handling and first aid treatment and a warning statement to keep the product out of reach of children.

10. Business and Professions Code section 4081, provides:

(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, licensed correctional clinic, as defined in Section 4187, 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. . . .

11. No person or entity is permitted to purchase, trade, sell, or transfer dangerous drugs or dangerous devices after the beyond use date on the label or fail to maintain records of the acquisition or disposition of dangerous drugs or dangerous devices for at least three years. (Bus. & Prof. Code, § 4169, subd. (a)(4) & (a)(5).)

12. The board shall take disciplinary action against any holder of a license who is guilty of unprofessional conduct, which includes the commission of any act involving moral turpitude, dishonesty, fraud, deceit, or corruption, whether the act is committed in the course of relations as a licensee or otherwise, and whether the act is a felony or misdemeanor or not. (Bus. & Prof. Code, § 4301, subd. (f).)

13. Business and Professions Code section 4342 provides:

(a) The board may institute any action or actions as may be provided by law and that, in its discretion, are necessary, to prevent the sale of pharmaceutical preparations and drugs that do not conform to the standard and tests as to quality and strength, provided in the latest edition of the United States Pharmacopoeia or the National Formulary, or that violate any provision of the Sherman Food, Drug, and Cosmetic Law (Part 5 (commencing with Section 109875) of Division 104 of the Health and Safety Code).

(b) Any knowing or willful violation of any regulation adopted pursuant to Section 4006 shall be subject to punishment in the same manner as is provided in Sections 4321 and 4336.

14. Health and Safety Code section 111440 provides that it is unlawful for any person to manufacture, sell, deliver, hold, or offer for sale any drug or device that is misbranded.

## **Regulations**

15. California Code of Regulations, title 16, section 1714, subdivision (b), provides that 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. (*Ibid.*)

16. California Code of Regulations, title 16, section 1714, subdivision (d), provides that 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. (*Ibid.*)

## **Cause Exists to Impose Discipline**

17. First Cause for Discipline: Cause exists to impose discipline pursuant to Business and Professions Code section 4011, and California Code of Regulations, title 16, section 1714, subdivisions (b) and (d). Respondents failed to ensure adequate security and control over the purchase, inventory, order, and delivery of controlled substances, specifically Xanax, from September 2015 to December 2015. This led to the ordering and/or theft of 27,285 Xanax pills, of which only 5,000 were recovered.

18. Second Cause for Discipline: Cause exists to impose discipline pursuant to Business and Professions Code sections 4011; 4059, subdivisions (a) and (b); and 4081, subdivision (a). Respondents failed to maintain appropriate and complete records in at least nine instances of transfers for progesterone and testosterone from Fireside to Las Palmas between October 25, 2014, and February 2, 2016.

19. Third Cause for Discipline: Cause exists to impose discipline pursuant to Business and Professions Code sections 4011; 4076, subdivision (a)(9); and 4077, subdivision (a). Between February 1, 2016, and February 9, 2016, respondents dispensed 28 compounded medications with incorrect BUDs. In each of the 28 compounded medications, there was at least one ingredient with an expiration date that was shorter than six months but the BUD on the ultimate product contained a BUD of six months.

20. Fourth Cause for Discipline: Cause exists to impose discipline pursuant to Business and Professions Code sections 4011; 4301, subdivision (f); and 4342, because respondents dispensed compounded medications that were labeled with incorrect BUD dates, as described above in Legal Conclusions Paragraph 19.

21. Fifth Cause for Discipline: Cause exists to impose discipline pursuant to Business and Professions Code section 4011, and Health and Safety Code section 111440 because the 28 compounded medications dispensed by respondents between February 1, 2016, and February 9, 2016, as identified above in Legal Conclusions Paragraph 19, were dangerous drugs and contained incorrect BUD dates.

## **Evaluation**

22. The purpose of an administrative proceeding seeking the revocation or suspension of a professional license is not to punish the individual; the purpose is to protect the public from dishonest, immoral, disreputable or incompetent practitioners. (*Ettinger v. Board of Medical Quality Assurance* (1982) 135 Cal.App.3d 853, 856.)

23. Rehabilitation is a state of mind. The law looks with favor on one who has achieved reformation and regeneration. (*Hightower v. State Bar* (1983) 34 Cal.3d 150, 157.) While a candid admission of misconduct and full acknowledgment of

wrongdoing may be a necessary step in the rehabilitation process, it is only a first step; a truer indication of rehabilitation is presented if an individual demonstrates by sustained conduct over an extended period of time that he is fit to practice. (*In re Trebilcock* (1981) 30 Cal.3d 312, 315-316.)

24. The board has set forth Disciplinary Guidelines (Rev. 2/2017) to assist in determining the appropriate level of discipline. Those factors include: actual or potential harm to the public; actual or potential harm to any consumer; prior disciplinary record, including level of compliance with disciplinary order(s); prior warning(s), including but not limited to citation(s) and fine(s), letter(s) of admonishment, and/or correction notice(s); number and/or variety of current violations; nature and severity of the act(s), offense(s) or crime(s) under consideration; aggravating evidence; mitigating evidence; rehabilitation evidence; time passed since the act(s) or offense(s); whether the conduct was intentional or negligent, demonstrated incompetence, or, if the respondent is being held to account for conduct committed by another, the respondent had knowledge of or knowingly participated in such conduct; financial benefit to the respondent from the misconduct; and other licenses held by the respondent and license history of those licenses.

25. Considering both the guidelines and applicable law, in this case, a public reproof is appropriate. The loss of 27,285 high potency Xanax pills is serious; however, the loss was the result of negligence rather than an intentional act, tempering Mr. Omilana's culpability. Mr. Omilana had an employee that both he and his employees all trusted. That employee, Ms. Fernandez, utilized her position to obtain 5,000 Xanax pills from Fireside. Although several thousand were also dispensed through normal procedures, that still left over 20,000 pills unaccounted for. Because the ordering procedures were so relaxed, Mr. Omilana failed to notice that someone at the

pharmacy, which may or may not have been Ms. Fernandez, ordered tens of thousands of Xanax pills and diverted them prior to anyone at Fireside ever noticing.

Immediately upon uncovering the theft, respondent self-reported the 5,000 Xanax pill loss/recovery as required by law. Respondent immediately began taking remedial measures to better secure all controlled substances at Fireside. He implemented a number of other changes as well to better ensure overall pharmacy security. Those measures included verifying all orders from the wholesaler; having his wife verify all invoices twice per month; having the wholesaler create a unique username and password for anyone charged with ordering product from them; placing additional cameras around the pharmacy to cover all locations where pharmaceuticals are kept; requiring employees to bring their personal belongings in and out of the pharmacy in clear plastic bags; placing bars in the windows and doors; and ordering a machine that photographs pills as they are being counted, so the count can be verified for accuracy. Mr. Omilana's testimony regarding those security efforts were corroborated by several witnesses.

Regarding the other allegations, which included failure to maintain proper records of transfers between Fireside and Las Palmas, and dispensing compounded medications without proper BUD dates, Mr. Omilana took responsibility for what occurred, expressed great remorse and self-reflection, and has taken steps to make sure that it does not occur again. There have been six inspections at Fireside since 2015; none of the inspections have uncovered any misconduct. In that respect, Mr. Omilana has already spent four years ensuring that he rectified any procedural problems at Fireside that led to the first amended accusation in this case.

The conduct at issue in this case occurred in 2015 and 2016, over four years ago. Mr. Omilana has been a practicing pharmacist for 27 years. His character



witnesses were impeccable. All indications are that Mr. Omilana took this action very seriously and took the necessary steps to ensure Fireside operates in accordance with applicable law. Had this action been brought several years ago, a probationary period might be appropriate. In this case, however, Mr. Omilana's diligent efforts at recognizing and remedying the problems at Fireside is the type of rehabilitation the board looks for when deciding whether to impose discipline.

Taking into account Mr. Omilana's long history of practice free of discipline, the nature and extent of the misconduct, and Mr. Omilana's credible evidence in extenuation, explanation, and rehabilitation, it is concluded the public will be adequately protected by issuing a public reproof<sup>9</sup> to respondents. While issuing a public reproof is not a measure of discipline that falls squarely within the disciplinary guidelines, it is the most appropriate sanction under the circumstances. Placing Mr. Omilana or Fireside on probation at this late juncture, when he has spent the past four years doing exactly what one would expect of a licensee who is in probation, would constitute punishment, which is not the purpose of administrative proceedings.

A public reproof is not a free pass. A public reproof constitutes the board's formal criticism and censure of a licensed pharmacist. It reminds a pharmacist that engaging in the same or similar conduct will likely result in more serious consequences. A public reproof provides notice to the general public and others of the nature and extent of a pharmacist's wrongdoing. While a public reproof may not

---

<sup>9</sup> The board is authorized to issue a public reproof pursuant to Business and Professions Code section 495.

be as drastic as other disciplinary measures, it is a humbling experience when it represents the only stain on an otherwise stellar professional record.

## **Costs**

26. The California Supreme Court in *Zuckerman v. State Board of Chiropractic Examiners* (2002) 29 Cal.4th 32, held that a regulation imposing costs for investigation and enforcement under California Code of Regulations, title 16, section 317.5, which is similar to Business and Professions Code section 125.3, did not violate due process. But it was incumbent on the board in that case to exercise discretion to reduce or eliminate cost awards in a manner such that costs imposed did not “deter [licensees] with potentially meritorious claims or defenses from exercising their right to a hearing.” (*Ibid.*)

The Supreme Court set forth five factors to consider in deciding whether to reduce or eliminate costs: whether the licensee used the hearing process to obtain dismissal of other charges or a reduction in the severity of the discipline imposed; whether the licensee had a “subjective” good faith belief in the merits of his or her position; whether the licensee raised a “colorable challenge” to the proposed discipline; whether the licensee had the financial ability to make payments; and whether the scope of the investigation was appropriate in light of the alleged misconduct. The reasoning of *Zuckerman* must be applied to Business and Professions Code section 125.3 since the language in the cost recovery regulation at issue in *Zuckerman* and section 125.3 are substantially the same.

Applying the *Zuckerman* criteria, Mr. Omilana displayed a good faith belief in the merits of his position; he raised a colorable challenge to the proposed discipline; as the owner of three pharmacies, he has the financial ability to make payments; and

the scope of the investigation was appropriate in light of the misconduct. The costs are therefore reduced by half, to \$11,392.50.

## **ORDER**

1. Pharmacy Permit Number PHY 47407, and Sterile Compounding Pharmacy License Number LSC 99523, issued to Pathway Pharmaceuticals, Inc., dba Fireside Pharmacy, are hereby publicly reprovved. This decision shall constitute such public reprovval.

2. Pharmacist License Number RPH 46012, issued to Adeyemi Akintunde Omilana, is hereby publicly reprovved. This decision shall constitute such public reprovval.

3. Respondent, Pathway Pharmaceuticals, Inc., dba Fireside Pharmacy, and respondent Adeyemi Akintunde Omilana, shall be jointly and severally liable to pay to the board its costs of investigation and prosecution in the amount of \$11,392.50. The amount shall be paid in full within 90 days of the effective date of this decision and order, unless respondents make arrangements to make the payments pursuant to a payment plan that shall not exceed one year from the date of this decision and order.

DATE: March 12, 2020

DocuSigned by:  
  
D566BE70E0E24D3  
KIMBERLY J. BELVEDERE

Administrative Law Judge

Office of Administrative Hearings

1 XAVIER BECERRA  
Attorney General of California  
2 CARL W. SONNE  
Supervising Deputy Attorney General  
3 THEODORE S. DRCAR  
Deputy Attorney General  
4 State Bar No. 174951  
600 West Broadway, Suite 1800  
5 San Diego, CA 92101  
P.O. Box 85266  
6 San Diego, CA 92186-5266  
Telephone: (619) 738-9517  
7 Facsimile: (619) 645-2061  
E-mail: Ted.Drcar@doj.ca.gov  
8 *Attorneys for Complainant*

9  
10 **BEFORE THE**  
**BOARD OF PHARMACY**  
11 **DEPARTMENT OF CONSUMER AFFAIRS**  
12 **STATE OF CALIFORNIA**

13 In the Matter of the Accusation Against:

Case No. 6470

14 **PATHWAY PHARMACEUTICALS INC.,**  
15 **DBA FIRESIDE PHARMACY**  
16 **73847 Highway 111**  
**Palm Desert, CA 92260**

17 **Pharmacy Permit No. PHY 47407**  
18 **Sterile Compounding Pharmacy License No.**  
**LSC 99523,**

19 **and**

20 **ADEYEMI AKINTUNDE OMILANA**  
21 **74600 Old Prospector Trail**  
**Palm Desert, CA 92260**

22 **Pharmacist License No. RPH 46012**

23 Respondents.

**FIRST AMENDED ACCUSATION**

24  
25 **PARTIES**

26 1. Anne Sodergren (Complainant) brings this First Amended Accusation solely in her  
27 official capacity as the Interim Executive Officer of the Board of Pharmacy (Board), Department  
28 of Consumer Affairs.

2. On February 16, 2006, the Board issued Pharmacy Permit Number PHY 47407 to Pathway Pharmaceuticals Inc., doing business as Fireside Pharmacy (Respondent Fireside Pharmacy), with Respondent Adeyemi Akintunde Omilana as the Pharmacist-in-Charge (PIC). The Pharmacy Permit was in full force and effect at all times relevant to the charges brought herein and will expire on February 1, 2020, unless renewed.

3. On October 7, 2008, the Board issued Sterile Compounding Pharmacy Number LSC 99523 to Fireside Pharmacy. The Sterile Compounding Pharmacy License was in full force and effect at all times relevant to the charges brought herein and will expire on February 1, 2020, unless renewed.

4. On or about March 10, 1993, the Board issued Pharmacist License Number RPH 46012 to Respondent Adeyemi Akintunde Omilana. The Pharmacist License was in full force and effect at all times relevant to the charges brought herein and will expire on May 31, 2020, unless renewed. Omilana has been the Pharmacist in Charge for Fireside Pharmacy since its inception.

### **JURISDICTION**

5. This First Amended Accusation is brought before the Board under the authority of the following laws. All section references are to the Business and Professions Code unless otherwise indicated.

6. Section 4011 of the Code states that the Board shall administer and enforce both the Pharmacy Law (Code § 4000, *et seq.*) and the Uniform Controlled Substances Act (Health & Safety Code, § 11000, *et seq.*).

7. Code section 4300, subdivision (a), states that “[e]very license issued may be suspended or revoked.”

8. Code section 4300.1 states:

The expiration, cancellation, forfeiture, or suspension of a board-issued license by operation of law or by order or decision of the board or a court of law, the placement of a license on a retired status, or the voluntary surrender of a license by a licensee shall not deprive the board of jurisdiction to commence or proceed with any investigation of, or action or disciplinary proceeding against, the licensee or to render a decision suspending or revoking the license.

///

## STATUTORY PROVISIONS

9. Code section 4022, subdivision (a), states that a “dangerous drug” includes “[a]ny drug that bears the legend: ‘Caution: federal law prohibits dispensing without prescription,’ ‘Rx only,’ or words of similar import.”

10. Code section 4059 states, in pertinent part:

(a) A person may not furnish any dangerous drug, except upon the prescription of a physician, dentist, podiatrist, optometrist, veterinarian, or naturopathic doctor pursuant to Section 3640.7. A person may not furnish any dangerous device, except upon the prescription of a physician, dentist, podiatrist, optometrist, veterinarian, or naturopathic doctor pursuant to Section 3640.7.

(b) This section does not apply to the furnishing of any dangerous drug or dangerous device by a manufacturer, wholesaler, or pharmacy to each other or to a physician, dentist, podiatrist, optometrist, veterinarian, or naturopathic doctor pursuant to Section 3640.7, or to a laboratory under sales and purchase records that correctly give the date, the names and addresses of the supplier and the buyer, the drug or device, and its quantity. This section does not apply to the furnishing of any dangerous device by a manufacturer, wholesaler, or pharmacy to a physical therapist acting within the scope of his or her license under sales and purchase records that correctly provide the date the device is provided, the names and addresses of the supplier and the buyer, a description of the device, and the quantity supplied.

11. Code section 4060 states:

No person shall possess any controlled substance, except that furnished to a person upon the prescription of a physician, dentist, podiatrist, optometrist, veterinarian, or naturopathic doctor pursuant to Section 3640.7, or furnished pursuant to a drug order issued by a certified nurse-midwife pursuant to Section 2746.51, a nurse practitioner pursuant to Section 2836.1, or a physician assistant pursuant to Section 3502.1, or naturopathic doctor pursuant to Section 3640.5, or a pharmacist pursuant to either subparagraph (D) of paragraph (4) of, or clause (iv) of subparagraph (A) of paragraph (5) of, subdivision (a) of Section 4052. This section shall not apply to the possession of any controlled substance by a manufacturer, wholesaler, pharmacy, pharmacist, physician, podiatrist, dentist, optometrist, veterinarian, naturopathic doctor, certified nurse-midwife, nurse practitioner, or physician assistant, when in stock in containers correctly labeled with the name and address of the supplier or producer.

Nothing in this section authorizes a certified nurse-midwife, a nurse practitioner, a physician assistant, or a naturopathic doctor, to order his or her own stock of dangerous drugs and devices.

///

///

12. Code section 4076 states:

(a) A pharmacist shall not dispense any prescription except 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 . . .

13. Code section 4077 states that except as provided in subdivisions (b) and (c) of this section, no person shall dispense any dangerous drug upon prescription except in a container correctly labeled with the information required by Section 4076.

14. Code section 4081 states:

(a) All records of manufacture and of sale, acquisition, 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, pharmacy, veterinary food-animal drug retailer, 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 any pharmacy, wholesaler, or veterinary food-animal drug retailer shall be jointly responsible, with the pharmacist-in-charge or representative-in-charge, for maintaining the records and inventory described in this section. . . .

15. Code section 4169 states:

(a) A person or entity shall not do any of the following:

(4) Purchase, trade, sell, or transfer dangerous drugs or dangerous devices after the beyond use date on the label.

(5) Fail to maintain records of the acquisition or disposition of dangerous drugs or dangerous devices for at least three years . . .

16. Code section 4301 states, in pertinent part:

The board shall take action against any holder of a license who is guilty of unprofessional conduct or whose license has been issued by mistake.

Unprofessional conduct shall include, but is not limited to, any of the following:

....



1 (c) Gross negligence

2 . . .

3 (f) The commission of any act involving moral turpitude, dishonesty, fraud,  
4 deceit, or corruption, whether the act is committed in the course of relations as a  
5 licensee or otherwise, and whether the act is a felony or misdemeanor or not.

6 . . . .

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

9 17. Code section 4306.5 states:

10 Unprofessional conduct for a pharmacist may include any of the following:

11 (a) Acts or omissions that involve, in whole or in part, the inappropriate exercise  
12 of his or her education, training, or experience as a pharmacist, whether or not the act  
13 or omission arises in the course of the practice of pharmacy or the ownership,  
14 management, administration, or operation of a pharmacy or other entity licensed by the  
15 board.

16 (b) Acts or omissions that involve, in whole or in part, the failure to exercise  
17 or implement his or her best professional judgment or corresponding responsibility  
18 with regard to the dispensing or furnishing of controlled substances, dangerous  
19 drugs, or dangerous devices, or with regard to the provision of services.

20 (c) Acts or omissions that involve, in whole or in part, the failure to consult  
21 appropriate patient, prescription, and other records pertaining to the performance of  
22 any pharmacy function. . . .

23 18. Code section 4342 provides:

24 (a) The board may institute any action or actions as may be provided by law  
25 and that, in its discretion, are necessary, to prevent the sale of pharmaceutical  
26 preparations and drugs that do not conform to the standard and tests as to quality  
27 and strength, provided in the latest edition of the United States Pharmacopoeia or  
28 the National Formulary, or that violate any provision of the Sherman Food, Drug,  
and Cosmetic Law (Part 5 (commencing with Section 109875) of Division 104 of  
the Health and Safety Code).

(b) Any knowing or willful violation of any regulation adopted pursuant to  
Section 4006 shall be subject to punishment in the same manner as is provided in  
Sections 4321 and 4336.

19. Health & Safety Code section 11057 provides:

(a) The controlled substances listed in this section are included in Schedule  
IV.

///  
5

1 (b) Schedule IV shall consist of the drugs and other substances, by whatever  
2 official name, common or usual name, chemical name, or brand name designated,  
3 listed in this section.

4 . . . .

5 (d) Depressants. Unless specifically excepted or unless listed in another  
6 schedule, any material, compound, mixture, or preparation which contains any  
7 quantity of the following substances, including its salts, isomers, and salts of  
8 isomers whenever the existence of those salts, isomers, and salts of isomers is  
9 possible within the specific chemical designation:

10 (1) Alprazolam . . . . .

11 20. Health & Safety Code section 11377, subdivision (a), provides:

12 Except as authorized by law and as otherwise provided in subdivision (b) or Section  
13 11375, or in Article 7 (commencing with Section 4211) of Chapter 9 of Division 2  
14 of the Business and Professions Code, every person who possesses any controlled  
15 substance which is (1) classified in Schedule III, IV, or V, and which is not a  
16 narcotic drug, (2) specified in subdivision (d) of Section 11054, except paragraphs  
17 (13), (14), (15), and (20) of subdivision (d), (3) specified in paragraph (11) of  
18 subdivision (c) of Section 11056, (4) specified in paragraph (2) or (3) of subdivision  
19 (f) of Section 11054, or (5) specified in subdivision (d), (e), or (f) of Section 11055,  
20 unless upon the prescription of a physician, dentist, podiatrist, or veterinarian,  
21 licensed to practice in this state, shall be punished by imprisonment in a county jail  
22 for a period of not more than one year, except that such person may instead be  
23 punished pursuant to subdivision (h) of Section 1170 of the Penal Code if that  
24 person has one or more prior convictions for an offense specified in clause (iv) of  
25 subparagraph (C) of paragraph (2) of subdivision (e) of Section 667 of the Penal  
26 Code or for an offense requiring registration pursuant to subdivision (c) of Section  
27 290 of the Penal Code.

28 21. Health & Safety Code section 111330 states: "A drug or device is misbranded if its  
labeling is false or misleading in any particular."

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

## 24 **REGULATORY PROVISIONS**

25 23. California Code of Regulations, title 16 (CCR), section 1714 states, in pertinent part:

26 (b) Each pharmacy licensed by the board shall maintain its facilities, space,  
27 fixtures, and equipment so that drugs are safely and properly prepared, maintained,  
28 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

ordiversion 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.

. . . .

(f) The board shall require an applicant for a licensed premise or for renewal of that license to certify that it meets the requirements of this section at the time of licensure or renewal.

24. CCR section 1716, states:

Pharmacists shall not deviate from the requirements of a prescription except upon the prior consent of the prescriber or to select the drug product in accordance with Section 4073 of the Business and Professions Code.

Nothing in this regulation is intended to prohibit a pharmacist from exercising commonly-accepted pharmaceutical practice in the compounding or dispensing of a prescription.

25. CCR 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.

The controlled substances inventories required by Title 21, CFR, Section 1304 shall be available for inspection upon request for at least 3 years after the date of the inventory.

26. CCR section 1718.1 states:

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.

27. CCR section 1735.2 provides, in pertinent part:

(h) All chemicals, bulk drug substances, drug products, and other components used for drug compounding shall be stored and used according to compendia and other applicable requirements to maintain their integrity, potency, quality, and labeled strength.

(i) Every compounded drug preparation shall be given a beyond use date representing the date or date and time beyond which the compounded drug preparation should not be used, stored, transported or administered, and determined based on the professional judgment of the pharmacist performing or supervising the compounding.

(1) For non-sterile compounded drug preparation(s), the beyond use date shall not exceed any of the following:

1 (A) the shortest expiration date or beyond use date of any  
2 ingredient in the compounded drug preparation,

3 . . . .

4 (2) For sterile compounded drug preparations, the beyond use date  
5 shall not exceed any of the following:

6 (A) The shortest expiration date or beyond use date of any  
7 ingredient in the sterile compounded drug product preparation,

8 . . . .

9 (5) Shorter dating than set forth in this subdivision may be used if it  
10 is deemed appropriate in the professional judgment of the responsible  
11 pharmacist.

12 (j) The pharmacist performing or supervising compounding is responsible  
13 for the proper preparation, labeling, storage, and delivery of the compounded drug  
14 preparation.

15 . . . .

16 (l) Packages of ingredients, both active and inactive, that lack a supplier's  
17 expiration date are subject to the following limitations:

18 (1) such ingredients cannot be used for any non-sterile compounded  
19 drug preparation more than three (3) years after the date of receipt by the  
20 pharmacy.

21 (2) such ingredients cannot be used for any sterile compounded drug  
22 preparation more than one (1) year after the date of receipt by the pharmacy.

23 28. CCR section 1761, subdivision (a), states:

24 No pharmacist shall compound or dispense any prescription which contains any  
25 significant error, omission, irregularity, uncertainty, ambiguity or alteration. Upon  
26 receipt of any such prescription, the pharmacist shall contact the prescriber to obtain  
27 the information needed to validate the prescription.

28 29. CCR section 1793 provides:

“Pharmacy technician” means an individual who, under the direct supervision and  
control of a pharmacist, performs packaging, manipulative, repetitive, or other  
nondiscretionary tasks related to the processing of a prescription in a pharmacy, but  
who does not perform duties restricted to a pharmacist under section 1793.1.

///

///

///

1 **COST RECOVERY**

2 30. Code section 125.3 provides that the Board may ask the administrative law judge to  
3 direct a licensee found to have committed a violation or violations of the licensing act to pay a  
4 sum not to exceed the reasonable costs of the investigation and enforcement of the case.

5 **DRUG**

6 31. Xanax is the brand name for alprazolam, a Schedule IV controlled substance pursuant  
7 to Health and Safety Code section 11057, subdivision (d)(1), and a dangerous drug pursuant to  
8 Code section 4022. Alprazolam is a short-acting benzodiazepine which is most commonly used  
9 for short-term management of anxiety disorders, and is one of the most frequently prescribed  
10 benzodiazepines. Use of alprazolam, particularly when taken for extended periods or in high  
11 doses, can lead to physical or psychological dependence. Alprazolam is used more for  
12 nonmedical/recreational purposes than any other pharmaceutical drug except oxycodone. In 2011,  
13 the U.S. Department of Health and Human services reported that benzodiazepines were involved  
14 in 28.7% of emergency room visits due to use of nonmedical use of prescription drugs, with  
15 alprazolam accounting for just over a third of those visits.

16 **FACTUAL ALLEGATIONS**

17 32. At all times relevant herein, Respondent Omilana served as the PIC for Fireside  
18 Pharmacy in Palm Desert, California.

19 33. On Saturday December 12, 2015, registered pharmacist H.M. was on duty at Fireside  
20 Pharmacy when supplier Amerisource Bergen delivered drugs, including a large quantity of  
21 alprazolam 2mg, 10 bottles of 500 pills each. H.M. thought this was an error, so she set the  
22 alprazolam aside in a bag and instructed a clerk to arrange for its return to the supplier. The  
23 pharmacy closed at 2 p.m. that day, and was not open on Sunday December 13.

24 34. On the Monday morning, December 14, 2015, the 5,000 pills of alprazolam 2mg that  
25 had been delivered on December 12 went missing. PIC Omilana questioned the staff on hand if  
26 any of them had taken it, and all said no. Omilana attempted to review footage from the  
27 pharmacy's security camera system, but was unable to view any video. Subsequent consultation  
28 ///

by technicians revealed that the security camera system was not working, and no video could be retrieved.

35. On the afternoon of December 18, 2015, registered Pharmacy Technician Susana J. Fernandez (Fernandez), who was employed by Respondent Fireside Pharmacy, admitted to PIC Omilana and S.L., a clerk at Fireside Pharmacy, that she had taken 10 bottles of 500 alprazolam 2mg. Fernandez said that she would return the 10 bottles later, and she did at about 8:00 p.m. that day. Omilana put the 10 bottles of alprazolam in locked storage.

36. On December 22, 2015, Fernandez resigned from Fireside Pharmacy and she signed a statement which admitted that on December 14, 2015, she took ten bottles of 500 alprazolam 2mg, a total of 5,000 pills, and returned them to Fireside Pharmacy on December 18, 2015.

37. On December 28, 2015, Fireside Pharmacy conducted an audit of its inventory of alprazolam 2mg, and found a shortage of 27,285 pills.

| <b>Drug</b>    | <b>Inventory Count<br/>6/25/2015</b> | <b>Acquisition<br/>6/25/2015-<br/>12/28/2015</b> | <b>Total Disposition<br/>6/25/2015-<br/>12/28/2016</b> | <b>Expected on-Hand Inventory</b> | <b>Inventory Count on<br/>1/22/2016</b> | <b>Variance</b> |
|----------------|--------------------------------------|--|--|-----------------------------------|---|-----------------|
| Alprazolam 2mg | 30                                   | 30,000   | 2,745  | 27,285                            | 600                                     | -27,285         |

This audit overstated the shortage by 5,000 pills because it overlooked the 10 bottles of 500 alprazolam that were set aside by Omilana on December 18, 2014.

38. On December 31, 2015, PIC Omilana submitted Fireside Pharmacy's Report of Theft or Loss of Controlled Substances to the Board. It only disclosed the theft of 5,000 tablets of alprazolam 2mg by TCH Fernandez on December 14, 2015, and stated that all bottles were returned. The report did not disclose the other 17,285 missing pills of alprazolam 2mg.

39. On January 4, 2016, the Board sent a letter to the pharmacy requesting the documents related to the loss of alprazolam. The Board inspector's review of sales records and an inspection at Fireside Pharmacy on February 10, 2016, revealed that Fireside Pharmacy was short 22,285 tablets of alprazolam.

40. On February 10, 2016, PIC Omilana admitted to the Board inspector that all pharmacy staff had access to ordering drugs except Schedule II controlled substances, which only

he could order. He also admitted that Fireside Pharmacy did not secure its controlled substances in a locked storage area, and stated that he had ordered hardware so that controlled substances would be stored in a locked area in the future.

41. On February 10, 2016, inspection revealed that Fireside Pharmacy prepared compounded cosmetic and pharmaceutical products which had been given beyond-use dates (BUD) that exceeded the expiration dates of individual ingredients. An audit of 10 days of Fireside Pharmacy's compounding worksheets revealed that during this time period, 28 pharmaceutical compounded products were dispensed with BUDs that exceeded the expiration dates of individual ingredients:

| Date Compounded and ID # | Drug                       | Expired Ingredient                           | Expiration Date of Ingredient | BUD given to final product |
|--------------------------|----------------------------|--|-------------------------------|----------------------------|
| 2/8/2016, 4994           | Libido Cream Plus          | Aminophylline<br>Pentoxifylline              | 2/2016<br>12/2015             | 8/8/2016                   |
| 2/9/2016, 4705           | Test/Biest<br>2/2mg/0.1ml  | Testosterone                                 | 5/2016                        | 8/9/2016                   |
| 2/9/2016, 1308           | Testosterone 15%           | Testosterone                                 | 5/2016                        | 8/9/2016                   |
| 2/9/2016-, 4085          | Prednisolone<br>20mg/ml    | Stevia 95%                                   | 2/2016                        | 5/9/2016                   |
| 2/9/2016, 3043           | Estriol 0.5mg              | Silica                                       | 3/2016                        | 8/9/2016                   |
| 2/9/2016, 7648           | Pent/Nife 5/5%             | Pentoxifylline                               | 12/2015                       | 8/9/2016                   |
| 2/9/2016, 7048           | Testosterone<br>112mg/gm   | Testosterone<br>Alcohol 200                  | 5/2016<br>4/2016              | 8/9/2016                   |
| 2/9/2016, 7462           | Metronidazole<br>60mg/ml   | Metronidazole<br>Flavor chicken broth        | 5/2016<br>5/2016              | 8/9/2016                   |
| 2/9/2016-7341            | Test/estra 50/14mg         | Testosterone                                 | 5/2016                        | 8/9/2016                   |
| 2/9/2016-17              | Testosterone 1%            | Testosterone                                 | 5/2016                        | 8/9/2016                   |
| 2/9/2016-5061            | Sildenafil 40mg/ml         | Flavor chicken liquid                        | 4/2016                        | 8/9/2016                   |
| 2/8/2016-7642            | Test/biest<br>4/1.75/0.1ml | Testosterone                                 | 5/2016                        | 8/8/2016                   |
| 2/9/2016, 7539           | Testosterone 1mg/gm        | Testosterone                                 | 5/2016                        | 8/9/2016                   |
| 2/8/2016, 530            | Testosterone 50mg          | Testosterone                                 | 5/2016                        | 8/8/2016                   |
| 2/7/2016, 4341           | Monobenzene 25%            | Monobenzene<br>Base emollient cream          | 4/2015<br>6/2016              | 8/2016                     |
| 2/8/2016, 6994           | Testosterone 1mg           | Testosterone<br>Silica<br>Flavor bitter stop | 5/2016<br>3/2016<br>4/2016    | 8/8/2016                   |

|                |                                 |  |                            |          |
|----------------|---------------------------------|--|----------------------------|----------|
| 2/8/2016, 3626 | Tylosin 200mg/ml                | Stevia 95%   | 2/2016                     | 8/8/2016 |
| 2/6/2016, 5708 | Testosterone 4mg/gm             | Testosterone   | 5/2016                     | 8/6/2016 |
| 2/6/2016, 4402 | Testosterone 1.75%              | Testosterone   | 5/2016                     | 8/6/2016 |
| 2/8/2016, 7643 | Prog/E2/E3/Test<br>25/0.25/0.5  | Testosterone<br>Silica                                 | 5/2016<br>3/2016           | 8/8/2016 |
| 2/7/2016, 2508 | Prednisolone<br>10mg/ml         | Stevia 95%<br>Flavor chicken broth                     | 2/2016<br>5/2016           | 8/7/2016 |
| 2/8/2016, 6971 | Pro/biest/test<br>150/1.25/0.25 | Testosterone   | 5/2016                     | 8/8/2016 |
| 2/2/2016, 2508 | Prednisolone<br>10mg/ml         | Stevia 95%<br>Flavor tuna                              | 2/2016<br>6/2016           | 8/2016   |
| 2/2/2016, 2641 | Test/estra 0.5/2mg              | Testosterone<br>Silica<br>Base polyglycol troche       | 5/2016<br>3/2016<br>6/2016 | 8/2016   |
| 2/2/2016, 5737 | Prog/estra 150/2mg              | Silica<br>Flavor bitter stop<br>Base polyglycol troche | 3/2016<br>4/2016<br>6/2016 | 8/2016   |
| 2/2/2016, 1719 | Progesterone 150mg              | Silica<br>Flavor bitter stop<br>Base polyglycol troche | 3/2016<br>4/2016<br>6/2016 | 8/2016   |
| 2/2/2016, 252  | Magic Mouth wash                | Lidocaine 2%   | 3/2016                     | 8/2016   |
| 2/1/2016, 3540 | Estradiol 1mg/gm                | Base carbopol  | 4/2016                     | 8/2016   |

42. The above data demonstrates that Fireside Pharmacy assigned a 180-day expiration date to its compounded products, even if one of the ingredients had a shorter expiration date.

43. During the inspection on February 10, 2016, PIC Omilana admitted that Fireside Pharmacy had transferred compounding ingredients to Las Palmas Pharmacy in Palm Springs<sup>1</sup>, and that Fireside Pharmacy only created and kept transfer orders for transfers of controlled substances between the two pharmacies. Inspection revealed that between October 25, 2014 and February 2, 2016, Fireside Pharmacy made five transfers of bulk progesterone and four transfers of bulk testosterone to Las Palmas Pharmacy without creating the required sales and purchase records. Fireside Pharmacy only kept handwritten receipts on generic forms that listed the drug, quantity and date, but did not state the names and addresses of the seller and the buyer.

44. Fireside Pharmacy did not keep any record of other compounding ingredients, which are dangerous drugs, that it transferred to Las Palmas Pharmacy.

<sup>1</sup> Respondent Omilana is also the PIC of Las Palmas Pharmacy.



45. After being served with the original Accusation in this matter, Fernandez entered a written stipulation calling for the revocation of her Pharmacy Technician Registration. In that stipulation, Fernandez admitted the truth of each and every charge and allegation in the original Accusation. The charges against Fernandez were for violation of statutes regarding controlled substances (Code, §4301, subd. (j); Health & Saf. Code, § 11170); unprofessional conduct including acts of dishonesty, fraud and deceit (Code, § 4301, subd. (f)); and violating laws governing pharmacy (Code sections 4059, 4060 and 4301, subd. (o)). On July 29, 2019, the Board issued an Order adopting Fernandez's stipulation effective August 28, 2019.

**FIRST CAUSE FOR DISCIPLINE**

**(Against Respondents Fireside Pharmacy and Omilana)**

**(Failure to Adhere to Operational Standards and Security - Controlled Substances)**

46. Respondents Fireside Pharmacy and Omilana are subject to disciplinary action under CCR section 1714, subdivisions (b) and (d), for the reasons set forth above in paragraphs 34 to 41, which are summarized here:

a. Fireside Pharmacy and Omilana as PIC failed to maintain adequate control over the purchase, intake, storage and security of controlled substances. As a result, a pharmacy technician was able to remove 5,000 pills of alprazolam 2mg from the pharmacy, and 22,285 pills of alprazolam 2mg disappeared from Fireside Pharmacy.

b. All staff at Fireside Pharmacy had access to controlled substances because Fireside Pharmacy did not limit the personnel who could order Schedule III and IV controlled substances, and it did not keep controlled substances like alprazolam in a locked area.

c. Fireside Pharmacy had an inoperative video surveillance system. After 5,000 pills of alprazolam were taken from Fireside Pharmacy, no security footage was available because the pharmacy's video surveillance system was not working. No video could be retrieved.

///

///

///

1 **SECOND CAUSE FOR DISCIPLINE**

2 **(Against Respondents Fireside Pharmacy and Omilana)**

3 **(Failure to Maintain Records of Disposition of Dangerous Drugs)**

4 47. Respondents Fireside Pharmacy and Omilana are subject to disciplinary action under  
5 sections 4059, subdivisions (a) and (b), and 4081, subdivision (a), because the pharmacy failed to  
6 maintain complete records for the transfer of controlled substances to Las Palmas Pharmacy, and  
7 it kept no record of the transfer to Las Palmas Pharmacy of bases, devices, filler, non-bulk items,  
8 and dangerous drugs that are not controlled substances. The circumstances are described above in  
9 paragraphs 44 and 45, and are summarized as follows:

10 a. During the inspection of Fireside Pharmacy on February 10, 2016, the Board's  
11 investigator found that nine written orders for transfer of progesterone and testosterone to Las  
12 Palmas Pharmacy in Palm Springs did not include the name and address of the buyer and seller,  
13 as required by section 4059, subdivision (b).

14 b. During the inspection on February 10, 2016, Omilana admitted that transfer records  
15 were only kept for controlled substances, and that no transfer records were kept for other  
16 dangerous drugs or for bases, devices, fillers and non-bulk items.

17 **THIRD CAUSE FOR DISCIPLINE**

18 **(Against Respondents Fireside Pharmacy and Omilana)**

19 **(Dispensing Dangerous Drugs in Incorrectly Labeled Containers)**

20 48. Respondents Fireside Pharmacy and Omilana are subject to disciplinary action under  
21 Code sections 4076, subdivision (a)(9), and 4077, subdivision (a), because Fireside Pharmacy  
22 dispensed compounded medications that were labeled with incorrect expiration dates that  
23 exceeded the expiration date(s) of one or more ingredients, as set forth in paragraphs 42 and 43,  
24 above.

25 ///

26 ///

27 ///

28 ///

1 **FOURTH CAUSE FOR DISCIPLINE**

2 **(Against Respondents Fireside Pharmacy and Omilana)**

3 **(Action by the Board to Prevent Sales of Drugs Lacking Quality or Strength)**

4 49. Respondents Fireside Pharmacy and Omilana are subject to disciplinary action under  
5 Code sections 4301, subdivision (f), and 4342, because Fireside Pharmacy dispensed  
6 compounded medications that were labeled with incorrect expiration dates that exceeded the  
7 expiration date(s) of one or more ingredients, as set forth in paragraphs 42 and 43, above.

8 **FIFTH CAUSE FOR DISCIPLINE**

9 **(Against Respondents Fireside Pharmacy and Omilana)**

10 **(Misbranding of Dangerous Drugs)**

11 50. Respondents Fireside Pharmacy and Omilana are subject to disciplinary action under  
12 Health and Safety Code sections 111440 because Fireside Pharmacy dispensed compounded  
13 medications that had false and/or misleading labels because they stated expiration dates which  
14 exceeded the expiration date(s) of one or more ingredients, as set forth in paragraphs 42 and 43,  
15 above.

16 **DISCIPLINE CONSIDERATIONS**

17 51. To determine the degree of discipline, if any, to be imposed on Respondents Fireside  
18 Pharmacy and Omilana, on February 13, 2015, the Board issued two citations, Number CI 2013  
19 59864 and CI 2014 64267, and ordered them to pay \$500.00 each for violation of Code sections  
20 4030, 4114 and CCR section 1793.1, for having an intern pharmacist work at the pharmacy  
21 without a current intern pharmacist license from October 1 to December 27, 2013. Those citations  
22 are final and the fines were paid.

23 52. To determine the degree of discipline, if any, to be imposed on Respondent Omilana,  
24 on November 3, 2017, in a prior action, the Board issued Citation Number CI 2017 75949 and  
25 ordered Respondent to pay fines totaling \$750. That Citation is now final and the fines were paid.  
26 The citation was issued for the following violations discovered at Las Palmas Pharmacy where  
27 Omilana was also the PIC:

28 ///

1 a. In violation of Code section 4169, subdivision (a)(4), a prescription medication that  
2 had expired was dispensed on May 5, 2015.

3 b. In violation of Code section 4076, subdivision (a)(9), between May 5 and December  
4 17, 2015, five prescription medications were dispensed without expiration dates on the  
5 prescription labels.

6 c. In violation of CCR section 1714, subdivision (b), on December 17, 2015, dangerous  
7 drugs that were required to be stored between 36 and 46 degrees Fahrenheit were being stored at  
8 31 degrees Fahrenheit.

9 d. In violation of Code section 4169, subdivision (a)(2), and Health & Safety Code  
10 section 111255, on December 17, 2015, two expired medications were being held in the  
11 pharmacy's drug stock.

12 53. Omilana was the PIC for both Las Palmas Pharmacy and Fireside Pharmacy. On  
13 December 18, 2015, TCH M.J., who worked at both pharmacies, admitted that she took four  
14 bottles of 500 alprazolam 2mg from Las Palmas Pharmacy. On December 22, 2015, TCH M.J.  
15 drafted and signed a written statement admitting that she did this in November 2015. This is the  
16 subject of a separate disciplinary action against TCH M.J., OAH case number 2019020363, which  
17 is set for hearing on August 1, 2019.

### 18 PRAYER

19 WHEREFORE, Complainant requests that a hearing be held on the matters herein alleged,  
20 and that following the hearing, the Board of Pharmacy issue a decision:

21 1. Revoking or suspending Pharmacy Permit Number PHY 47407, issued to Pathway  
22 Pharmaceuticals Inc., dba Fireside Pharmacy;

23 2. Revoking or suspending Sterile Compounding Pharmacy Number LSC 99523, issued  
24 to Pathway Pharmaceuticals Inc., dba Fireside Pharmacy;

25 3. Revoking or suspending Pharmacist License Number RPH 46012, issued to Adeyemi  
26 Akintunde Omilana;

27 ///

28 ///

1           4.     Ordering Pathway Pharmaceuticals, Inc. and Adeyemi Akintunde Omilana to pay the  
2 Board of Pharmacy the reasonable costs of the investigation and enforcement of this case,  
3 pursuant to Business and Professions Code section 125.3; and

4           5.     Taking such other and further action as deemed necessary and proper.  
5

6  
7     DATED:     August 30, 2019



8           ANNE SODERGREN  
9           Interim Executive Officer  
10          Board of Pharmacy  
11          Department of Consumer Affairs  
12          State of California  
13          Complainant

12     SD2018700779  
13     71799285\_4.docx  
14  
15  
16  
17  
18  
19  
20  
21  
22  
23  
24  
25  
26  
27  
28

XAVIER BECERRA  
Attorney General of California  
ANTOINETTE B. CINCOTTA  
Supervising Deputy Attorney General  
THEODORE S. DRCAR  
Deputy Attorney General  
State Bar No. 174951  
600 West Broadway, Suite 1800  
San Diego, CA 92101  
P.O. Box 85266  
San Diego, CA 92186-5266  
Telephone: (619) 738-9517  
Facsimile: (619) 645-2061  
E-mail: Ted.Drcar@doj.ca.gov  
*Attorneys for Complainant*

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

In the Matter of the Accusation Against:

Case No. 6470

**PATHWAY PHARMACEUTICALS INC.,  
DBA FIRESIDE PHARMACY  
73847 Highway 111  
Palm Desert, CA 92260**

**ACCUSATION**

**Pharmacy Permit No. PHY 47407  
Sterile Compounding Pharmacy License No.  
LSC 99523,**

**ADEYEMI AKINTUNDE OMILANA  
74600 Old Prospector Trail  
Palm Desert, CA 92260**

**Pharmacist License No. RPH 46012,**

**and**

**SUSANA J. FERNANDEZ  
83529 Mecca Hills Ave.  
Coachella, CA 92236**

**Pharmacy Technician Registration No. TCH  
40737**

Respondents.

## **PARTIES**

1  
2 1. Anne Sodergren (Complainant) brings this Accusation solely in her official capacity  
3 as the Interim Executive Officer of the Board of Pharmacy (Board), Department of Consumer  
4 Affairs.

5 2. On February 16, 2006, the Board issued Pharmacy Permit Number PHY 47407 to  
6 Pathway Pharmaceuticals Inc., doing business as Fireside Pharmacy (Respondent Fireside  
7 Pharmacy), with Respondent Adeyemi Akintunde Omilana as the Pharmacist-in-Charge (PIC).  
8 The Pharmacy Permit was in full force and effect at all times relevant to the charges brought  
9 herein and will expire on February 1, 2020, unless renewed.

10 3. On October 7, 2008, the Board issued Sterile Compounding Pharmacy Number LSC  
11 99523 to Fireside Pharmacy. The Sterile Compounding Pharmacy License was in full force and  
12 effect at all times relevant to the charges brought herein and will expire on February 1, 2020,  
13 unless renewed.

14 4. On or about March 10, 1993, the Board issued Pharmacist License Number RPH  
15 46012 to Respondent Adeyemi Akintunde Omilana. The Pharmacist License was in full force and  
16 effect at all times relevant to the charges brought herein and will expire on May 31, 2020, unless  
17 renewed. Omilana has been the Pharmacist in Charge for Fireside Pharmacy since its inception.

18 5. On or about December 12, 2001, the Board issued Pharmacy Technician Registration  
19 Number TCH 40737 to Susana J. Fernandez. This Pharmacy Technician Registration was in full  
20 force and effect at all times relevant to the charges brought herein and will expire on October 31,  
21 2019, unless renewed.

## **JURISDICTION**

22  
23 6. This Accusation is brought before the Board under the authority of the following  
24 laws. All section references are to the Business and Professions Code unless otherwise indicated.

25 7. Section 4011 of the Code states that the Board shall administer and enforce both the  
26 Pharmacy Law (Code § 4000, *et seq.*) and the Uniform Controlled Substances Act (Health &  
27 Safety Code, § 11000, *et seq.*).  
28

1 8. Code section 4300, subdivision (a), states that “[e]very license issued may be  
2 suspended or revoked.”

3 9. Code section 4300.1 states:

4 The expiration, cancellation, forfeiture, or suspension of a board-issued license by  
5 operation of law or by order or decision of the board or a court of law, the  
6 placement of a license on a retired status, or the voluntary surrender of a license by  
7 a licensee shall not deprive the board of jurisdiction to commence or proceed with  
any investigation of, or action or disciplinary proceeding against, the licensee or to  
render a decision suspending or revoking the license.

### 8 **STATUTORY PROVISIONS**

9 10. Code section 4022, subdivision (a), states that a “dangerous drug” includes “[a]ny  
10 drug that bears the legend: ‘Caution: federal law prohibits dispensing without prescription,’ ‘Rx  
11 only,’ or words of similar import.”

12 11. Code section 4059 states, in pertinent part:

13 (a) A person may not furnish any dangerous drug, except upon the  
14 prescription of a physician, dentist, podiatrist, optometrist, veterinarian, or  
15 naturopathic doctor pursuant to Section 3640.7. A person may not furnish any  
16 dangerous device, except upon the prescription of a physician, dentist, podiatrist,  
optometrist, veterinarian, or naturopathic doctor pursuant to Section 3640.7.

17 (b) This section does not apply to the furnishing of any dangerous drug or  
18 dangerous device by a manufacturer, wholesaler, or pharmacy to each other or to a  
19 physician, dentist, podiatrist, optometrist, veterinarian, or naturopathic doctor  
20 pursuant to Section 3640.7, or to a laboratory under sales and purchase records that  
21 correctly give the date, the names and addresses of the supplier and the buyer, the  
22 drug or device, and its quantity. This section does not apply to the furnishing of  
any dangerous device by a manufacturer, wholesaler, or pharmacy to a physical  
therapist acting within the scope of his or her license under sales and purchase  
records that correctly provide the date the device is provided, the names and  
addresses of the supplier and the buyer, a description of the device, and the  
quantity supplied.

23 12. Code section 4060 states:

24 No person shall possess any controlled substance, except that furnished to a person  
25 upon the prescription of a physician, dentist, podiatrist, optometrist, veterinarian, or  
26 naturopathic doctor pursuant to Section 3640.7, or furnished pursuant to a drug  
27 order issued by a certified nurse-midwife pursuant to Section 2746.51, a nurse  
28 practitioner pursuant to Section 2836.1, or a physician assistant pursuant to Section  
3502.1, or naturopathic doctor pursuant to Section 3640.5, or a pharmacist pursuant  
to either subparagraph (D) of paragraph (4) of, or clause (iv) of subparagraph (A) of  
paragraph (5) of, subdivision (a) of Section 4052. This section shall not apply to the



possession of any controlled substance by a manufacturer, wholesaler, pharmacy, pharmacist, physician, podiatrist, dentist, optometrist, veterinarian, naturopathic doctor, certified nurse-midwife, nurse practitioner, or physician assistant, when in stock in containers correctly labeled with the name and address of the supplier or producer.

Nothing in this section authorizes a certified nurse-midwife, a nurse practitioner, a physician assistant, or a naturopathic doctor, to order his or her own stock of dangerous drugs and devices.

13. Code section 4076 states:

(a) A pharmacist shall not dispense any prescription except 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 . . .

14. Code section 4077 states that except as provided in subdivisions (b) and (c) of this section, no person shall dispense any dangerous drug upon prescription except in a container correctly labeled with the information required by Section 4076.

15. Code section 4081 states:

(a) All records of manufacture and of sale, acquisition, 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, pharmacy, veterinary food-animal drug retailer, 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 any pharmacy, wholesaler, or veterinary food-animal drug retailer shall be jointly responsible, with the pharmacist-in-charge or representative-in-charge, for maintaining the records and inventory described in this section. . . .

16. Code section 4169 states:

(a) A person or entity shall not do any of the following:

(4) Purchase, trade, sell, or transfer dangerous drugs or dangerous devices after the beyond use date on the label.

(5) Fail to maintain records of the acquisition or disposition of dangerous drugs or dangerous devices for at least three years . . .

17. Code section 4301 states, in pertinent part:

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

....

(c) Gross negligence

...

(f) The commission of any act involving moral turpitude, dishonesty, fraud, deceit, or corruption, whether the act is committed in the course of relations as a licensee or otherwise, and whether the act is a felony or misdemeanor or not.

....

(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.

18. Code section 4306.5 states:

Unprofessional conduct for a pharmacist may include any of the following:

(a) Acts or omissions that involve, in whole or in part, the inappropriate exercise of his or her education, training, or experience as a pharmacist, whether or not the act or omission arises in the course of the practice of pharmacy or the ownership, management, administration, or operation of a pharmacy or other entity licensed by the board.

(b) Acts or omissions that involve, in whole or in part, the failure to exercise or implement his or her best professional judgment or corresponding responsibility with regard to the dispensing or furnishing of controlled substances, dangerous drugs, or dangerous devices, or with regard to the provision of services.

(c) Acts or omissions that involve, in whole or in part, the failure to consult appropriate patient, prescription, and other records pertaining to the performance of any pharmacy function. ....

19. Code section 4342 provides:

(a) The board may institute any action or actions as may be provided by law and that, in its discretion, are necessary, to prevent the sale of pharmaceutical preparations and drugs that do not conform to the standard and tests as to quality and strength, provided in the latest edition of the United States Pharmacopoeia or the National Formulary, or that violate any provision of the Sherman Food, Drug, and Cosmetic Law (Part 5 (commencing with Section 109875) of Division 104 of the Health and Safety Code).

(b) Any knowing or willful violation of any regulation adopted pursuant to Section 4006 shall be subject to punishment in the same manner as is provided in Sections 4321 and 4336.

- 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

2  
34  
5

6

7  
8  
9

10

11

12  
13  
14  
15  
16  
17  
18  
19  
20

21  
2223  
24

## 25

26

27

28

1       secured and distributed. The pharmacy shall be of sufficient size and unobstructed  
2       area to accommodate the safe practice of pharmacy.

3               . . . .

4               (d) Each pharmacist while on duty shall be responsible for the security of the  
5       prescription department, including provisions for effective control against theft or  
6       diversion of dangerous drugs and devices, and records for such drugs and devices.

7       Possession of a key to the pharmacy where dangerous drugs and controlled  
8       substances are stored shall be restricted to a pharmacist.

9               . . . .

10              (f) The board shall require an applicant for a licensed premise or for renewal  
11       of that license to certify that it meets the requirements of this section at the time of  
12       licensure or renewal.

13       25.   CCR section 1716, states:

14              Pharmacists shall not deviate from the requirements of a prescription except upon  
15       the prior consent of the prescriber or to select the drug product in accordance with  
16       Section 4073 of the Business and Professions Code.

17              Nothing in this regulation is intended to prohibit a pharmacist from exercising  
18       commonly-accepted pharmaceutical practice in the compounding or dispensing of a  
19       prescription.

20       26.   CCR section 1718 states:

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

24              The controlled substances inventories required by Title 21, CFR, Section 1304 shall  
25       be available for inspection upon request for at least 3 years after the date of the  
26       inventory.

27       27.   CCR section 1718.1 states:

28              All prescription drugs not bearing a manufacturer's expiration date pursuant to Title  
29       21, Code of Federal Regulations, section 211.137 are deemed to have expired and  
30       may not be manufactured, distributed, held for sale, or dispensed by any  
31       manufacturer, distributor, pharmacist, pharmacy or other persons authorized to  
32       dispense such drugs in California.

33       28.   CCR section 1735.2 provides, in pertinent part:

34              (h) All chemicals, bulk drug substances, drug products, and other  
35       components used for drug compounding shall be stored and used according to  
36       compendia and other applicable requirements to maintain their integrity, potency,  
37       quality, and labeled strength.

1 (i) Every compounded drug preparation shall be given a beyond use date  
2 representing the date or date and time beyond which the compounded drug  
3 preparation should not be used, stored, transported or administered, and determined  
4 based on the professional judgment of the pharmacist performing or supervising the  
5 compounding.

6 (1) For non-sterile compounded drug preparation(s), the beyond use  
7 date shall not exceed any of the following:

8 (A) the shortest expiration date or beyond use date of any  
9 ingredient in the compounded drug preparation,

10 . . . .

11 (2) For sterile compounded drug preparations, the beyond use date  
12 shall not exceed any of the following:

13 (A) The shortest expiration date or beyond use date of any  
14 ingredient in the sterile compounded drug product preparation,

15 . . . .

16 (5) Shorter dating than set forth in this subdivision may be used if it  
17 is deemed appropriate in the professional judgment of the responsible  
18 pharmacist.

19 (j) The pharmacist performing or supervising compounding is responsible  
20 for the proper preparation, labeling, storage, and delivery of the compounded drug  
21 preparation.

22 . . . .

23 (l) Packages of ingredients, both active and inactive, that lack a supplier's  
24 expiration date are subject to the following limitations:

25 (1) such ingredients cannot be used for any non-sterile compounded  
26 drug preparation more than three (3) years after the date of receipt by the  
27 pharmacy.

28 (2) such ingredients cannot be used for any sterile compounded drug  
preparation more than one (1) year after the date of receipt by the pharmacy.

29. CCR section 1761, subdivision (a), states:

30 No pharmacist shall compound or dispense any prescription which contains any  
31 significant error, omission, irregularity, uncertainty, ambiguity or alteration. Upon  
32 receipt of any such prescription, the pharmacist shall contact the prescriber to obtain  
33 the information needed to validate the prescription.

34 30. CCR section 1793 provides:

35 "Pharmacy technician" means an individual who, under the direct supervision and  
36 control of a pharmacist, performs packaging, manipulative, repetitive, or other

1 nondiscretionary tasks related to the processing of a prescription in a pharmacy, but  
2 who does not perform duties restricted to a pharmacist under section 1793.1.

### 3 **COST RECOVERY**

4 31. Code section 125.3 provides that the Board may ask the administrative law judge to  
5 direct a licensee found to have committed a violation or violations of the licensing act to pay a  
6 sum not to exceed the reasonable costs of the investigation and enforcement of the case.

### 7 **DRUG**

8 32. Xanax is the brand name for alprazolam, a Schedule IV controlled substance pursuant  
9 to Health and Safety Code section 11057, subdivision (d)(1), and a dangerous drug pursuant to  
10 Code section 4022. Alprazolam is a short-acting benzodiazepine which is most commonly used  
11 for short-term management of anxiety disorders, and is one of the most frequently prescribed  
12 benzodiazepines. Use of alprazolam, particularly when taken for extended periods or in high  
13 doses, can lead to physical or psychological dependence. Alprazolam is used more for  
14 nonmedical/recreational purposes than any other pharmaceutical drug except oxycodone. In 2011,  
15 the U.S. Department of Health and Human services reported that benzodiazepines were involved  
16 in 28.7% of emergency room visits due to use of nonmedical use of prescription drugs, with  
17 alprazolam accounting for just over a third of those visits.

### 18 **FACTUAL ALLEGATIONS**

19 33. At all times relevant herein, Respondent Omilana served as the PIC for Fireside  
20 Pharmacy in Palm Desert, California, and Respondent Fernandez was employed there as a  
21 pharmacy technician.

22 34. On Saturday December 12, 2015, registered pharmacist H.M. was on duty at Fireside  
23 Pharmacy when supplier Amerisource Bergen delivered drugs, including a large quantity of  
24 alprazolam 2mg, 10 bottles of 500 pills each. H.M. thought this was an error, so she set the  
25 alprazolam aside in a bag and instructed a clerk to arrange for its return to the supplier. The  
26 pharmacy closed at 2 p.m. that day, and was not open on Sunday December 13.

27 35. On the Monday morning, December 14, 2015, the 5,000 pills of alprazolam 2mg that  
28 had been delivered on December 12 went missing. PIC Omilana questioned the staff on hand if  
any of them had taken it, and all said no. Omilana attempted to review footage from the

pharmacy's security camera system, but was unable to view any video. Subsequent consultation by technicians revealed that the security camera system was not working, and no video could be retrieved.

36. On the afternoon of December 18, 2015, Fernandez admitted to PIC Omilana and S.L., a clerk at Fireside Pharmacy, that she had taken 10 bottles of 500 alprazolam 2mg. Fernandez said that she would return the 10 bottles later, and she did at about 8:00 p.m. that day. Omilana put the 10 bottles of alprazolam in locked storage.

37. On December 22, 2015, Fernandez resigned from Fireside Pharmacy and she signed a statement which admitted that on December 14, 2015, she took ten bottles of 500 alprazolam 2mg, a total of 5,000 pills, and returned them to Fireside Pharmacy on December 18, 2015.

38. On December 28, 2015, Fireside Pharmacy conducted an audit of its inventory of alprazolam 2mg, and found a shortage of 27,285 pills.

| <b>Drug</b>    | <b>Inventory Count<br/>6/25/2015</b> | <b>Acquisition<br/>6/25/2015-<br/>12/28/2015</b> | <b>Total Disposition<br/>6/25/2015-<br/>12/28/2016</b> | <b>Expected on-Hand Inventory</b> | <b>Inventory Count on<br/>1/22/2016</b> | <b>Variance</b> |
|----------------|--------------------------------------|--|--|-----------------------------------|---|-----------------|
| Alprazolam 2mg | 30                                   | 30,000   | 2,745  | 27,285                            | 600                                     | -27,285         |

This audit overstated the shortage by 5,000 pills because it overlooked the 10 bottles of 500 alprazolam that were set aside by Omilana on December 18, 2014.

39. On December 31, 2015, PIC Omilana submitted Fireside Pharmacy's Report of Theft or Loss of Controlled Substances to the Board. It only disclosed the theft of 5,000 tablets of alprazolam 2mg by TCH Fernandez on December 14, 2015, and stated that all bottles were returned. The report did not disclose the other 17,285 missing pills of alprazolam 2mg.

40. On January 4, 2016, the Board sent a letter to the pharmacy requesting the documents related to the loss of alprazolam. The Board inspector's review of sales records and an inspection at Fireside Pharmacy on February 10, 2016, revealed that Fireside Pharmacy was short 22,285 tablets of alprazolam.

41. On February 10, 2016, PIC Omilana admitted to the Board inspector that all pharmacy staff had access to ordering drugs except Schedule II controlled substances, which only

he could order. He also admitted that Fireside Pharmacy did not secure its controlled substances in a locked storage area, and stated that he had ordered hardware so that controlled substances would be stored in a locked area in the future.

42. On February 10, 2016, inspection revealed that Fireside Pharmacy prepared compounded cosmetic and pharmaceutical products which had been given beyond-use dates (BUD) that exceeded the expiration dates of individual ingredients. An audit of 10 days of Fireside Pharmacy's compounding worksheets revealed that during this time period, 28 pharmaceutical compounded products were dispensed with BUDs that exceeded the expiration dates of individual ingredients:

| Date Compounded and ID # | Drug                       | Expired Ingredient                           | Expiration Date of Ingredient | BUD given to final product |
|--------------------------|----------------------------|--|-------------------------------|----------------------------|
| 2/8/2016, 4994           | Libido Cream Plus          | Aminophylline<br>Pentoxifylline              | 2/2016<br>12/2015             | 8/8/2016                   |
| 2/9/2016, 4705           | Test/Biest<br>2/2mg/0.1ml  | Testosterone                                 | 5/2016                        | 8/9/2016                   |
| 2/9/2016, 1308           | Testosterone 15%           | Testosterone                                 | 5/2016                        | 8/9/2016                   |
| 2/9/2016-, 4085          | Prednisolone<br>20mg/ml    | Stevia 95%                                   | 2/2016                        | 5/9/2016                   |
| 2/9/2016, 3043           | Estriol 0.5mg              | Silica                                       | 3/2016                        | 8/9/2016                   |
| 2/9/2016, 7648           | Pent/Nife 5/5%             | Pentoxifylline                               | 12/2015                       | 8/9/2016                   |
| 2/9/2016, 7048           | Testosterone<br>112mg/gm   | Testosterone<br>Alcohol 200                  | 5/2016<br>4/2016              | 8/9/2016                   |
| 2/9/2016, 7462           | Metronidazole<br>60mg/ml   | Metronidazole<br>Flavor chicken broth        | 5/2016<br>5/2016              | 8/9/2016                   |
| 2/9/2016-7341            | Test/estra 50/14mg         | Testosterone                                 | 5/2016                        | 8/9/2016                   |
| 2/9/2016-17              | Testosterone 1%            | Testosterone                                 | 5/2016                        | 8/9/2016                   |
| 2/9/2016-5061            | Sildenafil 40mg/ml         | Flavor chicken liquid                        | 4/2016                        | 8/9/2016                   |
| 2/8/2016-7642            | Test/biest<br>4/1.75/0.1ml | Testosterone                                 | 5/2016                        | 8/8/2016                   |
| 2/9/2016, 7539           | Testosterone 1mg/gm        | Testosterone                                 | 5/2016                        | 8/9/2016                   |
| 2/8/2016, 530            | Testosterone 50mg          | Testosterone                                 | 5/2016                        | 8/8/2016                   |
| 2/7/2016, 4341           | Monobenzene 25%            | Monobenzene<br>Base emollient cream          | 4/2015<br>6/2016              | 8/2016                     |
| 2/8/2016, 6994           | Testosterone 1mg           | Testosterone<br>Silica<br>Flavor bitter stop | 5/2016<br>3/2016<br>4/2016    | 8/8/2016                   |



|                |                                 |  |                            |          |
|----------------|---------------------------------|--|----------------------------|----------|
| 2/8/2016, 3626 | Tylosin 200mg/ml                | Stevia 95%   | 2/2016                     | 8/8/2016 |
| 2/6/2016, 5708 | Testosterone 4mg/gm             | Testosterone   | 5/2016                     | 8/6/2016 |
| 2/6/2016, 4402 | Testosterone 1.75%              | Testosterone   | 5/2016                     | 8/6/2016 |
| 2/8/2016, 7643 | Prog/E2/E3/Test<br>25/0.25/0.5  | Testosterone<br>Silica                                 | 5/2016<br>3/2016           | 8/8/2016 |
| 2/7/2016, 2508 | Prednisolone<br>10mg/ml         | Stevia 95%<br>Flavor chicken broth                     | 2/2016<br>5/2016           | 8/7/2016 |
| 2/8/2016, 6971 | Pro/biest/test<br>150/1.25/0.25 | Testosterone   | 5/2016                     | 8/8/2016 |
| 2/2/2016, 2508 | Prednisolone<br>10mg/ml         | Stevia 95%<br>Flavor tuna                              | 2/2016<br>6/2016           | 8/2016   |
| 2/2/2016, 2641 | Test/estra 0.5/2mg              | Testosterone<br>Silica<br>Base polyglycol troche       | 5/2016<br>3/2016<br>6/2016 | 8/2016   |
| 2/2/2016, 5737 | Prog/estra 150/2mg              | Silica<br>Flavor bitter stop<br>Base polyglycol troche | 3/2016<br>4/2016<br>6/2016 | 8/2016   |
| 2/2/2016, 1719 | Progesterone 150mg              | Silica<br>Flavor bitter stop<br>Base polyglycol troche | 3/2016<br>4/2016<br>6/2016 | 8/2016   |
| 2/2/2016, 252  | Magic Mouth wash                | Lidocaine 2%   | 3/2016                     | 8/2016   |
| 2/1/2016, 3540 | Estradiol 1mg/gm                | Base carbopol  | 4/2016                     | 8/2016   |

43. The above data demonstrates that Fireside Pharmacy assigned a 180-day expiration date to its compounded products, even if one of the ingredients had a shorter expiration date.

44. During the inspection on February 10, 2016, PIC Omilana admitted that Fireside Pharmacy had transferred compounding ingredients to Las Palmas Pharmacy in Palm Springs<sup>1</sup>, and that Fireside Pharmacy only created and kept transfer orders for transfers of controlled substances between the two pharmacies. Inspection revealed that between October 25, 2014 and February 2, 2016, Fireside Pharmacy made five transfers of bulk progesterone and four transfers of bulk testosterone to Las Palmas Pharmacy without creating the required sales and purchase records. Fireside Pharmacy only kept handwritten receipts on generic forms that listed the drug, quantity and date, but did not state the names and addresses of the seller and the buyer.

45. Fireside Pharmacy did not keep any record of other compounding ingredients, which are dangerous drugs, that it transferred to Las Palmas Pharmacy.

///

<sup>1</sup> Respondent Omilana is also the PIC of Las Palmas Pharmacy.

1 **FIRST CAUSE FOR DISCIPLINE**

2 **(Against Respondents Fireside Pharmacy and Omilana)**

3 **(Failure to Adhere to Operational Standards and Security - Controlled Substances)**

4 46. Respondents Fireside Pharmacy and Omilana are subject to disciplinary action under  
5 CCR section 1714, subdivisions (b) and (d), for the reasons set forth above in paragraphs 34 to  
6 41, which are summarized here:

7 a. Fireside Pharmacy and Omilana as PIC failed to maintain adequate control over the  
8 purchase, intake, storage and security of controlled substances. As a result, a pharmacy technician  
9 was able to remove 5,000 pills of alprazolam 2mg from the pharmacy, and 22,285 pills of  
10 alprazolam 2mg disappeared from Fireside Pharmacy.

11 b. All staff at Fireside Pharmacy had access to controlled substances because Fireside  
12 Pharmacy did not limit the personnel who could order Schedule III and IV controlled substances,  
13 and it did not keep controlled substances like alprazolam in a locked area.

14 c. Fireside Pharmacy had an inoperative video surveillance system. After 5,000 pills of  
15 alprazolam were taken from Fireside Pharmacy, no security footage was available because the  
16 pharmacy's video surveillance system was not working. No video could be retrieved.

17 **SECOND CAUSE FOR DISCIPLINE**

18 **(Against Respondents Fireside Pharmacy and Omilana)**

19 **(Failure to Maintain Records of Disposition of Dangerous Drugs)**

20 47. Respondents Fireside Pharmacy and Omilana are subject to disciplinary action under  
21 sections 4059, subdivisions (a) and (b), and 4081, subdivision (a), because the pharmacy failed to  
22 maintain complete records for the transfer of controlled substances to Las Palmas Pharmacy, and  
23 it kept no record of the transfer to Las Palmas Pharmacy of bases, devices, filler, non-bulk items,  
24 and dangerous drugs that are not controlled substances. The circumstances are described above in  
25 paragraphs 44 and 45, and are summarized as follows:

26 a. During the inspection of Fireside Pharmacy on February 10, 2016, the Board's  
27 investigator found that nine written orders for transfer of progesterone and testosterone to Las

28 ///

Palmas Pharmacy in Palm Springs did not include the name and address of the buyer and seller, as required by section 4059, subdivision (b).

b. During the inspection on February 10, 2016, Omilana admitted that transfer records were only kept for controlled substances, and that no transfer records were kept for other dangerous drugs or for bases, devices, fillers and non-bulk items.

### **THIRD CAUSE FOR DISCIPLINE**

#### **(Against Respondents Fireside Pharmacy and Omilana)**

#### **(Dispensing Dangerous Drugs in Incorrectly Labeled Containers)**

48. Respondents Fireside Pharmacy and Omilana are subject to disciplinary action under Code sections 4076, subdivision (a)(9), and 4077, subdivision (a), because Fireside Pharmacy dispensed compounded medications that were labeled with incorrect expiration dates that exceeded the expiration date(s) of one or more ingredients, as set forth in paragraphs 42 and 43, above.

### **FOURTH CAUSE FOR DISCIPLINE**

#### **(Against Respondents Fireside Pharmacy and Omilana)**

#### **(Action by the Board to Prevent Sales of Drugs Lacking Quality or Strength)**

49. Respondents Fireside Pharmacy and Omilana are subject to disciplinary action under Code sections 4301, subdivision (f), and 4342, because Fireside Pharmacy dispensed compounded medications that were labeled with incorrect expiration dates that exceeded the expiration date(s) of one or more ingredients, as set forth in paragraphs 42 and 43, above.

### **FIFTH CAUSE FOR DISCIPLINE**

#### **(Against Respondents Fireside Pharmacy and Omilana)**

#### **(Misbranding of Dangerous Drugs)**

50. Respondents Fireside Pharmacy and Omilana are subject to disciplinary action under Health and Safety Code sections 111440 because Fireside Pharmacy dispensed compounded medications that had false and/or misleading labels because they stated expiration dates which exceeded the expiration date(s) of one or more ingredients, as set forth in paragraphs 42 and 43, above.

1 **SIXTH CAUSE FOR DISCIPLINE**

2 **(Against Respondent Fernandez)**

3 **(Violating Statutes Regulating Controlled Substances)**

4 51. Respondent Fernandez has subjected her registration to disciplinary action under  
5 Code section 4301, subdivision (j), for violation of Health and Safety Code section 11170,  
6 because she illegally obtained controlled substances, in that she possessed a controlled substance  
7 without a prescription, consisting of 5000 pills of alprazolam 2mg, as detailed above in  
8 paragraphs 34 through 37.

9 **SEVENTH CAUSE FOR DISCIPLINE**

10 **(Against Respondent Fernandez)**

11 **(Unprofessional Conduct: Acts of Dishonesty, Fraud or Deceit)**

12 52. Respondent Fernandez is subject to disciplinary action under Code section 4301,  
13 subdivision (f), in that she committed acts involving dishonesty, fraud, deceit, or corruption,  
14 because she illegally took 5000 pills alprazolam 2mg, a controlled substance, from her employer  
15 Fireside Pharmacy, as detailed above in paragraph 34 through 37.

16 **EIGHTH CAUSE FOR DISCIPLINE**

17 **(Against Respondent Fernandez)**

18 **(Violating Laws Governing Pharmacy)**

19 53. Respondent Fernandez has subjected her registrations to disciplinary action under  
20 Code section 4301, subdivision (o), for violation of Code sections 4059 and 4060, because she  
21 illegally furnished controlled substances to herself and illegally possessed controlled substances  
22 without a legitimate prescription, as detailed above in paragraphs 34 through 37.

23 **DISCIPLINE CONSIDERATIONS**

24 54. To determine the degree of discipline, if any, to be imposed on Respondents Fireside  
25 Pharmacy and Omilana, on February 13, 2015, the Board issued two citations, Number CI 2013  
26 59864 and CI 2014 64267, and ordered them to pay \$500.00 each for violation of Code sections  
27 4030, 4114 and CCR section 1793.1, for having an intern pharmacist work at the pharmacy

28 ///

1 without a current intern pharmacist license from October 1 to December 27, 2013. Those citations  
2 are final and the fines were paid.

3 55. To determine the degree of discipline, if any, to be imposed on Respondent Omilana,  
4 on November 3, 2017, in a prior action, the Board issued Citation Number CI 2017 75949 and  
5 ordered Respondent to pay fines totaling \$750. That Citation is now final and the fines were paid.  
6 The citation was issued for the following violations discovered at Las Palmas Pharmacy where  
7 Omilana was also the PIC:

8 a. In violation of Code section 4169, subdivision (a)(4), a prescription medication that  
9 had expired was dispensed on May 5, 2015.

10 b. In violation of Code section 4076, subdivision (a)(9), between May 5 and December  
11 17, 2015, five prescription medications were dispensed without expiration dates on the  
12 prescription labels.

13 c. In violation of CCR section 1714, subdivision (b), on December 17, 2015, dangerous  
14 drugs that were required to be stored between 36 and 46 degrees Fahrenheit were being stored at  
15 31 degrees Fahrenheit.

16 d. In violation of Code section 4169, subdivision (a)(2), and Health & Safety Code  
17 section 111255, on December 17, 2015, two expired medications were being held in the  
18 pharmacy's drug stock.

19 56. Omilana was the PIC for both Las Palmas Pharmacy and Fireside Pharmacy. On  
20 December 18, 2015, TCH M.J., who worked at both pharmacies, admitted that she took four  
21 bottles of 500 alprazolam 2mg from Las Palmas Pharmacy. On December 22, 2015, TCH M.J.  
22 drafted and signed a written statement admitting that she did this in November 2015. This is the  
23 subject of a separate disciplinary action against TCH M.J., OAH case number 2019020363, which  
24 is set for hearing on August 1, 2019.

### 25 PRAYER

26 WHEREFORE, Complainant requests that a hearing be held on the matters herein alleged,  
27 and that following the hearing, the Board of Pharmacy issue a decision:

28 ///

- 1           1.     Revoking or suspending Pharmacy Permit Number PHY 47407, issued to Pathway
- 2     Pharmaceuticals Inc., dba Fireside Pharmacy;
- 3           2.     Revoking or suspending Sterile Compounding Pharmacy Number LSC 99523, issued
- 4     to Pathway Pharmaceuticals Inc., dba Fireside Pharmacy;
- 5           3.     Revoking or suspending Pharmacist License Number RPH 46012, issued to Adeyemi
- 6     Akintunde Omilana;
- 7           4.     Revoking or suspending Pharmacy Technician Registration Number TCH 40737,
- 8     issued to Susana J. Fernandez;
- 9           5.     Revoking or suspending Pharmacy Technician Registration Number TCH 139128,
- 10    issued to Mariana Jimenez;
- 11          6.     Ordering Pathway Pharmaceuticals, Inc., Adeyemi Akintunde Omilana, Susana J.
- 12    Fernandez and Mariana Jimenez to pay the Board of Pharmacy the reasonable costs of the
- 13    investigation and enforcement of this case, pursuant to Business and Professions Code section
- 14    125.3; and
- 15          7.     Taking such other and further action as deemed necessary and proper.

16  
17  
18    DATED:   May 10, 2019



19                   ANNE SODERGREN  
20                   Interim Executive Officer  
21                   Board of Pharmacy  
22                   Department of Consumer Affairs  
23                   State of California  
24                   Complainant

25  
26  
27  
28    SD2018700779  
      71799285\_3.docx