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

In the Matter of the Accusation Against: **UNICARE PHARMACY, INC. DBA MEDICORX SPECIALTY** **7039 Valjean Avenue** **Van Nuys, CA 91406** **Original Permit No. PHY 50336,** **VLADIMIR LENCHITSKY** **3514 Cody Road** **Sherman Oaks, CA 91403** **Pharmacist License No. RPH 51484,** **and** **MICHAEL J. STERLING** **7039 Valjean Avenue** **Van Nuys, CA 91406** **Pharmacist License No. RPH 36628** Respondents.	Case No. 5622 **ACCUSATION**

Complainant alleges:

PARTIES

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

2. On July 14, 2010, the Board of Pharmacy issued Original Permit Number PHY 50336 to Unicare Pharmacy, Inc. dba Medicorx Specialty. Vladimir Lenchitsky owns 60% of the corporation's shares and is its President. He was also its Pharmacist-in-Charge from July 14, 2010 to September 23, 2013. Sofia Kravchinsky owns 40% of its shares and is its Vice President. From September 23, 2013 to the present, Michael Sterling has been its Pharmacist-in-Charge. Unicare Pharmacy, Inc's permit was in force at all times alleged in this Accusation will expire on July 1, 2016, unless renewed.

3. On or about March 28, 2000, the Board of Pharmacy issued Pharmacist License Number RPH 51484 to Vladimir Lenchitsky. The license was in force and at all times alleged in this Accusation and will expire on February 29, 2018, unless renewed.

4. On or about August 20, 1981, the Board of Pharmacy issued Pharmacist License Number RPH 36628 to Michael J. Sterling (Respondents). The license was in force and at all times alleged in this Accusation and will expire on March 31, 2017, unless renewed.

JURISDICTION

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

6. In relevant part, section 4300 authorizes the Board to discipline license holders:

> (a) Every license issued may be suspended or revoked.
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> (b) The board shall discipline the holder of any license issued by the board, whose default has been entered or whose case has been heard by the board and found guilty, by any of the following methods:
>
> (1) Suspending judgment.
>
> (2) Placing him or her upon probation.
>
> (3) Suspending his or her right to practice for a period not exceeding one year.
>
> (4) Revoking his or her license.
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> (5) Taking any other action in relation to disciplining him or her as the board in its discretion may deem proper.
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> . . .
>
> (e) The proceedings under this article shall be conducted in accordance with Chapter 5 (commencing with Section 11500) of Part 1 of Division 3 of the Government Code, and the board shall have all the powers granted therein. The action

shall be final, except that the propriety of the action is subject to review by the superior court pursuant to Section 1094.5 of the Code of Civil Procedure.

BUSINESS AND PROFESSIONS CODE STATUTES

7. Section 4022 defines dangerous drugs:

'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 defines "pharmacist-in-charge":

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 4076 mandates proper labeling:

(a) A pharmacist shall not dispense any prescription except in a container that meets the requirements of state and federal law and is correctly labeled with all of the following:

(1) Except where the prescriber or the certified nurse-midwife who functions pursuant to a standardized procedure or protocol described in Section 2746.51, the nurse practitioner who functions pursuant to a standardized procedure described in Section 2836.1, or protocol, or the physician assistant who functions pursuant to Section 3502.1, the naturopathic doctor who functions pursuant to a standardized procedure or protocol described in Section 3640.5, or the pharmacist who functions pursuant to a policy, procedure, or protocol pursuant to either subparagraph (D) of paragraph (4) of, or clause (iv) of subparagraph (A) of paragraph (5) of, subdivision (a) of Section 4052 orders otherwise, either the manufacturer's trade name of the drug or the generic name and the name of the manufacturer. Commonly used abbreviations may be used. Preparations containing two or more active ingredients may be identified by the manufacturer's trade name or the commonly used name or the principal active ingredients.

(2) The directions for the use of the drug.

(3) The name of the patient or patients.

(4) The name of the prescriber or, if applicable, the name of certified nurse-midwife who functions pursuant to a standardized procedure or protocol described in Section 2746.51, the nurse practitioner who functions pursuant to a standardized procedure described in Section 2836.1, or protocol, the physician assistant who functions pursuant to Section 3502.1., the naturopathic doctor who

functions pursuant to a standardized procedure or protocol described in Section 3640.5, or the pharmacist who functions pursuant to a policy, procedure, or protocol pursuant to either subparagraph (D) of paragraph (4) of, or clause (iv) of subparagraph (A) of paragraph (5) of, subdivision (a) of Section 4052.

(5) The date of issue.

(6) The name and address of the pharmacy, and prescription number or other means of identifying the prescription.

(7) The strength of the drug or drugs dispensed.

(8) The quantity of the drug or drugs dispensed.

(9) The expiration date of the effectiveness of the drug dispensed.

(10) The condition for which the drug was prescribed if requested by the patient and the condition is indicated on the prescription.

(11)(A) Commencing January 1, 2006, the physical description of the dispensed medication, including its color, shape, and any identification code that appears on the tablets or capsules, except as follows:

(i) Prescriptions dispensed by a veterinarian.

(ii) An exemption from the requirements of this paragraph shall be granted to a new drug for the first 120 days that the drug is on the market and for the 90 days during which the national reference file has no description on file.

(iii) Dispensed medications for which no physical description exists in any commercially available database.

(B) This paragraph applies to outpatient pharmacies only.

(C) The information required by this paragraph may be printed on an auxiliary label that is affixed to the prescription container.

(D) This paragraph shall not become operative if the board, prior to January 1, 2006, adopts regulations that mandate the same labeling requirements set forth in this paragraph.

(b) If a pharmacist dispenses a prescribed drug by means of a unit dose medication system, as defined by administrative regulation, for a patient in a skilled nursing, intermediate care, or other health care facility, the requirements of this section will be satisfied if the unit dose medication system contains the aforementioned information or the information is otherwise readily available at the time of drug administration.

(c) If a pharmacist dispenses a dangerous drug or device in a facility licensed pursuant to Section 1250 of the Health and Safety Code, it is not necessary to include on individual unit dose containers for a specific patient, the name of the certified nurse-midwife who functions pursuant to a standardized procedure or protocol described in Section 2746.51, the nurse practitioner who functions pursuant to a standardized procedure described in Section 2836.1, the physician assistant who functions pursuant to Section 3502.1, the naturopathic doctor who functions pursuant to a standardized procedure or protocol described in Section 3640.5, or the pharmacist who functions pursuant to a policy, procedure, or protocol pursuant to either subparagraph (D) of paragraph (4) of, or clause (iv) of subparagraph (A) of paragraph (5) of, subdivision (a) of Section 4052,

(d) If a pharmacist dispenses a prescription drug for use in a facility licensed pursuant to Section 1250 of the Health and Safety Code, it is not necessary to include the information required in paragraph (11) of subdivision (a) when the prescription drug is administered to a patient by a person licensed under the Medical

Practice Act (Chapter 5 (commencing with Section 2000), the Nursing Practice Act (Chapter 6 (commencing with Section 2700), or the Vocational Nursing Act (Chapter 6.5 (commencing with Section 2840), who is acting within his or her scope of practice."

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

11. In relevant part, section 4301 authorizes disciplinary action for certain misconduct:

> The board shall take action against any holder of a license who is guilty of unprofessional conduct or whose license has been procured by fraud or misrepresentation or issued by mistake. Unprofessional conduct shall include, but is not limited to, any of the following:
>
> . . .
>
> (j) The violation of any of the statutes of this state, of any other state, or of the United States regulating controlled substances and dangerous drugs.
>
> . . .
>
> (o) Violating or attempting to violate, directly or indirectly, or assisting in or abetting the violation of or conspiring to violate any provision or term of this chapter or of the applicable federal and state laws and regulations governing pharmacy, including regulations established by the board or by any other state or federal regulatory agency.

HEALTH AND SAFETY CODE STATUTES

12. In relevant part, section 4169 imposes restrictions on the selling of misbranded dangerous drugs:

> (a) A person or entity shall not do any of the following:
>
> . . .
>
> (3) Purchase, trade, sell, or transfer dangerous drugs that the person knew or reasonably should have known were misbranded, as defined in Section 111335 of the Health and Safety Code.

13. Health and Safety Code section 111340 is one of several statutes specifying when a drug is misbranded:

> Any drug or device is misbranded unless it bears a label containing all of the following information:
>
> (a) The name and place of business of the manufacturer, packer, or distributor.
>
> (b) An accurate statement of the quantity of the contents in terms of weight, measure, or numerical count.

Reasonable variations from the requirements of subdivision (b) shall be permitted. Requirements for placement and prominence of the information and exemptions as to small packages shall be established in accordance with regulations adopted pursuant to Section 110380.

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

BOARD OF PHARMACY REGULATIONS

15. California Code of Regulations, title 16, section 1717, sets standards for pharmacy practice:

(a) No medication shall be dispensed on prescription except in a new container which conforms with standards established in the official compendia.

Notwithstanding the above, a pharmacist may dispense and refill a prescription for non-liquid oral products in a clean multiple-drug patient medication package (patient med pak), provided:

(1) a patient med pak is reused only for the same patient;

(2) no more than a one-month supply is dispensed at one time; and

(3) each patient med pak bears an auxiliary label which reads, store in a cool, dry place.

(b) In addition to the requirements of Section 4040, Business and Professions Code, the following information shall be maintained for each prescription on file and shall be readily retrievable:

(1) The date dispensed, and the name or initials of the dispensing pharmacist. All prescriptions filled or refilled by an intern pharmacist must also be initialed by the supervising pharmacist before they are dispensed.

(2) The brand name of the drug or device; or if a generic drug or device is dispensed, the distributor's name which appears on the commercial package label; and

(3) If a prescription for a drug or device is refilled, a record of each refill, quantity dispensed, if different, and the initials or name of the dispensing pharmacist.

(4) A new prescription must be created if there is a change in the drug, strength, prescriber or directions for use, unless a complete record of all such changes is otherwise maintained.

(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.

(d) A pharmacist may furnish a drug or device pursuant to a written or oral order from a prescriber licensed in a State other than California in accordance with Business and Professions Code Section 4005.

(e) A pharmacist may transfer a prescription for Schedule III, IV, or V

controlled substances to another pharmacy for refill purposes in accordance with Title 21, Code of Federal Regulations, section 1306.26.

Prescriptions for other dangerous drugs which are not controlled substances may also be transferred by direct communication between pharmacists or by the receiving pharmacist's access to prescriptions or electronic files that have been created or verified by a pharmacist at the transferring pharmacy. The receiving pharmacist shall create a written prescription; identifying it as a transferred prescription; and record the date of transfer and the original prescription number. When a prescription transfer is accomplished via direct access by the receiving pharmacist, the receiving pharmacist shall notify the transferring pharmacy of the transfer. A pharmacist at the transferring pharmacy shall then assure that there is a record of the prescription as having been transferred, and the date of transfer. Each pharmacy shall maintain inventory accountability and pharmacist accountability and dispense in accordance with the provisions of section 1716 of this Division. Information maintained by each pharmacy shall at least include:

(1) Identification of pharmacist(s) transferring information;

(2) Name and identification code or address of the pharmacy from which the prescription was received or to which the prescription was transferred, as appropriate;

(3) Original date and last dispensing date;

(4) Number of refills and date originally authorized;

(5) Number of refills remaining but not dispensed;

(6) Number of refills transferred.

(f) The pharmacy must have written procedures that identify each individual pharmacist responsible for the filling of a prescription and a corresponding entry of information into an automated data processing system, or a manual record system, and the pharmacist shall create in his/her handwriting or through hand-initializing a record of such filling, not later than the beginning of the pharmacy's next operating day. Such record shall be maintained for at least three years.

COST RECOVERY

16. Section 125.3 authorizes the Board to ask an administrative law judge to direct licensees found to have violated licensing acts to pay their case's reasonable investigation and enforcement costs.

CAUSE FOR DISCIPLINE

(Against All Respondents)

(Misbranded Medications)

17. Respondents Unicare Pharmacy, Inc., Michael Sterling, and Vladimir Lenchitsky are subject to disciplinary action under section 4301 subdivision (o) for violating Health and Safety Code section 111440 in conjunction with Health and Safety Code section 111340 subdivision (b) by holding numerous misbranded drugs at the pharmacy.

18. Complainant realleges paragraphs 2 through 4.

19. On March 10 and March 11, 2015, Board investigators inspected Unicare Pharmacy, Inc.'s pharmacy at 7039 Valjean Avenue in Van Nuys, California.

20. During their inspection, on the pharmacy's shelves they found medication stock bottles with more pills than their labels indicated.

21. When asked about this, Vladimir Lenchitsky explained that on occasion pharmacy technicians would combine bottles of the same medication, strength, manufacturer, lot number and expiration date to manage large number of bottles accumulated on the active medication shelves.

22. The table below, with one exception, shows the medication stock bottles the inspectors found at the pharmacy that contained more tablets or capsules than they should have. All of the medications listed are dangerous drugs under Business and Professions Code section 4022 because they can be dispensed only with a prescription. None of them are controlled substances. Each of these were found in their original manufacturer's container.

Brand Name	Generic Name	Quantity in Original Manufacturer's Container	Quantity Found at Pharmacy
Plavix 75mg	clopidogrel	90 tablets	125 tablets
Fanapt 2mg	iloperidone	60 tablets	75 tablets
Cymbalta 60mg	duloxetine	30 capsules	57 tablets
Rapaflo 4mg	silodosin	30 capsules	109 capsules
Tindamax 500 mg	tinidazole	20 tablets	43 tablets
Dexilant 30mg	dexlansoprazole	30 capsules	44 capsules
Abilify 15mg	aripiprazole	30 tablets	29 half-tablets
Cymbalta 60mg	duloxetine	30 capsules	54 capsules
Geodon 80mg	ziprasidone	60 capsules	88 capsules
Geodon 60mg	ziprasidone	60 capsules	93 capsules
Dexilant 30mg	dexlansoprazole	30 capsules	52 capsules
Januvia 100mg	sitagliptin	90 tablets	53 whole tablets and 64 half-tablets
Diovan HCT 80/12.5mg	valsartan/hctz	90 tablets	165 tablets

Fanapt 10mg	iloperidone	60 tablets	79 tablets
Coumadin 7.5mg	warfarin	100 tablets	152 tablets
Brintellix 5mg	vortioxetine	30 tablets	76 tablets
Latuda 40mg	lurasidone	30 tablets	85 tablets
Benicar 5mg	olmesartan	30 tablets	64 tablets
Geodon 80mg	ziprasidone	60 capsules	66 capsules
Geodon 20mg	ziprasidone	60 capsules	99 capsules
Aricept 23mg	donepezil	30 tablets	118 tablets
Sensipar 90mg	cinacalcet	30 tablets	60 tablets
Prandin 2mg	repaglinide	100 tablets	186 tablets
Prandin 1mg	repaglinide	100 tablets	110 tablets

23. As noted in the table, the bottles of Ability and Januvia contained half-tablets, tablets that someone had cut in half.

24. In addition, the inspectors found a bottle of the brand name drug Zocor, whose generic name is simvastatin, that was not in the original manufacturer's bottle, but instead was in a bottle with another pharmacy's label upon it.

25. The bottles listed in the table did not have an accurate statement of the quantity of their contents in terms of numerical count, in violation of Health and Safety Code section 111340 subdivision (b).

26. The bottles of Ability and Januvia that contained half-tablets also did not have an accurate statement of the weight of those half-tablets, also in violation of Health and Safety Code section 111340 subdivision (b).

27. The pharmacy's variations from the requirements of section 111340 subdivision (b) were not reasonable.

28. Respondent Vladimir Lenchitsky was aware of or participated in the stocking of these medications.

29. Respondent Michael Sterling was aware of the stocking of these medications. Furthermore, as the pharmacist-in-charge he is strictly or vicariously liable or both for the actions of the pharmacy or its pharmacists or pharmacy technicians.

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DISCIPLINARY CONSIDERATIONS

30. To determine the degree of discipline, if any, to be imposed on Respondent Vladimir Lenchitsky, Complainant alleges that on or about August 23, 2012, in a prior action, the Board of Pharmacy issued Citation Number CI 2012 53625 fining Mr. Lenchitsky $1,000 for failing to maintain accurate records of schedule II controlled substance prescriptions, for failing to label drug canisters with the expiration date of the drug inside, and for failing to keep records of the date or quantity of schedule II controlled substances received. That Citation is now final and is incorporated by reference as if fully set forth.

31. To determine the degree of discipline, if any, to be imposed on Respondent Vladimir Lenchitsky, Complainant alleges that on or about July 1, 2013, in a prior action, the Board of Pharmacy issued Citation Number CI 2012 55139 fining Mr. Lenchitsky $1,000 for a May 2013 driving under the influence conviction. That Citation is now final and is incorporated by reference as if fully set forth.

32. To determine the degree of discipline, if any, to be imposed on Respondent Michael J. Sterling, Complainant alleges that on or about June 7, 2014, in a prior action, the Board of Pharmacy issued Citation Number CI 2013 62487 fining Mr. Sterling $750 for incorrectly dispensing the wrong medication to a patient. That Citation is now final and is incorporated by reference as if fully set forth.

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 50336, issued to Unicare Pharmacy, Inc. dba Medicorx Specialty;

2. Revoking or suspending Pharmacist License Number RPH 51484, issued to Vladimir Lenchitsky;

3. Revoking or suspending Pharmacist License Number RPH 36628, issued to Michael J. Sterling;

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4. Ordering Medicorx Specialty, Vladimir Lenchitsky and Michael J. Sterling 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

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

DATED: 3/11/16

Virginia Herold

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

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