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8
9 **BEFORE THE**
BOARD OF PHARMACY
10 **DEPARTMENT OF CONSUMER AFFAIRS**
STATE OF CALIFORNIA

11 In the Matter of the Accusation Against:

Case No. 5117

12 **ROCHESTER ENTERPRISES INC.**
13 **2061 Business Center Drive, Ste. 204**
14 **Irvine, CA 92612**

ACCUSATION

15 **Wholesale Permit No. WLS 5966**

16 **ROGER SERNA**
17 **12560 Haster St., Spc. 84**
Garden Grove, CA 92840

18 **Designated Representative License**
No. EXC 21937

19 Respondents.

20
21
22 Complainant alleges:

23 **PARTIES**

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

26 2. On or about April 27, 2012, the Board of Pharmacy issued Wholesale Permit Number
27 WLS 5966 to Rochester Enterprises Inc. (Respondent Rochester Enterprises). The Wholesale
28 Permit expired on April 1, 2013, and has not been renewed.

1 3. On or about October 3, 2012, the Board of Pharmacy issued Designated
2 Representative License Number EXC 21937 to Roger Serna (Respondent Roger Serna). The
3 Designated Representative License expired on October 1, 2013, and has not been renewed.

4 **JURISDICTION**

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

8 5. Section 4011 of the Code provides that the Board shall administer and enforce both
9 the Pharmacy Law [Bus. & Prof. Code, § 4000 et seq.] and the Uniform Controlled Substances
10 Act [Health & Safety Code, § 11000 et seq.].

11 6. Section 4300 (a) of the Code provides that every license issued by the Board may be
12 suspended or revoked.

13 7. Section 4300.1 of the Code states:

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

20 8. Section 4307(a) of the Code states that:

21 Any person who has been denied a license or whose license has been revoked or
22 is under suspension, or who has failed to renew his or her license while it was under
23 suspension, or who has been a manager, administrator, owner member, officer,
24 director, associate, or partner of any partnership, corporation, firm, or association
25 whose application for a license has been denied or revoked, is under suspension or
26 has been placed on probation, and while acting as the manger, administrator, owner,
27 member, officer, director, associate, or partner had knowledge or knowingly
28 participated in any conduct for which the license was denied, revoked, suspended, or
placed on probation, shall be prohibited from serving as a manger, administrator,
owner, member, officer, director, associate, or partner of a licensee 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 pronibition shall continue until
the license is issued or reinstated.

1 **STATUTORY AND REGULATORY PROVISIONS**

2 9. Section 4022 of the Code states:

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

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

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

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

13 10. Section 4043 of the Code, in pertinent part, defines "wholesaler" to mean and include
14 "a person who acts as a wholesale merchant, broker, jobber, customs broker, reverse distributor,
15 agent, or a nonresident wholesaler, who sells for resale, or negotiates for distribution, or takes
16 possession of, any drug or device included in Section 4022."

17 11. Section 4053 (a) of the Code states:

18 Notwithstanding Section 4051, the board may issue a license as a designated
19 representative to provide sufficient and qualified supervision in a wholesaler or
20 veterinary food-animal drug retailer. The designated representative shall protect the
21 public health and safety in the handling, storage, and shipment of dangerous drugs
22 and dangerous devices in the wholesaler or veterinary food-animal drug retailer.

23 12. Section 4081 of the Code states:

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

(b) The owner, officer, and partner of any pharmacy, wholesaler, or veterinary
food-animal drug retailer shall be jointly responsible, with the

1 pharmacist-in-charge or representative-in-charge, for maintaining the records and
2 inventory described in this section.

3 13. Section 4105 of the Code states in pertinent part that:

4 (a) All records or other documentation of the acquisition and disposition of
5 dangerous drugs and dangerous devices by any entity licensed by the board shall be
6 retained on the licensed premises in a readily retrievable form.”

7

8 (c) The records required by this section shall be retained on the licensed
9 premises for a period of three years from the date of making.

10 14. Section 4160 of the Code provides, in pertinent part, that a wholesaler license shall be
11 required for a person or entity to act as a wholesaler, that every wholesaler shall be supervised or
12 managed by a Designated Representative in Charge, and that the Designated Representative in
13 Charge shall be responsible for the wholesaler’s compliance with state and federal laws.

14 15. Section 4163 (a) of the Code states:

15 (a) A manufacturer, wholesaler, repackager, or pharmacy may not furnish a
16 dangerous drug or dangerous device to an unauthorized person.

17 16. Section 4169 of the Code states in pertinent part:

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

19 (1) Purchase, trade, sell, or transfer dangerous drugs or dangerous devices at
20 wholesale with a person or entity that is not licensed with the board as a wholesaler
21 or pharmacy.

22

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

25

26 17. Section 4301 of the Code states in pertinent part:

27 The board shall take action against any holder of a license who is guilty of
28 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:

.....

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

3 ...

4
5 (o) Violating or attempting to violate, directly or indirectly, or assisting in or
6 abetting the violation of or conspiring to violate any provision or term of this
7 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.

8

9 (q) Engaging in any conduct that subverts or attempts to subvert an
10 investigation of the board.

11

12 18. California Code of Regulations, title 16, section 1718 states in pertinent part that
13 "Current Inventory" as used in Sections 4081 and 4332 of the Business and Professions Code
14 shall be considered to include complete accountability for all dangerous drugs handled by every
15 licensee enumerated in Sections 4081 and 4332.

16 COST RECOVERY

17 19. Section 125.3 of the Code provides, in pertinent part, that the Board may request the
18 administrative law judge to direct a licensee found to have committed a violation or violations of
19 the licensing act to pay a sum not to exceed the reasonable costs of the investigation and
20 enforcement of the case.

21 DRUGS

22 20. Drugs utilized to treat Human Immunodeficiency Virus (HIV) and Acquired Immune
23 Deficiency Syndrome (AIDS) including, abilify, actos, aptripla, baraclude, combivar, complera,
24 epzicom, gleevec, intelence, isentress, kaletra, norvir, prevista, reyataz, truvada, viramune, viread
25 and ziagen. These are dangerous drugs pursuant to Business and Professions Code section 4022
26 and possess a high resale and street dollar value.

1 **FACTUAL ALLEGATIONS**

2 21. On or about April 10, and May 18, 2012, AIDS Healthcare Foundation, a nonprofit
3 organization whose mission is to provide cutting edge medicine and advocacy for HIV and AIDS
4 patients, regardless of ability to pay, filed a complaint with the Board alleging that Respondent
5 Rochester Enterprises was engaged in a scheme whereby it knowingly and willfully offered HIV
6 and AIDS patients cash and in-kind inducements (i.e., gift cards, rent and utility subsidies) to
7 transfer their prescriptions for AIDS drugs, many of which were paid for by Medicare and
8 Medicaid to TLC Express Pharmacy and Beverly Hills Medical Plaza Pharmacy.

9 22. The Board investigation revealed that Respondents operated a "Confidential Patient
10 Services" (CPS) program, whereby they solicited AIDS and HIV patients to transfer their
11 prescriptions for drugs to their pharmacies. Respondent Rochester Enterprises' website stated
12 that it used "[trained] case/social workers [to] give personal care to members" and requested
13 patients' full medical records as part of an agreement to purchase "healthcare products or
14 services" from Respondent Rochester Enterprises. Respondents also represented on their website
15 that Respondent Rochester Enterprises "functioned like a normal pharmacy" and each prescription
16 was "processed by Rochester Enterprises' Physicians and Pharmacist."

17 23. From October 3, 2012 through April 1, 2013, Respondent Roger Serna was the
18 Designated Representative-in-Charge (DRIC) of Respondent Rochester Enterprises.

19 24. At all times mentioned herein, ST Trading was an entity that was not licensed by the
20 Board, had no premises or telephone numbers and was non-existent. From October 17, 2012
21 through May 14, 2013, Respondents purchased dangerous drugs, including drugs used for the
22 treatment of AIDS and HIV as described in paragraph 20, above, at the cost of \$3,062,122.78
23 from SD Trading. On October 10, 2012 and March 27, 2013, Respondents returned a portion of
24 those drugs to ST Trading.

25 25. From February 23, 2012 through March 28, 2012, Respondents sold dangerous drugs,
26 including drugs used for the treatment of HIV and AIDS to Beverly Hills Medical Plaza Pharmacy
27 when Respondent Rochester Enterprises was unlicensed by the Board.
28

1 26. From April 2, 2012 through April 26, 2012, Respondents sold dangerous drugs,
2 including drugs used for the treatment of AIDS and HIV to TLC Express Pharmacy when
3 Respondent Rochester Enterprises was unlicensed by the Board.

4 27. From February 23, 2012 through March 13, 2013, Respondents did not retain all
5 records reflecting the sales of dangerous drugs, including drugs used for the treatment of HIV and
6 AIDS to Beverly Hills Medical Plaza Pharmacy, TLC Express Pharmacy and Olympia Pharmacy.

7 28. From April 27, 2012 through April 1, 2013, Respondents did not maintain a current
8 inventory of dangerous drugs, including drugs used for the treatment of HIV and AIDS.

9 29. During the Board's investigation, Respondents sought records from the pharmacies it
10 sold drugs to, redacted those invoices to eliminate any information from the pharmacies and
11 represented to the Board inspector that these were Respondents' own records when they were
12 actually the records from the pharmacies (i.e., they passed off records of the pharmacies as their
13 own), claimed that they did not have access to records even though they had confirmed in writing
14 that they had access to their records and failed to respond to inquiries from the Board inspector.

15 30. Respondent Rochester Enterprises terminated business operations without notifying
16 the Board and without filing a Notice of Discontinuation of Business.

17 **FIRST CAUSE FOR DISCIPLINE**

18 **(Unlicensed Activity)**

19 31. Respondents are subject to disciplinary action under Code section 4301(o), for
20 violating Business and Professions Code section 4160(a), in that they purchased and sold
21 dangerous drugs, including drugs used for the treatment of HIV and AIDS drugs while unlicensed
22 as a wholesaler, as set forth in paragraphs 21 through 30 above, which are incorporated herein by
23 reference.

24 **SECOND CAUSE FOR DISCIPLINE**

25 **(Purchasing Drugs from an Unlicensed Entity)**

26 32. Respondents are subject to disciplinary action under Code section 4301(o), for
27 violating Business and Professions Code section 4169(a)(1), in that they purchased dangerous
28 drugs, including drugs used for the treatment of HIV and AIDS drugs from an unlicensed entity,

1 SD Trading, as set forth in paragraphs 21 through 30 above, which are incorporated herein by
2 reference.

3 **THIRD CAUSE FOR DISCIPLINE**

4 **(Failure to Keep Records of Acquisition and Disposition Open for Inspection and to Keep**
5 **Current Inventory)**

6 33. Respondents are subject to disciplinary action under Code sections 4301(o), for
7 violating Code sections 4081(a) and (b) in that they failed to keep records of the acquisition and
8 disposition of dangerous drugs open for inspection or keep a current inventory as defined by
9 California Code of Regulations, title 16, section 1718 for the dangerous drugs, including drugs
10 used for the treatment of AIDS and HIV, they sold to pharmacies, as set forth in paragraphs 21
11 through 30, which are incorporated herein by reference.

12 **FOURTH CAUSE FOR DISCIPLINE**

13 **(Failure to Retain Records of Dangerous Drugs on Licensed Premises)**

14 34. Respondents are subject to disciplinary action under Code section 4301(o), for
15 violating Code sections 4105(a) and (c), in that Respondents failed to retain records for the
16 dangerous drugs, including drugs used for the treatment of HIV and AIDS purchased and sold, as
17 set forth in paragraphs 21 through 30, which are incorporated herein by reference.

18 **FIFTH CAUSE FOR DISCIPLINE**

19 **(Subverting an Investigation)**

20 35. Respondents are subject to disciplinary action under Code section 4301(q), for
21 subverting an investigation of the Board in that they made misrepresentations to the Board
22 Inspector about their access to records, failed to respond to inquiries for records and produced
23 redacted copies of records, as set forth in paragraphs 21 through 30, which are incorporated herein
24 by reference.

1 **SIXTH CAUSE FOR DISCIPLINE**

2 **(Acts Involving Moral Turpitude, Dishonesty, Fraud, Deceit or Corruption)**

3 36. Respondents are subject to disciplinary action under Code section 4301(f), in that they
4 committed acts involving moral turpitude, dishonesty, fraud, deceit, or corruption, as set forth in
5 paragraphs 21 through 30, which are incorporated herein by reference.

6
7 **SEVENTH CAUSE FOR DISCIPLINE**

8 **(Unprofessional Conduct)**

9 37. Respondents are subject to disciplinary action under Code section 4301 for
10 unprofessional conduct in that they engaged in the activities described in paragraphs 21 through
11 30 above, which are incorporated herein by reference.

12 **OTHER MATTERS**

13 38. Pursuant to Code section 4307, if discipline is imposed on Wholesaler Permit
14 Number WLS 5966, issued to Rochester Enterprises Inc., and Roger Serna while acting as the
15 manager, administrator, owner, member, officer, director, associate, or partner of Rochester
16 Enterprises Inc. had knowledge of or knowingly participated in any conduct for which
17 Wholesaler Permit Number WLS 5966 was revoked, suspended or placed on probation, Roger
18 Serna shall be prohibited from serving as a manager, administrator, owner, member, officer,
19 director, associate, or partner of a licensee for five years if Wholesaler Permit Number WLS
20 5966 is placed on probation or until Wholesaler Permit Number WLS 5966 is reinstated if it is
21 revoked.

22 39. Pursuant to Code section 4307, if discipline is imposed on Designated
23 Representative License No. EXC 21937 issued to Roger Serna, Roger Serna shall be prohibited
24 from serving as a manager, administrator, owner, member, officer, director, associate, or partner
25 of a licensee for five years if Designated Representative License Number EXC 21937 is placed
26 on probation or until Designated Representative License Number EXC 21937 is reinstated if it is
27 revoked.

1 **PRAYER**

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

4 1. Revoking or suspending Wholesale Permit Number WLS 5966, issued to Rochester
5 Enterprises Inc.;

6 2. Revoking or suspending Designated Representative License Number EXC 21937,
7 issued to Roger Serna;

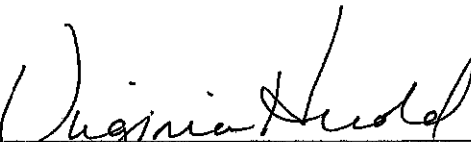
8 3. Prohibiting Roger Serna from serving as a manager, administrator, owner, member,
9 officer, director, associate, or partner of a licensee for five years if Wholesaler Permit Number
10 WLS 5966 is placed on probation or until Wholesaler Permit Number WLS 5966 is reinstated if
11 Wholesaler Permit Number WLS 5966 issued to Rochester Enterprises, Inc. is revoked;

12 4. Prohibiting Roger Serna from serving as a manager, administrator, owner, member,
13 officer, director, associate, or partner of a licensee for five years if Designated Representative
14 License Number EXC 21937 is placed on probation or until Designated Representative License
15 Number EXC 21937 is reinstated if Designated Representative License Number EXC 21937
16 issued to Roger Serna is revoked;

17 5. Ordering Rochester Enterprises Inc. and Roger Serna to pay the Board of Pharmacy
18 the reasonable costs of the investigation and enforcement of this case, pursuant to Business and
19 Professions Code section 125.3;

20 6. Taking such other and further action as deemed necessary and proper.

21
22
23 DATED: 9/28/14


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

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