

1 EDMUND G. BROWN JR.
Attorney General of California
2 FRANK H. PACOE
Supervising Deputy Attorney General
3 JOSHUA A. ROOM
Deputy Attorney General
4 State Bar No. 214663
455 Golden Gate Avenue, Suite 11000
5 San Francisco, CA 94102-7004
Telephone: (415) 703-1299
6 Facsimile: (415) 703-5480
Attorneys for Complainant

7
8 **BEFORE THE**
BOARD OF PHARMACY
9 **DEPARTMENT OF CONSUMER AFFAIRS**
STATE OF CALIFORNIA

10 In the Matter of the Accusation Against:

Case No. 3515

11 **ELMHURST PHARMACY**
12 **7400 MacArthur Boulevard**
13 **Oakland, CA 94605**

ACCUSATION

14 **Pharmacy License No. PHY 45683**

15 **and**

16 **PARAGI M. PATEL**
17 **16897 Robey Drive**
San Leandro, CA 94578

18 **Pharmacist License No. RPH 49421**

19 Respondents.

20 Complainant alleges:

21 PARTIES

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

24 2. On or about February 7, 2002, the Board of Pharmacy issued Pharmacy License No.
25 PHY 45683 to Medical Supply Corporation of America dba Elmhurst Pharmacy (Respondent
26 Elmhurst), Paragi M. Patel, President, Manjula I. Patel, Treasurer/CFO. The Pharmacy License
27 was in full force and effect at all times relevant to the charges brought herein and will expire on
28 February 1, 2011, unless renewed.

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

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

7 9. Section 4115 of the Code states, in pertinent part:

8 “(a) A pharmacy technician may perform packaging, manipulative, repetitive, or other
9 nondiscretionary tasks, only while assisting, and while under the direct supervision and control of
10 a pharmacist.”

11 “(e) No person shall act as a pharmacy technician without first being licensed by the board
12 as a pharmacy technician”

13 “(f)(1) A pharmacy with only one pharmacist shall have no more than one pharmacy
14 technician performing the tasks specified in subdivision (a). The ratio of pharmacy technicians
15 performing the tasks specified in subdivision (a) to any additional pharmacist shall not exceed
16 2:1, except that this ratio shall not apply to personnel performing clerical functions pursuant to
17 section 4116 or 4117. This ratio is applicable to all practice settings, except [for certain practice
18 settings not at issue in this case and therefore not relevant to this matter].”

19 10. Section 4116, subdivision (a) of the Code provides, in pertinent part, that no person
20 other than a pharmacist, an intern pharmacist, an authorized officer of the law, or a person
21 authorized to prescribe shall be permitted in that area, place, or premises described in the license
22 issued by the board wherein controlled substances or dangerous drugs or dangerous devices are
23 stored, possessed, prepared, manufactured, derived, compounded, dispensed, or repackaged.

24 11. Section 4081, subdivision (a) of the Code provides, in pertinent part, that all records
25 of manufacture and of sale, acquisition, or disposition of dangerous drugs or dangerous devices
26 shall be at all times during business hours open to inspection by authorized officers of the law,
27 and shall be preserved for at least three years from the date of making. A current inventory shall
28 be kept by every licensed pharmacy that maintains a stock of dangerous drugs or devices.

1 12. Section 4332 of the Code makes it unlawful for any person to fail, neglect, or refuse
2 to maintain the records required by section 4081 or, when called upon by an authorized officer or
3 a member of the board, to refuse to produce or provide the records within a reasonable time, or to
4 willfully produce or furnish records that are false.

5 13. Section 4113, subdivision (b) of the Code states:

6 “The pharmacist-in-charge shall be responsible for a pharmacy's compliance with all state
7 and federal laws and regulations pertaining to the practice of pharmacy.”

8 14. California Code of Regulations, title 16, section 1714, subdivision (b) provides that
9 each pharmacy licensed by the board shall maintain its facilities, space, fixtures, and equipment
10 so that drugs are safely and properly prepared, maintained, secured and distributed.

11 15. California Code of Regulations, title 16, section 1718, defines “current inventory” as
12 used in sections 4081 and 4332 to include complete accountability for all dangerous drugs
13 handled by every licensee enumerated in sections 4081 and 4332. It further requires that the
14 controlled substances inventories required by the Title 21, Code of Federal Regulations, section
15 1304, shall be available for inspection upon request for at least 3 years.

16 16. California Code of Regulations, title 16, section 1793.2, defines “nondiscretionary
17 tasks” as used in section 4115 to include (a) removing drug(s) from stock, (b) counting, pouring,
18 or mixing pharmaceuticals, (c) placing product(s) into container(s), (d) affixing label(s) to the
19 container(s), and/or (e) packaging and repackaging.

20 17. Title 21, Code of Federal Regulations, section 1301.11, subdivision (a) requires that
21 any person who manufactures, distributes, dispenses, imports, or exports any controlled substance
22 or who proposes to do so shall obtain a Drug Enforcement Administration (DEA) registration.

23 18. Title 21, Code of Federal Regulations, section 1304.11, subdivision (c) requires that
24 any registrant of the DEA take a new inventory of all stocks of controlled substances on hand at
25 least every two years, on any date within two years of the previous biennial inventory date.

26 19. Section 125.3 of the Code provides, in pertinent part, that the Board may request the
27 administrative law judge to direct a licentiate found to have committed a violation of the licensing
28 act to pay a sum not to exceed its reasonable costs of investigation and enforcement.

CONTROLLED SUBSTANCES / DANGEROUS DRUGS

20. Section 4021 of the Code states:

“‘Controlled substance’ means any substance listed in Chapter 2 (commencing with Section 11053) of Division 10 of the Health and Safety Code.”

21. Section 4022 of the Code states, in pertinent part:

“‘Dangerous drug’ or ‘dangerous device’ means any drug or device unsafe for self use, except veterinary drugs that are labeled as such, 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.

“(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.”

CAUSES FOR DISCIPLINE, AS TO BOTH RESPONDENTS

FIRST CAUSE FOR DISCIPLINE

(Exceeding Pharmacist to Technician Ratio)

22. Respondent Elmhurst and Respondent Patel are each and severally subject to discipline under section 4301(j) and/or (o), section 4115(f)(1), and/or section 4113(b) of the Code, as further defined by California Code of Regulations, title 16, section 1793.2, in that on or about May 12, 2009, three pharmacy technicians (S.P., D.G., H.B.)¹ performed nondiscretionary tasks while only a single pharmacist (S.B.)¹ was on duty to supervise these technicians.

SECOND CAUSE FOR DISCIPLINE

(Unlicensed Technician Activities)

23. Respondent Elmhurst and Respondent Patel are each and severally subject to discipline under section 4301(j) and/or (o), section 4115(e), and/or section 4113(b) of the Code, in that prior to and/or on or about May 12, 2009, a person not licensed as a pharmacy technician (H.B.)¹ was engaged in activities constituting nondiscretionary activities requiring such licensure.

¹ The full names of these individuals will be provided during discovery.

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

THIRD CAUSE FOR DISCIPLINE

(Failure to Maintain Operational Standards and Security)

24. Respondent Elmhurst and Respondent Patel are each and severally subject to discipline under section 4301(j) and/or (o), section 4116(a), and/or section 4113(b) of the Code, and/or California Code of Regulations, title 16, section 1714, in that on or about May 12, 2009, the pharmacy back door leading to the parking lot was not locked, leaving the pharmacy insecure.

FOURTH CAUSE FOR DISCIPLINE

(Failure to Conduct Biennial Inventory)

25. Respondent Elmhurst and Respondent Patel are each and severally subject to discipline under section 4301(j) and/or (o), section 4081, section 4332, and/or section 4113(b) of the Code, and/or California Code of Regulations, title 16, section 1718, by reference to Title 21, Code of Federal Regulations, sections 1301.11(a) and 1304.11(c), in that on or about May 12, 2009, pharmacy records revealed that the prior biennial inventory had been conducted January 2, 2007, a period of more than two years prior to the date of inspection.

DISCIPLINE CONSIDERATIONS

1
2 26. To determine the level of discipline, if any, to be imposed on Respondent Elmhurst
3 and/or Respondent Patel (collectively, "Respondents"), Complainant alleges that on or about July
4 20, 2005, in a prior disciplinary action titled *In the Matter of the Accusation Against Elmhurst*
5 *Pharmacy, Paragi Patel, and Michael Hall*, Case No. 2686 before the Board of Pharmacy,
6 Respondents' Licenses were subjected to prior discipline. By way of a Decision and Order of the
7 Board adopting a Stipulated Settlement effective July 20, 2005, Respondents admitted to eight of
8 nine causes for discipline alleged in Accusation No. 2686, including that on multiple occasions on
9 and between April 1, 2002 and June 30, 2002, Respondent engaged in dishonest conduct and/or
10 created or signed documents falsely representing the facts, by re-billing, and therefore overbilling,
11 Medi-Cal in the amount of \$23,878.40 for prescriptions of the dangerous drug Seroquel that had
12 been returned to the pharmacy by a physician to whom they had been delivered, and which were
13 reused and sold again to the same physician without credit to Medi-Cal. The Accusation further
14 alleged, and Respondents further admitted, that this redelivery of used Seroquel constituted the
15 delivery of drugs under conditions where it may have been contaminated with filth, or where it
16 may have been rendered injurious to health. Finally, the Accusation alleged, and Respondents
17 admitted, that they were unable to produce copies of invoices for at least five drug orders, that
18 they maintained inadequate supervision over pharmacy technicians, that they had an improper
19 pharmacist to technician ratio, that non-professional staff were permitted in the dispensing area
20 without a pharmacist being present, and that Respondents had failed to notify the Board when
21 Respondent Patel stopped being the Pharmacist in Charge, and then when he resumed that duty.
22 In the stipulated Decision and Order, both (Elmhurst) Pharmacy License No. PHY 45683 and
23 Pharmacist (Patel) License No. RPH 49421 were revoked, with revocation stayed and both of the
24 Respondents placed on probation for three (3) years with terms and conditions including payment
25 of \$6,000.00 in cost recovery, a prohibition on preceptorships, supervision, and ownership of any
26 licensed premises other than those (e.g., Respondent Elmhurst) already owned, and other standard
27 terms. That decision is now final and is incorporated by reference as if fully set forth herein.

28 ///

1 32. To determine the level of discipline, if any, to be imposed on Respondent Elmhurst
2 and/or Respondent Patel (collectively, "Respondents"), Complainant further alleges that:

3 a. On or about July 27, 2004, Citation No. CI 2002 24778 was issued to Respondent
4 Elmhurst for a violation of California Code of Regulations, title 16, sections 1716 and/or 1761: a
5 prescription prescribed for one patient was dispensed to another patient with a similar name. That
6 citation is now final and is incorporated by reference as if fully set forth herein.

7 b. On or about July 27, 2004, Citation No. CI 2003 27898 was issued to Respondent
8 Patel for a violation of California Code of Regulations, title 16, sections 1716 and/or 1761: a
9 prescription prescribed for one patient was dispensed to another patient with a similar name. That
10 citation is now final and is incorporated by reference as if fully set forth herein.

11 c. On or about December 1, 2009, Citation No. CI 2007 36113 with a fine of \$3,500.00
12 was issued to Respondent Elmhurst for violations of Business and Professions Code section 4037,
13 subdivision (a), section 4105, subdivision (a) and section 4333, section 4116, subdivision (a), and
14 California Code of Regulations, title 16, sections 1714, subdivision (b) and 1793.1: Respondent
15 operated an unlicensed pharmacy, stored prescription documents and drug records at unlicensed
16 premises, allowed a non-pharmacist access and a key to the drug dispensing area, and allowed a
17 non-pharmacist to fill and interpret dangerous device prescriptions, consult with nurses, package
18 and prepare dangerous devices for delivery, and perform acts requiring professional judgment.
19 That citation is now final and is incorporated by reference as if fully set forth herein.

20 d. On or about December 1, 2009, Citation No. CI 2008 40638 with a fine of \$1,750.00
21 was issued to Respondent Patel for violations of Business and Professions Code sections 4037,
22 subdivision (a), 4105, subdivision (a), 4333, 4116, subdivision (a), 4306.5, subdivision (b), and
23 California Code of Regulations, title 16, sections 1714, subdivision (b) and 1793.1: Respondent
24 operated an unlicensed pharmacy, stored prescription and drug records at an unlicensed premises,
25 allowed a non-pharmacist access to the drug dispensing area, allowed a non-pharmacist to fill and
26 interpret dangerous device prescriptions, consult with nurses, package/prepare dangerous devices
27 for delivery, and exercise professional judgment, all while failing to exercise his own professional
28 judgment. That citation is now final and is incorporated by reference as if fully set forth herein.

1 e. On or about February 2, 2010, Citation No. CI 2009 42059 with a fine of \$3,500.00
2 was issued to Respondent Elmhurst for violations of Business and Professions Code section 4076,
3 subdivision (a) and (11)(A), section 4077, and California Code of Regulations, title 16, section
4 1717, subdivision (b)(2): Respondent dispensed five prescriptions in unit dose packages that
5 were labeled with the incorrect manufacturers and/or the incorrect physical descriptions of the
6 dispensed medications, and for those same five prescriptions failed to maintain the distributors'
7 names that appeared on the commercial package labels of the drugs dispensed. That citation is
8 now final and is incorporated by reference as if fully set forth herein.

9 f. On or about February 2, 2010, Citation No. CI 2009 43319 with a fine of \$3,500.00
10 was issued to Respondent Patel for violations of Business and Professions Code section 4076,
11 subdivision (a) and (11)(A), section 4077, and California Code of Regulations, title 16, section
12 1717, subdivision (b)(2): Respondent dispensed five prescriptions in unit dose packages that
13 were labeled with the incorrect manufacturers and/or the incorrect physical descriptions of the
14 dispensed medications, and for those same five prescriptions failed to maintain the distributors'
15 names that appeared on the commercial package labels of the drugs dispensed. That citation is
16 now final and is incorporated by reference as if fully set forth herein.

17
18
19 **PRAYER**

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

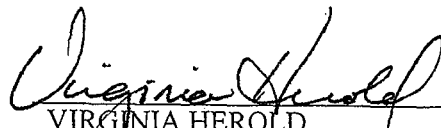
- 22 1. Revoking or suspending Pharmacy License Number PHY 45683, issued to
23 Medical Supply Corporation of America dba Elmhurst Pharmacy (Respondent Elmhurst);
- 24 2. Revoking or suspending Pharmacist License Number RPH 49421, issued to Paragi M.
25 Patel (Respondent Patel);
- 26 3. Ordering Respondent Elmhurst and Respondent Patel (Respondents) to pay the Board
27 of Pharmacy the reasonable costs of the investigation and enforcement of this case, pursuant to
28 Business and Professions Code section 125.3;

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

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

DATED:

5/28/10



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

SF2009405301
40429460.doc