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

In the Matter of the Accusation Against: **111 Pharmacy** 111 W. Beverly Blvd, Ste. B Montebello, CA 90640 BOO NAM SHIN, Pharmacist-In-Charge **Original Permit No. PHY 41023** **BOO NAM SHIN** 15909 Atitlan Dr. Hacienda Heights, CA 91745 **Original Pharmacist License No. RPH 42592** Respondents.	Case No. 5526 **A C C U S A T I O N**

Complainant alleges:

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 August 8, 1995, the Board of Pharmacy issued Original Permit Number PHY 41023 to 111 Pharmacy with Boo Nam Shin as the individual licensed owner and Pharmacist-In-Charge ("Respondent Pharmacy"). The Permit was in full force and effect at all times relevant to the charges brought herein, expired on June 23, 2015, and has been canceled.

3. On or about July 6, 1989, the Board of Pharmacy issued Original Pharmacist License Number RPH 42592 to Boo Nam Shin ("Respondent Shin"). The Original Pharmacist License was in full force and effect at all times relevant to the charges brought herein and will expire on August 31, 2016, unless renewed.

JURISDICTION

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

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

6. 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

7. Section 4022 states

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

"(a) Any drug that bears the legend: "Caution: federal law prohibits dispensing without prescription," "Rx only," or words of similar import.

"(b) Any device that bears the statement: "Caution: federal law restricts this device to sale by or on the order of a _____," "Rx only," or words of similar import, the blank to be filled in with the designation of the practitioner licensed to use or order use of the device.

"(c) Any other drug or device that by federal or state law can be lawfully dispensed only on prescription or furnished pursuant to Section 4006."

8. Section 4036.5 states: "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."

9. Section 4301 states:

"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:

....

"(d) The clearly excessive furnishing of controlled substances in violation of subdivision (a) of Section 11153 of the Health and Safety Code.

....

"(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."

10. Health and Safety Code Section 11153 states, in pertinent part:

"(a) A prescription for a controlled substance shall only be issued for a legitimate medical purpose by an individual practitioner acting in the usual course of his or her professional practice. The responsibility for the proper prescribing and dispensing of controlled substances is upon the prescribing practitioner, but a corresponding responsibility rests with the pharmacist who fills the prescription. Except as authorized by this division, the following are not legal prescriptions: (1) an order purporting to be a prescription which is issued not in the usual course of professional treatment or in legitimate and authorized research; or (2) an order for an addict or habitual user of controlled substances, which is issued not in the course of professional treatment or as part of an

authorized narcotic treatment program, for the purpose of providing the user with controlled substances, sufficient to keep him or her comfortable by maintaining customary use."

REGULATORY PROVISION

11. California Code of Regulations, title 16, section 1761, states:

"(a) No pharmacist shall compound or dispense any prescription which contains any significant error, omission, irregularity, uncertainty, ambiguity or alteration. Upon receipt of any such prescription, the pharmacist shall contact the prescriber to obtain the information needed to validate the prescription.

"(b) Even after conferring with the prescriber, a pharmacist shall not compound or dispense a controlled substance prescription where the pharmacist knows or has objective reason to know that said prescription was not issued for a legitimate medical purpose."

COST RECOVERY

12. Section 125.3 states, 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.

CONTROLLED SUBSTANCES AND DANGEROUS DRUGS

13. Oxycodone is a Schedule II controlled substance pursuant to Health and Safety Code section 11055, subdivision (b)(1)(M), and a dangerous drug pursuant to Business and Professions Code section 4022.

14. Alprazolam is a Schedule IV controlled substance pursuant to Health and Safety Code section 11057, subdivision (d)(1), and a dangerous drug pursuant to Business and Professions Code section 4022.

15. Norco, a combination product containing the controlled substance hydrocodone and non-narcotic acetaminophen, is a Schedule III controlled substance pursuant to Health and Safety Code section 11056, subdivision (e)(4), and a dangerous drug pursuant to Business and Professions Code section 4022.

16. Promethazine with codeine syrup is a Schedule V controlled substance pursuant to Health and Safety Code section 11058, subdivision (c)(1), and a dangerous drug pursuant to Business and Professions Code section 4022.

17. Carisoprodol is a Schedule IV controlled substance pursuant to Code of Federal Regulations, title 21, section 1308.14, subdivision (c)(6), and a dangerous drug pursuant to Business and Professions Code section 4022.

FACTUAL BACKGROUND

18. On or about January 5, 2015, Board Inspectors conducted an inspection of Respondent Pharmacy following reports that a doctor had written illegal prescriptions and investigation into that doctor revealed some of the prescriptions had been filled at Respondent Pharmacy. The Board Inspectors received electronic dispensing data for five doctors from January 1, 2011, through December 31, 2014: Dr. A.S., Dr. C.A., Dr. W.E., Dr. D.W., and Dr. S.K. The Board Inspectors also reviewed hard copies of prescriptions at Respondent Pharmacy, drug delivery invoices to Respondent Pharmacy, Respondent Pharmacy's electronic computer records of dispensed prescriptions, and CURES[1] data, among other documents.

19. The Board Inspectors' review identified factors of irregularity or red flags consistent with illegitimate doctor prescribing and indiscriminate pharmacy dispensing. These red flags included patients paying for the vast majority of reviewed prescriptions with cash (thus receiving no financial assistance from insurance), a uniformity in prescriptions for multiple patients, requests for early refills of prescriptions, and initial prescriptions written for strong dosages of opiates (in contrast to an initial prescription at a lower dose, which is slowly raised to a higher dose.) These red flags either gave, or should have given, Respondent Pharmacy and Respondent Shin sufficient

[1] Controlled Substance Utilization Review and Evaluation System, or CURES, is a database that contains over 100 million entries of controlled substance drugs that were dispensed in California. CURES is part of program developed by the California Department of Justice and Bureau of Narcotic Enforcement, which allows access to the Prescription Drug Monitoring Program (PDMP) system. The PDMP allows pre-registered users including licensed healthcare prescribers eligible to prescribe controlled substances, pharmacists authorized to dispense controlled substances, law enforcement and regulatory boards to access patient controlled substance history information. (http://oag.ca.gov/cures-pdmp)

information to identify potential problems with the prescriptions, and put them on notice to conduct further inquiries into the legitimacy of the prescriptions.

FIRST CAUSE FOR DISCIPLINE

(Filling Erroneous Prescriptions and Failure to Assume Corresponding Responsibility in Legitimacy of Prescriptions)

A. "Doctor Shoppers"[2]

20. Respondent Pharmacy and Respondent Shin (collectively, "Respondents") are subject to disciplinary action under section 4301, subdivisions (d), (j), and (o), in conjunction with Health and Safety Code section 11153, subdivision (a), and California Code of Regulations, title 16, section 1761, in that Respondents failed to comply with their corresponding responsibility to only fill medically legitimate prescriptions by dispensing controlled substances to "doctor shoppers," by failing to validate the legitimacy of prescriptions, by failing to review patients' drug history, and by dispensing erroneous/uncertain prescriptions. The circumstances include the presence of multiple red flags for irregular prescriptions coming from both the statistics of individual prescribing doctors and from patients who sought early refills.

21. The circumstances regarding the red flags and irregular prescriptions originating from specific prescribing doctors are as follows:

Dr. A.S.

a. Respondent Pharmacy dispensed 5,534 prescriptions written by Dr. A.S. for 501 unique patients. 5,484, or 99.06%, of these prescriptions were for controlled substances. 5,519, or 99.73%, of the prescriptions were paid with cash and no insurance was utilized. Both a prescribing profile consisting primarily of controlled substances and a profile showing nearly uniform cash payments are red flags of improper prescriptions.

b. The majority of Dr. A.S.' patients received a uniform combination of hydrocodone 10/325 mg, alprazolam 2 mg and promethazine with codeine syrup. All of these drugs are recognized as drugs of potential abuse individually. The medications are also from different

[2] The phrase "doctor shopper" refers to a patient that seeks out multiple doctors in order to obtain multiple prescriptions of drugs.

classes of drugs so it would be unlikely that most of Dr. A.S.' patients suffered from the same ailments necessitating the same combination of controlled substances.

c. Promethazine with codeine syrup should be used for the temporary relief of coughs and upper respiratory symptoms. The maximum suggested volume of medication per day of use is 30 milliliters, the dosage should not be increased if the cough fails to respond, and a cough that is unresponsive after five (5) days should be re-evaluated. Thus the total amount of promethazine with codeine syrup dispensed to a patient should not be dramatically more than 150 ml. Yet, the majority of promethazine with codeine prescriptions dispensed by Respondents were for 473 ml. Several patients were also dispensed 1 pint of promethazine with codeine for several months of treatment, with one patient receiving the promethazine with codeine for 11 consecutive months.

d. The second most frequent prescription written by Dr. A.S., and dispensed by Respondents by percentage was hydrocodone / acetaminophen 10/325 mg. The medication treats pain and Dr. A.S. did not self report as a pain management physician. A Family Medicine / General Practitioner prescribing pain medication at a high percentage is another red flag.

Dr. C.A.

e. Respondent Pharmacy dispensed 693 prescriptions written by Dr. C.A. for 160 unique patients. 649, or 93.94%, of these prescriptions were for controlled substances. 100% of the prescriptions were paid for with cash.

f. The majority of Dr. C.A.'s patients received oxycodone 30 mg, promethazine with codeine syrup, alprazolam 2 mg and carisoprodol either alone or in combination. All of these drugs are recognized as drugs of potential abuse individually. The medications are also from different classes of drugs so it would be unlikely that most of Dr. C.A.'s patients suffered from the same ailments necessitating the same combination of controlled substances.

g. Oxycodone is manufactured in varying doses of 5, 10, 15, 20, and 30 mg. Alprazolam is manufactured in varying doses of 0.25, 0.5, 1 and 2 mg. For each medication Dr. C.A.'s prescribing pattern showed no variation from the highest tablet strength possible.

h. Promethazine with codeine syrup was the prescription most frequently written by Dr. C.A. and dispensed by Respondents. Patients suffering from an infection often develop cough

symptoms so it is common to see a prescription written for an antibiotic and promethazine with codeine simultaneously. Respondent Pharmacy dispensed 234 prescriptions for promethazine with codeine written by Dr. C.A. Respondent Pharmacy dispensed only 12 prescriptions for an antibiotic within the same time period.

Dr. W.E.

i. Respondent Pharmacy dispensed 486 prescriptions written by Dr. W.E. for 54 unique patients. 477, or 98.15%, of these prescriptions were for controlled substances. 100% of the prescriptions were paid with cash and no insurance was utilized.

j. Between August 2012 and February 2013, the vast majority of Dr. W.E.'s patients received a combination of hydrocodone/acetaminophen products, alprazolam 2 mg, carisoprodol and promethazine with codeine syrup. All of these drugs are recognized as drugs of potential abuse individually. The medications are also from different classes of drugs so it would be unlikely that most of Dr. W.E.'s patients suffered from the same ailments necessitating the same combination of controlled substances.

k. Promethazine with codeine syrup is to be used for the temporary relief of coughs and upper respiratory symptoms. The maximum suggested volume of medication per day of use is 30 ml, the dosage should not be increased if the cough fails to respond, and a cough that is unresponsive after five (5) days should be re-evaluated. Thus the total amount dispensed to a patient should not be dramatically more than 150 ml. Yet, 100% of promethazine with codeine prescriptions dispensed by Respondents were for 473 ml.

l. Patients are also commonly written a prescription for an antibiotic simultaneously with promethazine with codeine. Although Dr. W.E.'s prescribing profile included 9 instances of prescribing an antibiotic, none of the patients receiving an antibiotic received it concurrently with a prescription for promethazine with codeine.

m. Prescription statistics indicated that multiple patients came to the pharmacy simultaneously to obtain similar cocktails of drugs. Several sequential prescription numbers showed the same drug cocktail and sometimes the same address for several different patients.

Both issuing sequential prescriptions for the same controlled substance and issuing the same prescription to multiple patients at the same address are red flags.

Dr. S.K.

n. Respondent Pharmacy dispensed 29 prescriptions written by Dr. S.K., or forged using Dr. S.K.'s information, for 19 unique patients. 100% of the dispensed prescriptions were for a controlled substance. 100% of the prescriptions were paid with cash and no insurance was utilized.

o. Oxycodone is manufactured in varying doses of 5, 10, 15, 20, and 30 mg. 24 of the 29 prescriptions written by Dr. S.K. and dispensed by Respondent Pharmacy were for oxycodone 30 mg. Each patient receiving oxycodone received the highest tablet strength possible.

Dr. D.W.

p. Respondent Pharmacy dispensed 291 prescriptions written by Dr. D.W. for 47 unique patients. 99.31% of the prescriptions were paid with cash and no insurance was utilized.

q. Oxycodone 30 mg was the prescription most frequently written by Dr. D.W. and dispensed by Respondents. Each patient receiving oxycodone received the highest tablet strength possible without any evidence of the patient first receiving lower doses of the controlled substance.

r. The primary practice area of Dr. D.W. is Cardiology. Only 6 out of 291 prescriptions written by Dr. D.W. and dispensed by Respondents may have been for a condition related to Cardiology. The majority of controlled dispensed were used to treat pain.

s. While a secondary are of practice for Dr. D.W. is pain, prescribing patterns for pain specialists typically contain medications for neuropathic pain and anti-inflammatory drugs in addition to muscle relaxants and opioid agonists. The dispensing record for Dr. D.W. showed only 5 prescriptions that may be used to treat neuropathic pain and 1 prescription that treats inflammation.

B. Controlled Substance Prescriptions Filled Too Early

22. Respondents also failed to assume corresponding responsibility in dispensing controlled substances by filling a large number of controlled substance prescriptions early or too soon. These controlled substance prescriptions were filled more than five days before a

prescription is scheduled to expire, and exceeds the time period in Respondent Shin's statement to Board Investigators that he allowed a three to four day grace period. The circumstances regarding early refills includes the following patients:

a. Patient B.W.: The Patient Activity Report ("PAR") showed that B.W. used 7 different prescribers and 7 different pharmacies, including Respondent Pharmacy, to obtain 12 early refills of H/APAP or alprazolam between January 2011 and June 2012. B.W. also primarily used cash payments and for his entire patient profile used 16 different prescribers and 19 different pharmacies to obtain controlled substances.

b. Patient D.W.: The PAR showed that D.W. obtained an early refill of alprazolam from Respondent Pharmacy only eight days after he had received a 90 day supply of alprazolam.

c. Patient P.W.: The PAR showed that P.W. used 2 different prescribers and 4 different pharmacies, including Respondent Pharmacy, to obtain 7 early refills of H/APAP or alprazolam between October 2011 and March 2012. P.W. primarily made cash payments and for his entire patient profile used 7 different prescribers and 9 different pharmacies to obtain controlled substances.

d. Patient L.T.: The PAR showed that L.T. used 4 different prescribers and 5 different pharmacies, including Respondent Pharmacy, to obtain 3 early refills of oxycodone between July 2011 and March 2014. L.T. primarily made cash payments and for her entire patient profile used 8 different prescribers and 14 different pharmacies to obtain controlled substances.

e. Patient C.S.: The PAR showed that C.S. obtained an early refill of H/APAP from Respondent Pharmacy only two days after he had received a 13 day supply of the controlled substance. C.S.' entire patient profile also indicated that he used 8 different prescribers and 8 different pharmacies to obtain controlled substances.

f. Patient G.H.: The PAR showed that G.H. used 6 different prescribers and 8 different pharmacies, including Respondent Pharmacy, to obtain 13 early refills of H/APAP or carisoprodol between August 2011 and September 2013. G.H. switched between using insurance and paying cash for the controlled substances and for her entire patient profile used 12 different prescribers and 16 different pharmacies to obtain controlled substances.

SECOND CAUSE FOR DISCIPLINE

(Excessive Furnishing of Controlled Substances)

23. Respondents are subject to disciplinary action under section 4301, subdivisions (d), (j), and (o), in conjunction with Health and Safety Code section 11153, subdivision (a), in that Respondents engaged in the clearly excessive furnishing of controlled substances, suggesting a level of specificity from patients when choosing what pharmacy to use when filling specific controlled substances, as follows:

a. Respondent Pharmacy dispensed 77,385 tablets of oxycodone 30 mg between January 3, 2011, and April 4, 2014, whereas a CVS pharmacy 0.9 miles away dispensed 270 tablets of the controlled substance at that strength, a Rite Aid pharmacy 0.6 miles away dispensed 300 tablets, Montebello Professional pharmacy 0.6 miles away dispensed 4,380 tablets and Beverly Professional pharmacy 0.2 miles away dispensed 0 tablets during this time period.

b. Respondent Pharmacy dispensed 320,636 tablets of hydrocodone acetaminophen 10/325 between January 3, 2011, and April 4, 2014, whereas a CVS pharmacy 0.9 miles away dispensed 107,744 tablets of the controlled substance at that strength, a Rite Aid pharmacy 0.6 miles away dispensed 91,8177 tablets, Montebello Professional pharmacy 0.6 miles away dispensed 8,665 tablets and Beverly Professional pharmacy 0.2 miles away dispensed 10,766 tablets during this time period.

c. Respondent Pharmacy dispensed 124,975 tablets of carisoprodol 350 between January 3, 2011, and April 4, 2014, whereas a CVS pharmacy 0.9 miles away dispensed 22,818 tablets of the controlled substance at that strength, a Rite Aid pharmacy 0.6 miles away dispensed 40,726 tablets, Montebello Professional pharmacy 0.6 miles away dispensed 1,912 tablets and Beverly Professional pharmacy 0.2 miles away dispensed 6,293 tablets during this time period.

d. Respondent Pharmacy dispensed 177,344 tablets of alprazolam 2 mg between January 3, 2011, and April 4, 2014, whereas a CVS pharmacy 0.9 miles away dispensed 6,624 tablets of the controlled substance at that strength, a Rite Aid pharmacy 0.6 miles away dispensed 8,388 tablets, Montebello Professional pharmacy 0.6 miles away dispensed 3,770 tablets and Beverly Professional pharmacy 0.2 miles away dispensed 0 tablets during this time period.

DISCIPLINARY CONSIDERATIONS

24. To determine the degree of discipline, if any, to be imposed on Respondents, Complainant alleges the following:

a. On or about June 5, 2012, the Board of Pharmacy issued Respondent Pharmacy Citation Number CI 2010 48804, with no associated fine. Respondent Pharmacy complied with the citation and it is final. The citation alleged that from March 2011 through October 2011, Respondent Pharmacy transmitted CURES data to the Department of Justice on a monthly basis instead of a weekly basis as required by Health and Safety Code section 11165, subdivision (d).

b. On or about June 5, 2012, the Board of Pharmacy issued Respondent Shin Citation Number CI 2011 52649, with no associated fine. Respondent Shin complied with the citation and it is final. The citation alleged that from March 2011 through October 2011, Respondent Shin transmitted CURES data to the Department of Justice on a monthly basis instead of a weekly basis as required by Health and Safety Code section 11165, subdivision (d).

PRAYER

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

1. Revoking or suspending Original Permit Number PHY 41023, issued to 111 Pharmacy with Boo Nam Shin as the individual licensed owner and Pharmacist-In-Charge;

2. Revoking or suspending Original Pharmacist License Number RPH 42592 issued to Boo Nam Shin;

3. Ordering 111 Pharmacy and Boo Nam Shin to pay the Board of Pharmacy the reasonable costs of the investigation and enforcement of this case, pursuant to Business and Professions Code section 125.3; and,

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

DATED: 2/20/16

VIRGINIA HEROLD
Executive Officer
Board of Pharmacy
Department of Consumer Affairs
State of California
Complainant

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