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

In the Matter of the Accusation Against:

Case No. 5687

OAH No. 2016100358

## WHITTIER PLAZA PHARMACY INC., DBA THE PRESCRIPTION SHOP – WHITTIER NAGI M. YOUSSEF, OWNER, PRES./SEC. Pharmacy Permit No. PHY 44877,

HANAA BASALIOUS,

Pharmacist License No. RPH 61004,

ATEF RIAD NEMETALLA Pharmacist License No. RPH 65460,

NAGI M. YOUSSEF Pharmacy Technician Registration No. TCH 30442,

and

**ANTOINETTE PEREZ** Pharmacy Technician Registration No. TCH 75855

Respondents.

## 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 November 23, 2017. It is so ORDERED on October 24, 2017.

> BOARD OF PHARMACY DEPARTMENT OF CONSUMER AFFAIRS STATE OF CALIFORNIA

nc, 1000

Ву

Amy Gutierrez, Pharm.D. Board President

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

In the Matter of the Accusation Against:

# WHITTIER PLAZA PHARMACY INC., dba THE PRESCRIPTION SHOP – WHITTIER

PIC SALLY M. DEMIAN (since 7/17/15), PIC HANAA BASALIOUS (3/10/14 to 7/16/15), PIC ATEF NEMETALLA (6/6/11 to 3/10/14), and NAGI M. YOUSSEF, OWNER, PRES./SEC. Pharmacy Permit No. PHY 44877,

# HANAA BASALIOUS,

Pharmacist License No. RPH 61004,

# ATEF RIAD NEMETALLA

Pharmacist License No. RPH 65460,

## NAGI YOUSSEF<sup>1</sup>

Pharmacy Technician Registration No. TCH 30442,

and

# **ANTOINETTE PEREZ,**

Pharmacy Technician Registration No. TCH 75855,

Respondents.

///

///

Case No. 5687

# OAH No. 2016100358

<sup>&</sup>lt;sup>1</sup> Spelling corrected from "Yousseff" in the caption of the Accusation.

## **PROPOSED DECISION**

Administrative Law Judge Thomas Heller, State of California, Office of Administrative Hearings, heard this matter in Los Angeles, California on March 27-30, 2017.

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

Armond Marcarian, Esq., represented respondents Whittier Plaza Pharmacy Inc., dba The Prescription Shop – Whittier (The Prescription Shop or Pharmacy), and Nagi Youssef.

Herbert L. Weinberg, Esq., Fenton Law Group LLP, represented respondent Hanaa Basalious.

Respondent Atef Riad Nemetalla did not appear, because he settled with complainant before the hearing began, pending the Board's final approval.

Respondent Antoinette Perez appeared only to testify, because she surrendered her pharmacy technician registration before the hearing.

After the hearing, the record was held open for closing briefs until June 15, 2017, a deadline later extended to June 29, 2017. Before they were due, the Pharmacy and Youssef filed a joint request on May 31, 2017, to open the record to introduce evidence of Nemetalla's completed settlement with the Board. Complainant opposed the request. The administrative law judge denied it on July 7, 2017.

The parties timely filed closing briefs, which were marked for identification purposes as exhibit 32 (Complainant's Trial Brief), exhibit N (Respondent Hanaa Basalious' Closing Argument), and exhibit O (Whittier Plaza Pharmacy, Inc.'s And Nagi Youssef's Closing Brief). Due to an internal error at the Office of Administrative Hearings, the closing brief of The Prescription Shop and Youssef was not processed and forwarded to the administrative law judge for review until August 7, 2017. Accordingly, the record was reopened to permit consideration of that brief, and the matter was deemed resubmitted as of that date.

## SUMMARY

Complainant requests that the Board discipline The Prescription Shop's pharmacy permit, Basalious's pharmacist license, and Youssef's pharmacy technician registration, alleging they violated the Pharmacy Law (Bus. & Prof. Code, § 4000 et seq.),<sup>2</sup> leading to losses of controlled substances. Respondents assert that they did all they could to avoid drug losses, and that discipline is unwarranted. The evidence established causes for discipline,

<sup>&</sup>lt;sup>2</sup> Undesignated statutory references are to the Business and Professions Code.

justifying revocation of The Prescription Shop's permit and Youssef's registration, a public reproval of Basalious, and an award of the Board's investigation and enforcement costs.

.

## FACTUAL FINDINGS

## Jurisdictional Facts

,

1. On June 14, 2001, the Board issued Original Permit Number PHY 44877 to The Prescription Shop. As of the hearing date, the permit was set to expire on June 1, 2017, unless renewed.

2. Youssef has been a registered pharmacy technician since August 24, 1999 (Original Pharmacy Technician Registration No. TCH 30442). Board records show he has been The Prescription Shop's sole shareholder, President, Chief Executive Officer, Secretary, Treasurer/Chief Financial Officer, and Director since May 18, 2011. His registration is set to expire on October 31, 2018, unless renewed.

3. Basalious has been a licensed pharmacist since June 12, 2008 (Original Pharmacist License No. RPH 61004), and was The Prescription Shop's pharmacist-in-charge<sup>3</sup> from March 10, 2014 to July 16, 2015. Her license is set to expire on September 30, 2017, unless renewed.

4. Nemetalla has been a licensed pharmacist since May 10, 2011 (Original Pharmacist License No. RPH 65460), and was The Prescription Shop's pharmacist-in-charge from June 6, 2011 to March 10, 2014. His license is set to expire on September 30, 2018, unless renewed.

5. Perez became a registered pharmacy technician on April 25, 2007 (Original Pharmacy Technician No. TCH 75855). After becoming registered, she worked as a pharmacy technician at The Prescription Shop until May 27, 2015. She surrendered her registration effective November 4, 2016.

6. On July 1, 2016, complainant served an Accusation on respondents, alleging five causes for discipline under the Pharmacy Law: two against the Pharmacy, Basalious, and Nemetalla; one against the Pharmacy, Basalious, and Youssef; one against Nemetalla alone; and one against Perez alone.

7. Basalious submitted a Notice of Defense, dated July 11, 2016. The Pharmacy and Youssef submitted Notices of Defense, dated July 13, 2016.

<sup>&</sup>lt;sup>3</sup> "'Pharmacist-in-charge' means a pharmacist proposed by a pharmacy and approved by the board as the supervisor or manager responsible for ensuring the pharmacy's compliance with all state and federal laws and regulations pertaining to the practice of pharmacy." (§ 4036.5.)

#### Background

8. The Prescription Shop operates a retail pharmacy in Whittier, California, that fills patient prescriptions and sells over-the-counter items, incontinence and wound care supplies, candy, condiments, soda, and ice cream. As of the hearing date, it had five employees, and has had as many as eight. Until a few years ago, it was open Monday through Saturday; it is now open Monday through Friday.

9. Youssef purchased the pharmacy in 2000 from a prior owner, and later incorporated The Prescription Shop. In June 2011, he hired Nemetalla as The Prescription Shop's pharmacist-in-charge. In March 2014, he hired Basalious as the pharmacist-in-charge to replace Nemetalla. Basalious had never been a pharmacist-in-charge, but was a staff pharmacist at another retail pharmacy for several years. She worked at The Prescription Shop during the week, and Nemetalla continued to work Saturdays as a staff pharmacist. Youssef often assisted Nemetalla on Saturdays.

#### Inspection

10. On March 13, 2015, Board inspectors Afrouz Nikmanesh, Noelle Randall, and Michael Capili, and two Drug Enforcement Administration (DEA) investigators, inspected The Prescription Shop for potential drug loss. They met with Youssef and Basalious, and asked for the Pharmacy's DEA biennial inventory of controlled substances. Controlled substances are drugs or other substances listed on one of five federal or state schedules (Schedules I-V), based on their accepted medical uses, the potential for abuse, and their psychological and physical effects on the body. (21 U.S.C. §§ 811, 812; 21 C.F.R. §§ 1308.11-1308.15; Health & Saf. Code, §§ 11007, 11054-11058.) The DEA requires every dispenser of controlled substances to perform an initial inventory, and a new inventory every two years thereafter. (21 C.F.R. § 1304.11.)

11. Basalious stated she had not performed an official DEA biennial inventory for the Pharmacy, but did inventory its controlled substances when she started. She provided inventory sheets of a March 6, 2014 count of Schedule II controlled substances, and of counts of Schedules III-V controlled substances over multiple days in June 2014. The sheets listed drug names, inventory dates, drug quantities, and corresponding National Drug Code (NDC) numbers, but did not state whether Basalious counted the drugs as of the opening or close of business on the inventory dates. She and Youssef also looked for any previous DEA biennial inventory that Nemetalla performed while he was pharmacist-in-charge, but could not find one.

12. The inspectors noticed inventory sheets taped to bottles containing controlled substances. Basalious explained she kept a "perpetual" (i.e., running) inventory of all controlled substances, and kept the inventory sheets taped to the bottles. The inspectors asked her to conduct a stock-on-hand count of 18 medications, including alprazolam (1 mg and 2 mg), clonazepam (2 mg), hydrocodone/acetaminophen (7.5-325 mg and 10-325 mg),

and promethazine/codeine syrup, among others. Basalious complied, with assistance from Youssef and Perez.

13. Nikmanesh collected sample invoices from Cardinal Health (Cardinal), Associated Pharmacies, Inc. (API), and Anda, Inc. (Anda), three wholesalers from which the Pharmacy ordered drugs. Before concluding the inspection, she also asked Basalious to email the DEA biennial inventory from Nemetalla's tenure as pharmacist-in-charge, along with disposition records for the drugs in the stock-on-hand count. A few days later, the Pharmacy forwarded the disposition records, but no biennial inventory from Nemetalla. Youssef requested more time to locate it, but Nikmanesh denied the request, and Youssef never sent it. Basalious later prepared a biennial inventory as of May 26, 2015, about two months after the inspection.

14. Nikmanesh requested records from the three wholesalers of the Pharmacy's purchases of the drugs in the stock-on-hand inventory from March 6, 2014 to March 13, 2015. Cardinal and API sent records, while Anda stated it had no records of any such purchases. Nikmanesh compared the Cardinal and API records with the Pharmacy's disposition records and inventory counts to determine if drugs were missing. She completed her audit, but complainant presented insufficient evidence to admit the underlying wholesalers' records under the business records exception to the hearsay rule. (Evid. Code, § 1271.) Therefore, over respondents' hearsay objection, those records are insufficient by themselves to support a finding, making Nikmanesh's audit results largely inadmissible. (Gov. Code, § 11513, subd. (d).) Only her finding that the Pharmacy was missing about 12,000 milliliters (i.e., approximately 25 one-pint bottles) of promethazine/codeine syrup was admitted, because Basalious later confirmed it.

15. In May and June 2015, Nikmanesh corresponded with Basalious, Nemetalla, the Pharmacy, and their attorneys about the inspection. On June 11, 2015, Youssef faxed Nikmanesh a letter stating he had fired Perez on May 27, 2015, after she admitted to stealing promethazine/codeine syrup. In early June 2015, Basalious also submitted a report of theft or loss of controlled substances to the DEA, stating that the Pharmacy was missing 12,000 milliliters of promethazine/codeine syrup due to employee theft. Perez testified at the hearing, and acknowledged stealing two one-pint bottles of the syrup (i.e., less than 1000 milliliters), but denied stealing other bottles, or any other drugs.

16. On June 16, 2015, Susan Angell, an attorney for Basalious, sent Nikmanesh additional documents, including a summary report of Basalious's own audit of the Pharmacy's inventory. That audit showed the Pharmacy was missing 30 pills of alprazolam 1 mg, 688 pills of alprazolam 2 mg, 105 pills of clonazepam 2 mg, 106 pills of hydrocodone/acetaminophen 7.5-325 mg, and 12,187 milliliters of promethazine/codeine 10-6.25 mg/5 mL syrup. All of these drugs are controlled substances.

17. In June and July 2015, Nikmanesh also investigated who was signing for deliveries of dangerous drugs to the Pharmacy. "Dangerous drug'... means any drug ... unsafe for self-use in humans or animals," including any drug that can be lawfully dispensed

5

only by prescription. (§ 4022.) She requested signature logs from Cardinal and API for all Saturday deliveries to the Pharmacy for the year beginning March 13, 2014, and all weekday deliveries between August 1 and September 1, 2014. Complainant offered those logs into evidence, but again presented insufficient evidence to admit them under the business records exception to the hearsay rule. (Evid. Code, § 1271.) Therefore, over respondents' hearsay objection, they are insufficient by themselves to support a finding. (Gov. Code, § 11513, subd. (d).)

.

18. Nikmanesh sent the Pharmacy a written notice alleging non-pharmacists signed for dangerous drugs from API on 24 occasions in August 2014, and from Cardinal on four Saturdays between April 2014 and February 2015. API delivered shipments by FedEx during the week, and a Cardinal driver delivered shipments Monday through Saturday. Armond Marcarian, replying as the attorney for the Pharmacy and Nemetalla, stated that API's use of FedEx for deliveries made it difficult to determine the contents of packages before opening them. Accordingly, non-pharmacists signed for shipments from API without knowing that dangerous drugs might be in them. As to deliveries from Cardinal, he stated, "the Pharmacy regrets the fact that deliveries were signed and received by a non-pharmacist" in "isolated instances." He also stated that the Pharmacy had instituted a compliance program to ensure all deliveries of dangerous drugs were signed for and received by a licensed pharmacist. (Exhibit 28.)

19. Marcarian's letter confirms that non-pharmacists signed for some Saturday deliveries of dangerous drugs from Cardinal, as Nikmanesh alleged. It also confirms that non-pharmacists signed for FedEx deliveries from API. In addition, Basalious acknowledged in her testimony that she did not always sign for FedEx deliveries before the inspection in 2015. Instead, other pharmacy personnel signed for and opened them, under instructions to stop immediately if the delivery contained controlled medication. (Tr., Vol. II, p. 181.) This evidence, supplemented with API's signature logs (see Gov. Code, § 11513, subd. (d)), makes it highly probable that non-pharmacists also signed for deliveries of dangerous drugs from API in August 2014.

20. Nikmanesh also asked for daily logs of dispensed medications for specific dates, including both weekdays and Saturdays. The Pharmacy produced them, and computer records for some Saturdays showed Basalious as the dispensing pharmacist on some prescriptions, even though she was not the pharmacist on duty at the time. The records also showed Youssef as the computer user who entered the information for many of those prescriptions. Youssef testified this was due to human error, or possibly a default setting on the Pharmacy's computer program. A few of the prescriptions were for promethazine/codeine syrup.

# **Basalious Resigns**

.

21. In June 2015, Basalious began to work on Saturdays, after determining that Nemetalla had not been following her instructions for receiving Saturday deliveries of Schedule III-V controlled substances. She had asked him to leave her copies of signed invoices for all controlled substances he received on Saturdays, and also to leave the drugs for her to add to inventory when she returned during the week. After the inspection and her audit, she determined he had been following those directions for Schedule II controlled substances, but not for Schedule III-IV controlled substances, including 16 bottles of promethazine/codeine syrup, an order of alprazolam 2 mg, and "many bottles" of hydrocodone/acetaminophen. (Tr., Vol. II, p. 124.) She confronted Nemetalla about this, and he stated he would no longer work on Saturdays.

.

22. After Basalious worked just three Saturdays, Youssef told her the Pharmacy would no longer open on Saturdays, because the volume of business no longer justified it. By then, Basalious was about to leave on a vacation. Before she did, she asked all Pharmacy employees to sign a list of procedures for them to follow in her absence, including requirements for receiving controlled substances. Youssef refused to sign, stating that he was the owner and did not have to do so.

23. Before her vacation, Basalious also learned Youssef had entered the prescription drug area of the Pharmacy on a Sunday, without a pharmacist present, using a spare key that a part-time pharmacist had left for her in sealed envelope. Youssef had opened the envelope himself, and Basalious told him he should not do that. Youssef said he did so for a customer who was traveling the next morning and needed medication right away. He also told Basalious he would do the same thing again.

24. After learning of the spare key incident, Basalious decided she had to leave. She resigned before her vacation.

# Pharmacy Security

÷

25. Basalious testified she kept Schedule II controlled substances in locked drawers or cabinets, and kept a perpetual inventory for all of the Pharmacy's controlled substances. She also reviewed all invoices for controlled substances as they arrived, and checked the quantities delivered against the invoices. If the Pharmacy ordered excess quantities of controlled substances, she made sure the excess was returned. She personally signed for every delivery from Cardinal every day she worked, and put medication on the shelf herself. She also did not allow purses in the medication area of the Pharmacy as a theft prevention measure. She gave clear instructions to Nemetalla about how to handle deliveries of controlled substances on Saturdays, and was unaware that having non-pharmacists sign for FedEx packages from drug wholesalers was a problem, because that happened routinely at her previous job. She had also never performed a DEA biennial inventory before, and was unaware of the requirement to note whether the inventory was performed as of the opening or closing of business on the inventory date.

26. Youssef testified the Pharmacy had an alarm system and surveillance cameras, but the surveillance cameras were old. At some point, they preserved recordings for two weeks before deletion, but a camera technician later told him the cameras were not recording. He testified he found this out after the inspection, and replaced the cameras. Around January 2014, the pharmacy also purchased a license protection handbook prepared by Jeb Sydejko, which included strategies for pharmacy security. Youssef did not describe these strategies.

27. Youssef also testified to two pre-inspection incidents involving Perez and bottles of promethazine/codeine syrup. Describing the first, he testified Basalious told him she caught Perez trying to take an eight-ounce bottle of the syrup out of the Pharmacy. Youssef did not talk to Perez about it or take disciplinary action against her because he considered it a "one-off." (Tr., Vol. III, pp. 144, 188-189.) Basalious testified she did not recall this incident, and would not have let Perez remain at the Pharmacy "a minute" if she discovered Perez was stealing. (Tr., Vol. IV, p. 38.) Her testimony on this subject was persuasive, given her other efforts to protect against drug losses, and suggests Youssef learned of the incident some other way.

28. Describing the second incident a few weeks later, Youssef testified Basalious and Henan Elmassry, a pharmacy technician, could not find a one-pint bottle of promethazine/codeine syrup from a four-bottle shipment that day. They told Youssef, and the three of them and Perez searched for the bottle, which Perez produced a short time later. Basalious confirmed this incident occurred, and testified she asked Youssef to check the surveillance cameras. He told her they were not recording, which indicates he knew they were not before the inspection, not just afterwards as he testified. He took no further action to investigate the incident.

#### Other Evidence

29. Respondents have no prior disciplinary history, and several witnesses testified to the good character, honesty, and professionalism of Basalious and Youssef, including two priests, a deacon, the Pharmacy's prior owner, and current and former Pharmacy employees. Basalious also offered letters from another priest, two friends, and a former customer attesting to her good character, honesty, and integrity.

#### Costs

30. Complainant presented certifications stating that the Board incurred \$15,129.25 in costs investigating the matters alleged in the Accusation, and that the Department of Justice has billed the Board an additional \$13,762.50 concerning the case.

#### LEGAL CONCLUSIONS

#### Legal Standards

1. The Board may suspend, revoke, or refuse to issue any license, permit, or registration for unprofessional conduct. (§§ 4032, 4300, subds. (a), (c), 4301; see *Hoang v. California State Board of Pharmacy* (2014) 230 Cal.App.4th 448, 456.) Unprofessional conduct includes "[v]iolating or attempting to violate, directly or indirectly, or assisting in or

abetting the violation of or conspiring to violate any provision or term of this chapter or of the applicable federal and state laws and regulations governing pharmacy, including regulations established by the board or by any other state or federal regulatory agency." (§ 4301, subd. (o).)

•

2. Basalious's pharmacist license is a professional license. (§ 4050; Murphy v. E. R. Squibb & Sons, Inc. (1985) 40 Cal.3d 672, 678-679.) To impose discipline on a professional license, complainant must prove cause for discipline by clear and convincing evidence to a reasonable certainty. (Sternberg v. California State Board of Pharmacy (2015) 239 Cal.App.4th 1159, 1171 (Sternberg); Ettinger v. Board of Medical Quality Assurance (1982) 135 Cal.App.3d 853, 856.) Clear and convincing evidence "requires a finding of high probability," and has been described as "requiring that the evidence be ' "so clear as to leave no substantial doubt"; "sufficiently strong to command the unhesitating assent of every reasonable mind." ' [Citation.]" (In re Angelia P. (1981) 28 Cal.3d 908, 919.)

3. In contrast, The Prescription Shop's pharmacy permit is a nonprofessional license, because it does not have extensive educational, training, or testing requirements similar to a professional license. (See *Mann v. Dept. of Motor Vehicles* (1999) 76 Cal.App.4th 312, 319; *San Benito Foods v. Veneman* (1996) 50 Cal.App.4th 1889, 1894.) An applicant for a pharmacy permit need not be a pharmacist; instead, the applicant must designate a pharmacist-in-charge with the requisite education, training, and licensure. (§§ 4110, subd. (a), 4113, subd. (a).) To impose discipline on The Prescription Shop's nonprofessional pharmacy permit, complainant must prove cause for discipline by a preponderance of the evidence, which is a lower standard of proof than clear and convincing evidence. (*Imports Performance v. Dept. of Consumer Affairs, Bureau of Automotive Repair* (2011) 201 Cal.App.4th 911, 916-917 (*Imports Performance*); Evid. Code, §115.) A preponderance of the evidence means "'evidence that has more convincing force than that opposed to it.' [Citation.]" (*People ex rel. Brown v. Tri-Union Seafoods, LLC* (2009) 171 Cal.App.4th 1549, 1567.)

4. Youssef's pharmacy technician registration is also a non-professional license, because it is "based on minimal education, training requirements or certification." (California State Board of Pharmacy, Disciplinary Guidelines (rev. 10/07) p. 43 (Guidelines).) The Board may issue a pharmacy technician registration to any person who is a high school graduate or has a general education development certificate equivalent, and has completed 240 hours of Board-approved training. (§ 4202, subd. (a)(2); Cal. Code Regs., tit. 16, § 1793.6, subd. (c).) No examination is required, and a pharmacy technician is not an independent practitioner. (Guidelines, p. 43.) Instead, ""[p]harmacy 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 . . . ." (Cal. Code Regs., tit. 16, § 1793; see also § 4115, subd. (a).) Those nondiscretionary tasks may include "(a) removing the drug or drugs from stock; (b) counting, pouring, or mixing pharmaceuticals; (c) placing the product into a container; (d) affixing the

label or labels to the container; (e) packaging and repackaging." (Cal. Code Regs., tit. 16, § 1793.2.)

,

5. Therefore, complainant's burden of proof to impose discipline on Youssef's registration is also proof by a preponderance of the evidence. (*Imports Performance, supra*, 201 Cal.App.4th at pp. 916-917; Evid. Code, §115.)

## First Cause for Discipline

6. First, the Accusation alleges the Pharmacy, Nemetalla, and Basalious are subject to discipline for failing to conduct a DEA biennial inventory of controlled substances. Nemetalla settled before the hearing, leaving just the Pharmacy and Basalious to respond to this allegation. Under the DEA's regulations, "[e]very person required to keep records shall take an inventory of all stocks of controlled substances on hand on the date he/she first engages in the manufacture, distribution, or dispensing of controlled substances . . . .," and take a new inventory at least biennially thereafter. (21 C.F.R. 1304.11(b), (c).) "Each inventory shall contain a complete and accurate record of all controlled substances on hand on the date the inventory is taken, and shall be maintained in written, typewritten, or printed form at the registered location. . . . The inventory may be taken either as of opening of business or as of the close of business on the inventory date and it shall be indicated on the inventory." (21 C.F.R. § 1304.11(a).) The Board requires the biennial inventory to be "available for inspection upon request for at least 3 years after the date of the inventory." (Cal. Code Regs., tit. 16, § 1718.)

7. Complainant established this cause for discipline by clear and convincing evidence. The Pharmacy was required to have a DEA biennial inventory available for inspection, but never produced one from when Nemetalla was pharmacist-in-charge. (Factual Findings 11, 13.) Furthermore, Basalious's inventories from 2014 did not indicate whether they were taken at the opening or closing of business on the inventory dates, as required for a DEA biennial inventory. (Factual Finding 11; 21 C.F.R. § 1304.11(a).) Her unfamiliarity with this requirement explains the violation, but as the pharmacist-in-charge, she was "responsible for [the Pharmacy's] compliance with all state and federal laws and regulations pertaining to the practice of pharmacy." (§ 4113, subd. (c).) Her perpetual inventory. Therefore, the Board may take disciplinary action against the Pharmacy and Basalious for the violation. (§ 4301, subd. (o).)

#### Second Cause for Discipline

8. Second, the Accusation alleges the Pharmacy, Youssef, and Basalious are subject to discipline for failing to secure the Pharmacy to prevent the loss of controlled substances, in violation of California Code of Regulations, title 16, section 1714, subdivisions (b) and (d). Subdivision (b) states, "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." Subdivision (d) states, "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."

,

Complainant established this cause for discipline by clear and convincing 9. evidence. The "security of the prescription department" was compromised in multiple ways, leading to the loss of controlled substances. (Cal. Code Regs., tit. 16, § 1714, subd. (d).) The Pharmacy either misplaced or never performed a DEA biennial inventory while Nemetalla was pharmacist-in-charge, and Basalious also did not prepare a compliant DEA biennial inventory before the inspection. (Factual Findings 11, 13.) Non-pharmacists signed for shipments of dangerous drugs from Cardinal on some Saturdays, and from API during the week, creating a risk of diversion. (Factual Findings 17-19.) On Saturdays, Nemetalla did not follow Basalious's instructions for deliveries of Schedule III-V controlled substances, undermining her inventory control efforts. (Factual Finding 21.) Youssef also created inaccurate computer records suggesting Basalious worked on Saturdays, and did not investigate two pre-inspection incidents involving Perez and missing promethazine/codeine syrup, despite understanding that Perez actually tried to leave the Pharmacy with a bottle of the syrup during the first incident. (Factual Findings 20, 27-28.) He also took possession of a key to the prescription drug area of the Pharmacy, although he is not a pharmacist. (Factual Finding 23.) While a pharmacy owner may possess a key to "provid[e] access in case of emergency" (Cal. Code Regs., tit. 16, § 1714, subd. (e)), no evidence suggested Youssef tried to contact Basalious or another pharmacist before entering the prescription drug area alone.

10. In addition, the Pharmacy's "fixtures" and "equipment" to secure drugs (Cal. Code Regs., tit. 16, § 1714, subd. (b)) included surveillance cameras, but the cameras were not recording. (Factual Finding 26.) Had they been, the recordings could have revealed Perez's theft of promethazine/codeine syrup earlier. In fact, Basalious specifically asked Youssef to check the surveillance system to investigate the second pre-inspection incident involving the temporary disappearance of a pint of promethazine/codeine syrup, which Perez later produced. (Factual Finding 28.) He replied there was nothing to review. (*Ibid.*)

11. Accordingly, the Board may take disciplinary action against the Pharmacy, Youssef, and Basalious for the violations. (§ 4301, subd. (o).) As a corporation, the Pharmacy's permit is subject to discipline for the violations of its agents or employees. (Arenstein v. California State Board of Pharmacy (1968) 265 Cal.App.2d 179, 192-93, overruled on another point as stated in Barber v. Long Beach Civil Service Com. (1996) 45 Cal.App.4th 652, 658.); see also California Assn. of Health Facilities v. Dept. of Health Services (1997) 16 Cal.4th 284, 296 ["[A] licensee will be held liable for the acts of its agents ...."].) Youssef's pharmacy technician registration is also subject to discipline, even though he is not a "pharmacy" or "pharmacist ... on duty" under California Code of Regulations, title 16, section 1714, subdivisions (b) and (d), because a licensee may be disciplined for "assisting in or abetting" a violation of the Pharmacy Law. (§ 4301, subd. (o).) Multiple security violations were due to his personal conduct, and thus he assisted in or abetted violations of the regulation. In addition, his possession and use of the key to the prescription drug area without a pharmacist present was a direct violation the regulation. (Cal. Code Regs., tit. 16, § 1714, subd. (d).)

12. Basalious asserts she is not subject to discipline on this cause, because she was not the "pharmacist . . . on duty" on Saturdays, and it was not shown by clear and convincing evidence that theft or other diversion occurred during the week. But the Pharmacy's security lapses were not confined entirely to Saturdays, and the evidence of drug security violations during the week is sufficient to impose discipline against her. While Basalious made considerable efforts to prevent theft or other diversion, her initial inventory of controlled substances did not comply with DEA requirements, and allowing non-pharmacists to sign for FedEx shipments from API was a security risk. These violations, together with the Pharmacy's other security lapses, created conditions conducive to drug losses, which in fact occurred.

## Third Cause for Discipline

13. Third, the Accusation alleges the Pharmacy, Nemetalla, and Basalious are subject to discipline because non-pharmacists signed for and received dangerous drugs upon delivery, in violation of section 4059.5. As noted previously, Nemetalla settled before the hearing, leaving just the Pharmacy and Basalious to respond to this allegation. Subdivision (a) of section 4059.5 states, "Except as otherwise provided in this chapter, dangerous drugs or dangerous devices may only be ordered by an entity licensed by the board and shall be delivered to the licensed premises and signed for and received by a pharmacist. Where a licensee is permitted to operate through a designated representative, the designated representative shall sign for and receive the delivery."

14. Complainant established this cause for discipline by clear and convincing evidence. Marcarian's letter on behalf of the Pharmacy and Nemetalla confirmed that non-pharmacists signed for deliveries of dangerous drugs on some Saturdays, as Nikmanesh alleged. (Factual Finding 19.) The letter and other evidence, including Basalious's testimony, also indicate it is highly probable that non-pharmacists signed for dangerous drugs from API in August 2014 during weekday FedEx deliveries. (Factual Findings 19-20.) Indeed, Basalious acknowledges in her closing brief that "some deliveries which were received by common carrier from a secondary source wholesaler were not signed for by a pharmacist, in violation of B&P 4059.5(a)." (Respondent Hanaa Basalious' Closing Argument (June 29, 2017) p. 3.) While the precise number of such violations was not established,<sup>4</sup> this evidence is sufficient to prove a violation of section 4059.5. Therefore, the Board may take disciplinary action against the Pharmacy and Basalious. (§ 4301, subd. (o).)

<sup>&</sup>lt;sup>4</sup> The Accusation repeats Nikmanesh's allegation that non-pharmacists signed for dangerous drugs from API a total of 24 times in August 2014. But the hearsay signature logs

15. At the hearing, respondents asserted that non-pharmacists could sign for controlled substances under Health and Safety Code section 11209, subdivision (a), which states, "No person shall deliver Schedule II, III, or IV controlled substances to a pharmacy or pharmacy receiving area, nor shall any person receive controlled substances on behalf of a pharmacy unless, at the time of delivery, a pharmacist or authorized receiving personnel signs a receipt showing the type and quantity of the controlled substances received." But this statute applies to persons delivering controlled substances; it does not create a safe harbor for respondents to violate section 4059.5. Section 4059.5 applies "[e]xcept as otherwise provided in this chapter" – i.e., the Pharmacy Law – and Health and Safety Code section 11209 is not within that chapter. (See also *Sternberg, supra*, 239 Cal.App.4th at p. 1172 [referring to a non-pharmacist signing for controlled substances deliveries as a "violation of the law"].)

• .

# Fourth and Fifth Causes for Discipline

16. The Fourth and Fifth Causes for discipline are against Nemetalla and Perez, respectively, both of whom have resolved the allegations against them. Therefore, no analysis of these causes for discipline is required.

# Level of Discipline

## DISCIPLINARY GUIDELINES

17. In reaching a decision on discipline, the Board's Guidelines are to be considered. (Cal. Code Regs., tit. 16, § 1760.) The Guidelines divide various types of violations into four categories, ranging from the least serious, Category I, to the most serious, Category IV. If there are violations in more than one category, "the minimum and maximum penalties shall be those recommended in the highest category." (Guidelines, p. 5.)

18. As to pharmacists and pharmacies, unprofessional conduct under section 4301, subdivision (o), is a Category III violation (Guidelines, pp. 16, 78), and the underlying statutory and regulatory violations at issue are either Category I or Category III violations. (*Id.* at pp. 9, 11, 15, 17, 70, 72, 77, 78.) As to pharmacy technicians, all causes for discipline are classified as Category III violations. (*Id.* at p. 44.) The recommended discipline for both Category I and Category III violations ranges from a minimum of probation for a number of years under various terms and conditions, to a maximum of revocation.

19. The Guidelines also list 15 factors to be considered in determining the appropriate level of discipline. (Guidelines, p. 3.) In this case, they apply as follows:

(1) Actual or potential harm to the public. The violations had the potential to harm the public. Controlled substances are controlled because they have a high potential

from API were the only source of that number, and are insufficient to support that finding. (Gov. Code, § 11513, subd. (d).)

of abuse, addiction, and diversion. Security and inventory deficiencies at the Pharmacy created conditions conducive to theft and loss of controlled substances, which in fact occurred. Such losses contribute to the illicit use and abuse of controlled substances.

(2) Actual or potential harm to any consumer. There was no evidence of actual or potential harm to any specific consumer.

(3) Prior disciplinary record, including level of compliance with disciplinary order(s). The Prescription Shop, Basalious, and Youssef have no prior disciplinary records.

(4) Prior warning(s), including citation(s) and fine(s), letter(s) of admonishment, and/or correction notice(s). There was no evidence of any prior warnings.

(5) Number and/or variety of current violations. There were three causes for discipline established, involving violations of laws and regulations designed to prevent drug losses. The Pharmacy and Basalious are subject to discipline for all three, and Youssef is subject to discipline for one.

(6) Nature and severity of the act(s), offense(s) or crime(s) under consideration. The violations involved missing and deficient DEA biennial inventories, failing to secure the Pharmacy to prevent the loss of controlled substances, and allowing nonpharmacists to sign for deliveries of dangerous drugs. These are a mix of Category I and Category III violations.

(7) Aggravating Evidence. Youssef resisted some of Basalious's efforts to prevent drug losses. He would not sign a list of procedures for employees to follow in Basalious's absence. (Factual Finding 22.) He used a spare key to access the prescription area of the Pharmacy without a pharmacist present, and said he would do it again. (Factual Finding 23.) Nemetalla also did not follow Basalious's instructions for the receipt of Schedule III-V controlled substances on Saturdays. (Factual Finding 21.) When Basalious started working on Saturdays herself, Youssef closed the Pharmacy on Saturdays after just three weeks (Factual Finding 22), raising questions about what else may have happened on Saturdays before.

(8) *Mitigating Evidence*. Basalious made concerted efforts to prevent drug losses. Her efforts, while imperfect, were undermined by others, including Perez, Youssef, and Nemetalla. She resigned rather than accede to practices that put the Pharmacy's security at continued risk. (Factual Findings 21-24.) She had never been a pharmacist-in-charge, and was unaware of the DEA biennial inventory requirement she violated. (Factual Finding 25.) She allowed non-pharmacists to sign for FedEx packages that might contain dangerous drugs because that was the practice at her prior employer. (*Ibid.*)

(9) *Rehabilitation Evidence*. Basalious displayed an understanding of the violations, and a commitment to future compliance. Youssef provided little evidence about

14

how the Pharmacy has changed, or how it will avoid similar violations and drug losses in the future. He denied responsibility for the violations.

(10) Compliance with terms of any criminal sentence, parole, or probation. This factor is not applicable.

(11) Overall criminal record. This factor is not applicable.

(12) If applicable, evidence of proceedings for case being set aside and dismissed pursuant to section 1203.4 of the Penal Code. This factor is not applicable.

(13) Time passed since the act(s) or offense(s). The violations and drug losses were discovered in 2015, which is relatively recent.

(14) 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. Basalious's violations largely reflected a lack of awareness of the law. Youssef's conduct reflected carelessness about pharmacy security, and resistance to Basalious's authority and efforts to control inventory and prevent drug losses.

(15) Financial benefit to the respondent from the misconduct. No evidence suggests the misconduct was of financial benefit to Basalious. There was insufficient evidence presented to determine whether the misconduct was of financial benefit to Youssef and the Pharmacy.

DISCIPLINE FOR THE PRESCRIPTION SHOP AND YOUSSEF

20. The drug losses at the Pharmacy, while not "'staggering'" like in *Sternberg*, *supra*, 239 Cal.App.4th at p. 1163, raise significant concerns about its operations. Consideration of the disciplinary factors in the Guidelines does not allay those concerns. Most notably, there is a marked lack of rehabilitation evidence for the Pharmacy, and several aggravating factors, including Youssef's resistance to Basalious's authority and policies concerning drug control as the pharmacist-in-charge. Youssef still owns the Pharmacy, and presented no evidence he acts differently now with a different pharmacist-in-charge. While he attributes the Pharmacy's drug losses to a single employee (i.e., Perez), firing that employee does not mean all of the Pharmacy's problems are solved.

21. "Protection of the public shall be the highest priority for the California State Board of Pharmacy 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." (§ 4001.1.) In this case, public protection requires a level of discipline that will prevent future drug losses from the Pharmacy. Given Youssef's behavior toward Basalious, and lacking sufficient evidence of rehabilitation, the only level of discipline that will ensure public protection is revocation of the Pharmacy's permit.

22. As to Youssef's pharmacy technician registration, "[t]he board files cases against pharmacy technicians where the violation(s) involve significant misconduct on the part of the licensee. The board believes that revocation is typically the appropriate penalty when grounds for discipline are found to exist. [¶]  $\dots$  [¶] To place a pharmacy technician on probation places an additional burden on the pharmacist  $\dots$  to ensure that the respondent pharmacy technician complies with the terms and conditions of his or her probation." (Guidelines, p. 43.) Here, the burden on the pharmacist would be increased, because Youssef is the Pharmacy's sole shareholder and President. Youssef resisted Basalious's compliance efforts, and has not provided evidence he would act differently if his registration was placed on probation. Accordingly, revocation of his registration is also warranted.

23. In their closing brief, the Pharmacy and Youssef assert revocation would amount to a discriminatory application of laws, because the Board only cited and fined Cardinal for six violations of section 4059.5 between 2008 and 2013. But the record includes no information about the facts underlying those citations and fines, and their dates alone prove they have nothing to do with this case. Moreover, even if the facts were comparable, "there is no requirement that charges similar in nature must result in identical penalties [citation]." (*Grannis v. Board of Medical Examiners* (1971) 19 Cal.App.3d 551, 565.) Furthermore, no evidence suggests the Pharmacy and Youssef are "victim[s] of arbitrary selective enforcement on an invidious basis." (*Overturf v. California Horse Racing Board* (1978) 86 Cal.App.3d 979, 986.) Thus, their affirmative defense of discriminatory application of laws fails.

## DISCIPLINE FOR BASALIOUS

24. Consideration of the disciplinary factors in the Guidelines warrants a different result for Basalious. There is significant mitigating evidence concerning her violations, and they are unlikely to be repeated in the future. Inexperience as a pharmacist-in-charge played a role in her violations, and she displayed a strong commitment to preventing drug losses.

25. In *Sternberg*, the Board imposed a stayed revocation and three years' probation on a pharmacist-in-charge for violations that included allowing a non-pharmacist to sign for controlled substances in violation of section 4095.5, and failing to secure the Pharmacy to prevent the loss of controlled substances, in violation of California Code of Regulations, title 16, section 1714, subdivisions (b) and (d). (*Sternberg, supra, 239* Cal.App.4th at p. 1163.) Those violations and others allowed a pharmacy technician to order, and then steal, at least 216,630 tablets of a controlled substance that the pharmacy did not ordinarily sell. (*Id.* at p. 1162.) But unlike Basalious, the pharmacist-in-charge in *Sternberg* "never" looked at incoming invoices for controlled substances. (*Id.* at p. 1164.) He only signed delivery logs listing how many containers were in a shipment, and did not conduct random checks of containers he and his staff were signing for. (*Ibid.*) Here, Basalious personally checked each shipment of controlled substances she received while on

duty, directed that Saturday shipments of controlled substances be left for her to check, and put medication on the shelf herself. (Factual Findings 21, 25.) For packages arriving by FedEx, she also instructed her staff to stop immediately if opening them revealed they contained controlled medication. (Factual Finding 19.)

,

26. Accordingly, Basalious's violations warrant a lesser discipline than that imposed on the pharmacist-in-charge in *Sternberg*. In that case, the Board rejected a proposed discipline of public reproval (239 Cal.App.4th at p. 1163), but that lesser discipline is warranted here. Public protection does not require a stayed revocation with a period of probation.

# Other Considerations

.

.

27. "Any person . . . whose license has been revoked . . . or who has been a manager, administrator, owner, member, officer, director, associate, partner, or any other person with management or control of any partnership, corporation, trust, firm, or association whose application for a license has been denied or revoked, is under suspension or has been placed on probation, and while acting as the manager, administrator, owner, member, officer, director, associate, partner, or any other person with management or control had knowledge of or knowingly participated in any conduct for which the license was denied, revoked, suspended, or placed on probation, shall be prohibited from serving as a manager, administrator, owner, member, officer, director, associate, partner, or in any other position with management or control of a licensee . . .." (§ 4307, subd. (a).) "Person' includes, but is not limited to, firm, association, partnership, corporation, limited liability company, state governmental agency, trust, or political subdivision." (§ 4035.) An order under section 4307 requires the pleading to allege the applicability of the statute, and proper notice to respondents. (§ 4307, subd. (c).)

28. The Accusation requests an order under section 4307 against The Prescription Shop and Youssef, and they were given proper notice. Youssef is the Pharmacy's sole shareholder and President, and had knowledge of and knowingly participated in conduct for which the Pharmacy's permit should be revoked. Accordingly, an order under section 4307 against The Prescription Shop and Youssef is appropriate.

# Costs

29. Complainant also requests an award of investigative and enforcement costs. "Except as otherwise provided by law, in any order issued in resolution of a disciplinary proceeding before any board within the [Department of Consumer Affairs] . . ., upon request of the entity bringing the proceeding, the administrative law judge may direct a licentiate found to have committed a violation or violations of the licensing act to pay a sum not to exceed the reasonable costs of the investigation and enforcement of the case." (§ 125.3, subd. (a).) 30. Complainant requests \$28,891.75 in investigation and enforcement costs under section 125.3, and presented prima facie evidence those costs are reasonable. (Factual Finding 30; see § 125.3, subds. (a), (c).) Respondents presented no evidence they are not. But the Board must not assess its full costs if doing so would unfairly penalize a licensee "who has committed some misconduct but used the hearing process to obtain dismissal of other charges or a reduction in the severity of the discipline imposed." (*Zuckerman v. State Board of Chiropractic Examiners* (2002) 29 Cal.4th 32, 45.) The Board must also consider respondents' "subjective good faith belief in the merits of [their] position;'" and whether [they] raised a "'colorable challenge'" to the proposed discipline. (*Ibid.* [quoting *California Teachers Assn. v. State of California* (1999) 20 Cal.4th 327, 342, 345].) Furthermore, the Board must determine respondents "will be financially able to make later payments," and "may not assess the full costs . . . when it has conducted a disproportionately large investigation to prove that [a licensee] engaged in relatively innocuous misconduct." (*Ibid.*]

31. None of the respondents presented evidence of financial inability to pay the Board's costs. The Pharmacy is responsible for all of the violations established in this case, and neither it nor Youssef obtained a reduction in the severity of the discipline imposed. Youssef is only personally responsible for the violations in the Second Cause for Discipline, but there was no evidence that distinct and separable efforts were made in connection with those allegations. Therefore, a pro rata reduction of costs for him is unwarranted. (See *Imports Performance, supra*, 201 Cal.App.4th at p. 921.)

32. In contrast, Basalious used the hearing process to obtain a reduction in the severity of the discipline imposed. Given this fact, the Board should not assess its full costs against her. Under the circumstances, an award of \$5,800, or about 20 percent, of the Boards' total costs is reasonable. The Pharmacy and Youssef should be responsible for the remainder of the costs.

#### ORDER

#### The Prescription Shop

Original Permit Number PHY 44877, issued to respondent Whittier Plaza Pharmacy, Inc., dba The Prescription Shop – Whittier, is revoked.

Respondent Nagi Youssef, the sole shareholder and President of the corporation, shall, by the effective date of this decision, arrange for the destruction of, the transfer to, sale of or storage in a facility licensed by the Board of all controlled substances and dangerous drugs and devices. Respondent Youssef shall provide written proof of such disposition, submit a completed Discontinuance of Business form and return the wall and renewal license to the Board within five days of disposition.

Respondent Youssef shall also, by the effective date of this decision, arrange for the continuation of care for ongoing patients of the pharmacy by, at minimum, providing a

written notice to ongoing patients that specifies the anticipated closing date of the pharmacy and that identifies one or more area pharmacies capable of taking up the patients' care, and by cooperating as may be necessary in the transfer of records or prescriptions for ongoing patients. Within five days of its provision to the pharmacy's ongoing patients, Respondent Youssef shall provide a copy of the written notice to the Board. For the purposes of this provision, "ongoing patients" means those patients for whom the pharmacy has on file a prescription with one or more refills outstanding, or for whom the pharmacy has filled a prescription within the preceding sixty (60) days.

Respondent Whittier Plaza Pharmacy, Inc., dba The Prescription Shop – Whittier is prohibited from serving as a manager, administrator, owner, member, officer, director, associate, or partner of a Board licensee. This prohibition shall continue until the license is reinstated.

## Youssef

.

Original Pharmacy Technician Registration Number TCH 30442, issued to respondent Nagi Youssef, is revoked. Respondent Youssef shall relinquish his technician license to the board within ten (10) days of the effective date of this decision. Respondent Youssef may not reapply or petition the board for reinstatement of his revoked technician license for three (3) years from the effective date of this decision.

A condition of reinstatement shall be that respondent Youssef is certified as defined in Business and Professions Code section 4202(a)(4) and provides satisfactory proof of certification to the Board.

Respondent Youssef is prohibited from serving as a manager, administrator, owner, member, officer, director, associate, or partner of a Board licensee. This prohibition shall continue until the license of Whittier Plaza Pharmacy, Inc., dba The Prescription Shop – Whittier is reinstated.

## Basalious

Respondent Hanaa Basalious, Original Pharmacist License Number RPH 61004, is hereby publicly reproved under Business and Professions Code section 495. Respondent Basalious is required to report this reproval as a disciplinary action.

## Costs

Respondents Whittier Plaza Pharmacy, Inc., dba The Prescription Shop – Whittier, and Nagi Youssef, shall pay to the Board its costs of investigation and prosecution in the amount of \$23,091.75 within fifteen (15) days of the effective date of this decision.

Respondent Hanaa Basalious shall pay to the Board its costs of investigation and prosecution in the amount of \$5,800 within fifteen (15) days of the effective date of this decision.

•

DATED: September 5, 2017

DocuSigned by: Thomas Heller -CFDEA01421714A4...

THOMAS HELLER Administrative Law Judge Office of Administrative Hearings

VANGALA D. HADDIS		
KAMALA D. HARRIS Attorney General of California ARMANDO ZAMBRANO		
Supervising Deputy Attorney General NANCY A. KAISER		
Deputy Attorney General State Bar No. 192083		
300 So. Spring Street, Suite 1702 Los Angeles, CA 90013		
Telephone: (213) 897-5794 Facsimile: (213) 897-2804		
Attorneys for Complainant BEFORE THE		
BOARD OF PHARMACY DEPARTMENT OF CONSUMER AFFAIRS		
STATE OF CALIFORM		
In the Matter of the Accusation Against:	Case No. 5687	
WHITTIER PLAZA PHARMACY INC., DBA		
THE PRESCRIPTION SHOP - WHITTIER PIC SALLY M. DEMIAN (since 7/17/15),	ACCUSATION	
PIC HANAA BASALIOUS (3/10/14 to 7/16/15), PIC ATEF NEMETALLA (6/6/2011 to 3/10/14), and		
NAGI YOUSSEFF, OWNER, PRES./SEC.		
14350 Whittier Blvd #103 Whittier, CA 90605		
Pharmacy Permit No. PHY 44877,		
HANAA BASALIOUS, 10420 Rosa Ann Circle		
Cypress, CA 90630. Pharmacist License No. RPH 61004,		
ATEF RIAD NEMETALLA		
15012 Baylor Cir. Huntington Beach, CA 92647		
Pharmacist License No. RPH 65460,		
NAGI YOUSSEFF 275 S. San Gabriel Blvd.,		
Pasadena, CA 91107-4893 Pharmacy Technician Registration No. TCH 30442,		
and		
ANTOINETTE PEREZ,		
4351 E. 55th ST. #8 Maywood, CA 90270		
Pharmacy Technician Registration No. TCH 75855		
	<u>}</u>	
(WHITTIER PLAZA PHARMACY INC., DBA THE PR	ESCRIPTION CHOP WIL	

.

i

• .

1.1. XVI 1 121-

Complainant alleges:

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

ij

#### **PARTIES**

( - - )

1. Virginia Herold (Complainant) brings this Accusation solely in her official capacity as the Executive Officer of the Board of Pharmacy, Department of Consumer Affairs.

2. On or about June 14, 2001, the Board of Pharmacy issued Pharmacy Permit Number PHY 44877 to Whittier Plaza Pharmacy Inc., dba The Prescription Shop – Whittier (Respondent Pharmacy). Respondent Nagi Youssef is and has been the owner, President and Secretary since May 18, 2011. Nagi M. Youssef is and has been the Director, Chief Executive Officer, and Treasurer/Chief Financial Officer of Respondent Pharmacy since May 18, 2011. Sally M. Demian, RPH 64473 is and has been the Pharmacist-in-Charge since July 17, 2015. Respondent Hanaa Basalious, RPH 61004 was the Pharmacist-in-Charge from March 10, 2014 to July 16, 2015. Respondent Atef Nemetalla, RPH 65460 was the Pharmacist-in-Charge from June 6, 2011 to March 10, 2014. The Pharmacy Permit was in full force and effect at all times relevant to the charges brought herein and will expire on June 1, 2017, unless renewed.

3. On or about June 12, 2008, the Board issued Original Pharmacist License Number RPH 61004 to Hanaa Basalious (Respondent Basalious). Pharmacist License Number RPH 61004 was in full force and effect at all times relevant to the charges brought herein and will expire on September 30, 2017, unless renewed.

4. On or about May 10, 2011, the Board issued Original Pharmacist License Number
RPH 65460 to Atef Riad Nemetalla (Respondent Nemetalla). Pharmacist License Number RPH
65460 was in full force and effect at all times relevant to the charges brought herein and will
expire on September 30, 2016, unless renewed.

On or about August 24, 1999, the Board issued Original Pharmacy Technician
 Registration Number TCH 30442 to Nagi Youssef (Respondent Youssef). Pharmacy Technician
 Registration Number TCH 30442 was in full force and effect at all times relevant to the charges
 brought herein and will expire on October 31, 2016, unless renewed.

6. On or about April 25, 2007, the Board issued Original Pharmacy Technician Registration Number TCH 75855 to Antoinette Tricia Perez (Respondent Perez). Pharmacy Technician Registration Number TCH 75855 was in full force and effect at all times relevant to the charges brought herein and will expire on September 30, 2016, unless renewed.

#### **JURISDICTION**

7. This Accusation is brought before the Board of Pharmacy (Board), Department of Consumer Affairs, under the authority of the following laws. All section references are to the Business and Professions Code unless otherwise indicated.

## STATUTORY PROVISIONS

8. Section 4300 provides in pertinent part, that every license issued by the Board is subject to discipline, including suspension or revocation.

9. Section 4300.1 of the Code 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."

16

17

18

19

20

21

22

23

24

25

26

27

28

. . .

15

1

2

3

4

5

6

7

8

9

10

11

12

13

14

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

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

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

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

11. Section 4302 of the Code states:

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

6

7

8

9

10

11

12

13

14

15

16

17

18

19

20

21

22

23

24

25

26

27

28

5

1

2

3

4

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

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

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

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

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

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

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

15. Section 4022 of the Code states

"Dangerous drug" or "dangerous device" means any drug or device unsafe for self-use in humans or animals, and includes the following:

	[ [
- 1	"(a) Any drug that bears the legend: "Caution: federal law prohibits dispensing without
2	prescription," "Rx only," or words of similar import.
3.	"(b) Any device that bears the statement: "Caution: federal law restricts this device to sale
4	by or on the order of a," "Rx only," or words of similar import, the blank to be filled
5	in with the designation of the practitioner licensed to use or order use of the device.
. 6	"(c) Any other drug or device that by federal or state law can be lawfully dispensed only on
7	prescription or furnished pursuant to Section 4006."
: 8 -	16. Section 4059.5 of the Code states, in part:
9	"(a) Except as otherwise provided in this chapter, dangerous drugs or dangerous devices
10	may only be ordered by an entity licensed by the board and shall be delivered to the licensed
. 11	premises and signed for and received by a pharmacist."
12	17. Section 4060 of the Code states:
13	"No person shall possess any controlled substance, except that furnished to a person upon
14	the prescription of a physician, dentist, podiatrist, optometrist, veterinarian, or naturopathic doctor
15	pursuant to Section 3640.7, or furnished pursuant to a drug order issued by a certified
16	nurse-midwife pursuant to Section 2746.51, a nurse practitioner pursuant to Section 2836.1, or a
17	physician assistant pursuant to Section 3502.1, or naturopathic doctor pursuant to Section 3640.5,
18	or a pharmacist pursuant to either subparagraph (D) of paragraph (4) of, or clause (iv) of
19	subparagraph (A) of paragraph (5) of, subdivision (a) of Section 4052. This section shall not
20	apply to the possession of any controlled substance by a manufacturer, wholesaler, pharmacy,
21	pharmacist, physician, podiatrist, dentist, optometrist, veterinarian, naturopathic doctor, certified
22	nurse-midwife, nurse practitioner, or physician assistant, when in stock in containers correctly
23	labeled with the name and address of the supplier or producer.
24	"Nothing in this section authorizes a certified nurse-midwife, a nurse practitioner, a
25	physician assistant, or a naturopathic doctor, to order his or her own stock of dangerous drugs and
26	devices."
27	

( -

- :

28

#### **REGULATORY PROVISIONS**

ţ

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

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



1

2

3

4

5

6

7

8

9

10

11

12

13

14

15

16

17

18

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

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

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

19

20

21

22

23

24

25

26

27

28

20. California Code of Regulations, title 16, section 1717, subdivision (c), states:

"(c) Promptly upon receipt of an orally transmitted prescription, the pharmacist shall reduce it to writing, and initial it, and identify it as an orally transmitted prescription. If the prescription is then dispensed by another pharmacist, the dispensing pharmacist shall also initial the prescription to identify him or herself. All orally transmitted prescriptions shall be received and transcribed by a pharmacist prior to compounding, filling, dispensing, or furnishing. Chart orders as defined in section 4019 of the Business and Professions Code are not subject to the provisions of this subsection."

21. California Code of Regulations, title 16, section 1718 states: "Current Inventory' as used in Sections 4081 and 4332 of the Business and Professions Code shall be considered to include complete accountability for all dangerous drugs handled by every licensee enumerated in Sections 4081 and 4332. "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." FEDERAL REGULATIONS 22. Code of Federal Regulations, title 21, section 1304.11, states, in pertinent part: "a. General requirements. Each inventory shall contain a complete and accurate record of all controlled substances on hand on the date the inventory is taken, and shall be maintained in written, typewritten, or printed form at the registered location. An inventory taken by use of an oral recording device must be promptly transcribed. Controlled substances shall be deemed to be 'on hand' if they are in the possession of or under the control of the registrant, including substances returned by a customer, ordered by a customer but not yet invoiced, stored in a warehouse on behalf of the registrant, and substances in the possession of employees of the registrant and intended for distribution as complimentary samples. A separate inventory shall be made for each registered location and each independent activity registered, except as provided in paragraph (e)(4) of this section. In the event controlled substances in the possession or under the control of the registrant are stored at a location for which he/she is not registered, the substances shall be included in the inventory of the registered location to which they are subject to control or to which the person possessing the substance is responsible. The inventory may be taken either as of opening of business or as of the close of business on the inventory date and it shall be indicated on the inventory.

 $i > \gamma$ 

í - - ::

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

"b. Initial inventory date. Every person required to keep records shall take an inventory of all stocks of controlled substances on hand on the date he/she first engages in the manufacture, distribution, or dispensing of controlled substances, in accordance with paragraph (e) of this section as applicable. In the event a person commences business with no controlled substances on hand, he/she shall record this fact as the initial inventory.

- 7

"c. Biennial inventory date. After the initial inventory is taken, the registrant shall take a new inventory of all stocks of controlled substances on hand at least every two years. The biennial inventory may be taken on any date which is within two years of the previous biennial inventory date."

ĩ

#### COST RECOVERY

23. Section 125.3 of the Code provides, in pertinent part, that the Board may request the administrative law judge to direct a licentiate found to have committed a violation or violations of the licensing act to pay a sum not to exceed the reasonable costs of the investigation and enforcement of the case, with failure of the licentiate to comply subjecting the license to not being renewed or reinstated. If a case settles, recovery of investigation and enforcement costs may be included in a stipulated settlement.

## 24. DRUG CLASSIFICATIONS

ž

Brand Name(s)	Generic Name	Dangerous Drug Per Bus. & Prof. Code § 4022	Scheduled Drug per Health & Safety Code (HSC)	Indications Fo Use
Klonopin	Clonazepam 2mg	Yes	Schedule IV HSC § 11057(d)(7)	Anxiety
Lorcet, Norco, Vicodin	Hydrocodone/ Acetaminophen (APAP)	Yes	Schedule III per HSC § 11056(e)(4) and Schedule II per 21 CFR 1308 (as of 10/6/14)	Moderate to Severe Pain
Phenergan- Codeine	Promethazine/codeine syrup 10 mg-6.25mg/5ml	Yes	Schedule V Per HSC § 11058(c)(l)	Cough Suppressant
Xanax	Alprazolam (non-barbiturate, benzodiazepine sedative hypnotic)	Yes	Schedule IV per HSC § 11057(d)(1)	Anxiety

1	FIRST CAUSE FOR DISCIPLINE		
2	(Failure to Conduct DEA Biennial Inventory)		
3	25. Respondent Pharmacy, Respondent Nemetalla, and Respondent Basalious are subject		
4	to disciplinary action under section 4301, subdivision (0), in that they violated Code of Federal		
5	Regulations, title 21, section 1304.11 and California Code of Regulations, title 16, section 1718,		
6	by failing to conduct the Drug Enforcement Administration (DEA) biennial inventory of		
7	controlled substances as required. The circumstances are as follows:		
8	26. On or about March 13, 2015, during a Board inspection of Respondent Pharmacy's		
. 9.	facility, located at 14350 Whittier Blvd. #103, Whittier, CA 90605, Respondent Pharmacy was		
10	unable to retrieve the DEA biennial inventory allegedly performed by Respondent Nemetalla,		
11	while he served as Pharmacist-in-Charge.		
12	27. Respondent Basalious failed to indicate on the inventories that she performed on		
13	March 6, 2014, of Schedule II drugs and on June 3, 2014, of Schedule III, IV, and V drugs		
14	whether she conducted the inventory at the open or close of business day as required.		
15	SECOND CAUSE FOR DISCIPLINE		
16	(Failure to Maintain Operational Standards and Security)		
17	28. Respondent Pharmacy, Respondent Nagi Youssef as the owner of Respondent		
18	Pharmacy, and Respondent Basalious are subject to disciplinary action under section 4301,		
19	subdivision (o), for violating California Code of Regulations, title 16, section 1714, subdivisions		
20	(b) and (d), in that they failed to secure the pharmacy to prevent loss of controlled substances.		
21	The circumstances are as follows:		
22	29. Between June 3, 2014, and March 13, 2015, while Respondent Basalious was serving		
23	as the Pharmacist-in-Charge and was responsible for the pharmacy, Respondent Pharmacy could		
24	not account for the following losses of controlled substances:		
25	a. 200 tablets of alprazolam 1 mg,		
26	b. 1188 tablets of alprazolam 2 mg,		
27	c. 155 of clonazepam 2 mg,		
28	d. 106 tablets of hydrocodone/acetaminophen 7.5-325 mg,		
	9 (WHITTIER PLAZA PHARMACY INC., DBA THE PRESCRIPTION SHOP - WHITTIER, ET AL.)		
	(WIIITTIERTEALATIIARMACTINC., DBA THETRESCRITTION SHOT - WIIITTIER, ET AL.) ACCUSATION		

1

[					
1	e. 1825 tablets of hydrocodone/acetaminophen 10-325 mg, and				
2	f. 11922 milliliters (approximately 25 pints/bottles) of promethazine/codeine syrup				
3	10mg-6.25mg/5ml.				
4	THIRD CAUSE FOR DISCIPLINE				
5	(Delivery of Dangerous Drugs)				
6	30. Respondent Pharmacy, Respondent Basalious, and Respondent Nemetalla are subject				
7	to disciplinary action under section 4301, subdivision (j), for violating section 4059.5,				
8,	subdivision (a), in that while Respondent Basalious was serving as Pharmacist-in-Charge,				
9	personnel who were not pharmacists signed for and received dangerous drugs upon delivery. The				
10	circumstances are as follows:				
11	31. Between August 1, 2014, and August 29, 2014, personnel who were not pharmacists				
12	signed for and received delivery of dangerous drugs shipped from Associated Pharmacies Inc., a				
13	drug wholesaler, approximately twenty-four (24) times.				
14	32. On April 5, 2014, August 16, 2014, January 17, 2015, and February 14, 2015, while				
15	Respondent Nemetalla was on duty, personnel who were not pharmacists signed for and received				
16	delivery of dangerous drugs shipped from Cardinal Health, a drug wholesaler.				
17	FOURTH CAUSE FOR DISCIPLINE				
18	(Failure to Initial Orally Transmitted Prescriptions)				
19	33. Respondent Nemetalla is subject to disciplinary action under section 4301,				
20	subdivision (0), for violating California Code of Regulations, title 16, section 1717, subdivision				
21	(c). The circumstances are as follows:				
22	34. Respondent Nemetalla received and transcribed the following orally transmitted				
23	prescriptions without initialing them, as required:				
24	a. Prescription #301042 for M.W. on January 17, 2015.				
25	b. Prescription #302372 for F.H. on February 14, 2015.				
26	c. Prescription #302373 for A.N. on February 14, 2015.				
27					
28					
	10 (WHITTIER PLAZA PHARMACY INC., DBA THE PRESCRIPTION SHOP - WHITTIER, ET AL.)				
	ACCUSATION				

₹ ÷;

i '

#### FIFTH CAUSE FOR DISCIPLINE

Ī

#### (Unlawful Possession of a Controlled Substance)

35. Respondent Perez is subject to disciplinary action under section 4301, subdivision (j), in conjunction with sections 4060, for violating Health and Safety Code section 11350, in that she was in unlawful possession of a controlled substance, namely, promethazine with codeine. The circumstances are as follows:

36. In 2014, while employed at Respondent Pharmacy, Respondent Perez removed two bottles of promethazine with codeine from Respondent Pharmacy without having a prescription for them.

#### **OTHER MATTERS**

37. Pursuant to Code section 4307, if discipline is imposed on Pharmacy Permit Number PHY 44877 issued to Whittier Plaza Pharmacy Inc., dba The Prescription Shop – Whittier shall be prohibited from serving as a manager, administrator, owner, member, officer, director, associate, or partner of a licensee for five years if Pharmacy Permit Number PHY 44877 is placed on probation or until Pharmacy Permit Number PHY 44877 is reinstated if it is revoked.

38. Pursuant to Code section 4307, if discipline is imposed on Pharmacy Permit Number PHY 44877 issued to Whittier Plaza Pharmacy Inc., dba The Prescription Shop – Whittier while Nagi Youssef has been an officer and/or owner and had knowledge of or knowingly participated in any conduct for which the licensee was disciplined, Nagi Youssef shall be prohibited from serving as a manager, administrator, owner, member, officer, director, associate, or partner of a licensee for five years if Pharmacy Permit Number PHY 44877 is placed on probation or until Pharmacy Permit Number PHY 44877 is reinstated if it is revoked.

III

111

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

**PRAYER** 1 WHEREFORE, Complainant requests that a hearing be held on the matters herein alleged, 2 and that following the hearing, the Board of Pharmacy issue a decision: 3 1. Revoking or suspending Pharmacy Permit Number PHY 44877, issued to Whittier 4 Plaza Pharmacy Inc., dba The Prescription Shop - Whittier, 5 6 2. Revoking or suspending Pharmacy Technician Registration No. TCH 30442, issued Nagi Youssef; 7 3. Revoking or suspending Pharmacist License No. RPH 61004, issued to Hanaa 8 Basalious; 9 4. Revoking or suspending Pharmacist License No. RPH 65460, issued to Atef Riad 10 Nemetalla; 11 5. Revoking or suspending Pharmacy Technician Registration No. TCH 75855, issued 12 to Antoinette Perez; 13 6. Prohibiting Whittier Plaza Pharmacy Inc. from serving as a manager, administrator, 14 owner, member, officer, director, associate, or partner of a licensee for five years if Pharmacy 15 Permit Number PHY 44877 is placed on probation or until Pharmacy Permit Number PHY 44877 16 is reinstated if Pharmacy Permit Number 44877 issued to Whittier Plaza Pharmacy Inc., dba The 1718 Prescription Shop – Whittier is revoked; 19 7. Prohibiting Nagi Youssef from serving as a manager, administrator, owner, member, officer, director, associate, or partner of a licensee for five years if Pharmacy Permit Number PHY 20 44877 is placed on probation or until Pharmacy Permit Number PHY 44877 is reinstated if 21 Pharmacy Permit Number PHY 44877 issued to Whittier Plaza Pharmacy Inc., dba The 22 Prescription Shop – Whittier is revoked; 23 8. Ordering Whittier Plaza Pharmacy Inc., dba The Prescription Shop – Whittier, Nagi 24 Youssef, Hanaa Basalious, Atef Riad Nemetalla, and Antoinette Perez to pay the Board of 25 Pharmacy the reasonable costs of the investigation and enforcement of this case, pursuant to 26 Business and Professions Code section 125.3; and, 27 111 28 12

ŧ - :

( · ·:

(WHITTIER PLAZA PHARMACY INC., DBA THE PRESCRIPTION SHOP - WHITTIER, ET AL.) ACCUSATION

Taking such other and further action as deemed necessary and proper. 9. 1 2 .A.J 6/13/16 3. DATED: 4 VIRGINIA HEROLD 5 **Executive Officer** Board of Pharmacy 6 Department of Consumer Affairs State of California 7 Complainant 8 LA2016600056 9 12080667\_3.doc 10 11 12 13 14 15 16 1718 19 20 21 22 23 24 25 26 27 :28 13 (WHITTIER PLAZA PHARMACY INC., DBA THE PRESCRIPTION SHOP - WHITTIER, ET AL.) ACCUSATION

¢.....