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

10 In the Matter of the Accusation Against:

Case No. 4248

11 **MILLS SQUARE PHARMACY**
12 **11 S. San Mateo Drive**
13 **San Mateo, CA 94401**

A C C U S A T I O N

14 **Pharmacy License No. PHY 46847**

15 **and**

16 **FRANK TSOLAKIS**
17 **P.O. Box 1126**
18 **San Carlos, CA 94070-1126**

19 **Pharmacist License No. RPH 49416**

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 August 3, 2004, the Board of Pharmacy issued Pharmacy License No.
25 PHY 46847 to Medicross Pharmaceutical Services dba Mills Square Pharmacy, Gary Toy, CEO,
26 Frank Tsolakis, Vice President (Respondent Mills Square). Beginning on or about November 27,
27 2009, Frank Tsolakis became CEO, President, and Secretary of the ownership entity. The
28 Pharmacy License expired on August 1, 2011, and has not been renewed.

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

5 9. Section 4113, subdivision (c) 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 10. Section 4059 of the Code, in pertinent part, prohibits furnishing of any dangerous
9 drug or dangerous device except upon the prescription of an authorized prescriber.

10 11. Section 4059.5 of the Code, in pertinent part, permits ordering/delivery of dangerous
11 drugs or devices only by and to entities licensed by the board and authorized prescribers, and
12 requires that all deliveries to a licensed premises shall be signed for and received by a pharmacist.

13 12. Section 4081 of the Code provides, in pertinent part, that all records of manufacture,
14 sale, acquisition, or disposition of dangerous drugs or dangerous devices shall be kept open to
15 inspection and retained for at least three years, that a current inventory shall be kept by every
16 pharmacy that maintains a stock of dangerous drugs or dangerous devices, and that the owner(s),
17 officer(s), partner(s), and pharmacist in charge or designated representative in charge shall be
18 jointly responsible for maintaining the records and keeping the inventory.

19 13. Section 4105 of the Code requires, in pertinent part, that unless a waiver is granted by
20 the board, all records and other documentation of the acquisition and disposition of dangerous
21 drugs and devices by any entity licensed by the board be retained on the licensed premises, in a
22 readily retrievable form, for three years from the date of making.

23 14. Section 4332 of the Code makes it unlawful for any person: to fail, neglect, or refuse
24 to maintain the records required by Section 4081; or, when called upon by an authorized officer
25 or a member of the board, to fail, neglect, or refuse to produce or provide the records within a
26 reasonable time; or to willfully produce or furnish records that are false:

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1 15. Section 4333 of the Code provides, in pertinent part, that all prescriptions filled by a
2 pharmacy and all other records required by Section 4081 shall be maintained on the premises and
3 available for inspection by authorized officers of the law for a period of at least three years and, in
4 cases where the pharmacy discontinues business, these records shall be maintained in a board-
5 licensed facility for at least three years.

6 16. Health and Safety Code section 11165 provides, in pertinent part, for establishment
7 and maintenance of a Controlled Substance Utilization Review and Evaluation System (CURES)
8 for the electronic monitoring of prescribing and dispensing of Schedule II, III, and IV controlled
9 substances, and requires, in pertinent part, that for each prescription for a Schedule II, III, or IV
10 controlled substance, the dispensing pharmacy or clinic transmit a report with certain information
11 on the patient, prescriber, controlled substance, and prescription, to the California Department of
12 Justice, on a weekly basis in a format prescribed by the California Department of Justice.¹

13 17. California Code of Regulations, title 16, section 1714, provides in pertinent part that
14 each pharmacy licensed by the board shall maintain its facilities, space, fixtures, and equipment
15 so that drugs are safely and properly prepared, maintained, secured and distributed, and that, with
16 one exception not relevant here, possession of a key to the pharmacy where dangerous drugs and
17 controlled substances are stored shall be restricted to a pharmacist.

18 18. California Code of Regulations, title 16, section 1715, subdivision (a), requires that
19 the pharmacist-in-charge of each pharmacy shall complete a self-assessment of the pharmacy's
20 compliance with federal and state pharmacy law before July 1 of every odd-numbered year, and
21 subdivision (d) requires that each self-assessment shall be kept for three years after completion.

22 19. California Code of Regulations, title 16, section 1717, subdivision (b) requires, in
23 pertinent part, that for each prescription on file, certain information shall be maintained and be
24 readily retrievable in the pharmacy, including the date dispensed, and the name or initials of the
25 dispensing pharmacist.

26 _____
27 ¹ Health and Safety Code section 11165 was first amended to impose CURES reporting
28 requirements effective January 1, 2005; as of that date, prescriptions for Schedule II and III drugs
had to be reported. Effective January 1, 2007, Schedule IV prescriptions also had to be reported.

1 20. California Code of Regulations, title 16, section 1718, states:

2 “Current Inventory’ as used in Sections 4081 and 4332 of the Business and Professions
3 Code shall be considered to include complete accountability for all dangerous drugs handled by
4 every licensee enumerated in Sections 4081 and 4332.

5 “The controlled substances inventories required by Title 21, CFR, Section 1304 shall be
6 available for inspection upon request for at least 3 years after the date of the inventory.”

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

10 22. Title 21, Code of Federal Regulations, section 1304.04(f) requires, in pertinent part,
11 that inventories and records of Schedule I and II controlled substances shall be kept separate from
12 all other records, and that inventories and records of Schedule III-V controlled substances shall be
13 either kept separate from other records, or be immediately retrievable from the business records.

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

17 24. Section 125.9 of the Code as well as California Code of Regulations, title 16, section
18 1775.1 provide, in pertinent part, that failure of a person or entity cited to pay a fine within 30
19 days of assessment, unless the citation is being appealed, may result in disciplinary action.

20 CONTROLLED SUBSTANCES / DANGEROUS DRUGS

21 25. Section 4021 of the Code provides that a “controlled substance” means any substance
22 listed in Schedules I through V contained in Health and Safety Code section 11053 et seq.

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

24 “‘Dangerous drug’ or ‘dangerous device’ means any drug or device unsafe for self use,
25 except veterinary drugs that are labeled as such, and includes the following:

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

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1 FOURTH CAUSE FOR DISCIPLINE

2 (Failure to Report Controlled Substance Prescriptions to CURES)

3 34. Respondents are subject to discipline under section(s) 4301(j) and/or (o), and/or
4 4113(c) of the Code, and/or Health and Safety Code section 11165, for violating statutes
5 regulating controlled substances or dangerous drugs, and/or directly or indirectly violating,
6 attempting to violate, or assisting in or abetting a violation of laws or regulations governing the
7 practice of pharmacy, in that, between in or about March 2010 and February 9, 2011, the
8 pharmacy had not successfully transmitted controlled substances dispensing data to CURES.

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10 FIFTH CAUSE FOR DISCIPLINE

11 (Possession of Pharmacy Key(s) by Non-Pharmacist(s))

12 35. Respondents are subject to discipline under section(s) 4301(j) and/or (o), and/or
13 4113(c) of the Code, and/or California Code of Regulations, title 16, section 1714, for violating
14 statutes regulating controlled substances or dangerous drugs, and/or directly or indirectly
15 violating, attempting to violate, or assisting in or abetting a violation of laws or regulations
16 governing the practice of pharmacy, in that, prior to and/or including March 2011, at least three
17 (3) non-pharmacist staff of the pharmacy were in possession of key(s) to the pharmacy.

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19 SIXTH CAUSE FOR DISCIPLINE

20 (Failure to Complete Biennial Pharmacy Self-Assessment Form(s))

21 36. Respondents are subject to discipline under section(s) 4301(j) and/or (o), and/or
22 4113(c) of the Code, and/or California Code of Regulations, title 16, section 1715, subdivision
23 (a), for violating statutes regulating controlled substances or dangerous drugs, and/or directly or
24 indirectly violating, attempting to violate, or assisting in or abetting a violation of laws or
25 regulations governing the practice of pharmacy, in that Respondent Tsolakis failed to complete
26 the biennial pharmacy self-assessment form due on or before July 1, 2009.

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SEVENTH CAUSE FOR DISCIPLINE

(Failure to Identify Dispensing Pharmacist)

37. Respondents are subject to discipline under section(s) 4301(j) and/or (o), and/or 4113(c) of the Code, and/or California Code of Regulations, title 16, section 1717, subdivision (a), for violating statutes regulating controlled substances or dangerous drugs, and/or directly or indirectly violating, attempting to violate, or assisting in or abetting a violation of laws or regulations governing the practice of pharmacy, in that, prior to and/or including March 2011, the pharmacy dispensed one or more medications without identifying the dispensing pharmacist.

EIGHTH CAUSE FOR DISCIPLINE

(Failure to Segregate Schedule II Records)

38. Respondents are subject to discipline under section(s) 4301(j) and/or (o), and/or 4113(c) of the Code, and/or Title 21, Code of Federal Regulations, section 1304.04(f), for violating statutes regulating controlled substances or dangerous drugs, and/or directly or indirectly violating, attempting to violate, or assisting in or abetting a violation of laws or regulations governing the practice of pharmacy, in that, prior to and/or including March 2011,, Schedule II records were not kept separate from all other other records.

NINTH CAUSE FOR DISCIPLINE

(Failure to Conduct Biennial Inventory)

39. Respondents are subject to discipline under section(s) 4301(j) and/or (o), 4113(c), 4081, 4105, 4332 and/or 4333 of the Code, and/or California Code of Regulations, title 16, section 1718, and/or Title 21, Code of Federal Regulations, section 1304.11(c), in that in or about March 2011, pharmacy records revealed that the prior biennial inventory had been conducted on or about June 8, 2007, more than two years prior to the date of inspection.

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TENTH CAUSE FOR DISCIPLINE

(Unprofessional Conduct)

40. Respondents are subject to discipline under section 4301 of the Code in that Respondents, as described in paragraphs 31 to 39 above, engaged in unprofessional conduct

CAUSE FOR DISCIPLINE, SOLELY AS TO RESPONDENT MILLS SQUARE

ELEVENTH CAUSE FOR DISCIPLINE

(Failure to Comply With/Pay Citation Fine)

41. Respondent Mills Square is subject to discipline under section 125.9 of the Code and/or California Code of Regulations, title 16, section 1775.1, in that on or about July 15, 2010, Citation No. CI 2007 35668, requiring payment of \$2,900.00 to the Board by August 13, 2010, was issued to Respondent Mills Square. Respondent did not appeal, and did not pay the fine.

DISCIPLINE CONSIDERATIONS

42. To determine the level of discipline, if any, to be imposed on Respondent Mills Square and/or Respondent Tsolakis (collectively, Respondents), Complainant further alleges that:

a. On or about November 15, 2007, Citation No. CI 2007 33797, with a \$2,250.00 fine (subsequently reduced to zero), was issued to Respondent Mills Square, for: (1) failing to comply with California Code of Regulations, title 16, section 1716, by varying from prescription; (2) failing to comply with Health and Safety Code section 11165 by not reporting controlled substance prescriptions dispensed to the Controlled Substance Utilization Review and Evaluation System (CURES); (3) failing to comply with California Code of Regulations, title 16, section 1711, by failing to complete a quality assurance review relating to a prescription error; (4) failing to comply with California Code of Regulations, title 16, section 1715.5, by failing to implement an electronic monitoring system for Schedule II controlled substance prescriptions; and (5) failing to comply with section 4076, subdivision (a)(11)(a) of the Code, by dispensing medication(s) with a label lacking a physical description of the medication. A modified citation was issued on or about November 10, 2011. That citation is now final and is incorporated herein by reference.

1 b. On or about November 15, 2007, Citation No. CI 2007 34637, with a \$3,250.00 fine
2 (subsequently reduced to zero), was issued to Respondent Tsolakis, for: (1) failing to comply
3 with California Code of Regulations, title 16, section 1716, by varying from a prescription; (2)
4 failing to comply with Health and Safety Code section 11165 by not reporting controlled
5 substance prescriptions dispensed to the Controlled Substance Utilization Review and Evaluation
6 System (CURES); (3) failing to comply with California Code of Regulations, title 16, section
7 1711, by failing to complete a quality assurance review relating to a prescription error; (4) failing
8 to comply with California Code of Regulations, title 16, section 1715.5, by failing to implement
9 an electronic monitoring system for Schedule II controlled substance prescriptions; and (5) failing
10 to comply with section 4076, subdivision (a)(11)(a) of the Code, by dispensing medication(s)
11 with a label lacking a physical description of the medication. That citation is now final and is
12 incorporated herein by reference.

13 c. On or about January 29, 2010, Citation No. CI 2007 35668, with a total fine of
14 \$2,900.00, was issued to Respondent Mills Square, for: (1) failing to comply with Title 21, Code
15 of Federal Regulations, section 1305.13, subdivision (e), by failing to complete DEA 222 Order
16 Forms with the number of Schedule II controlled substance containers received and date received;
17 and (2) failing to comply with section 4342, by having expired drugs in the pharmacy's active
18 inventory. A corrected citation with the same fine amount was issued on or about July 15, 2010.
19 That citation is now final and is incorporated herein by reference.

20 d. On or about January 29, 2010, Citation No. CI 2009 42902, with a total fine of
21 \$2,500.00, was issued to Respondent Tsolakis, for: (1) failing to comply with Title 21, Code of
22 Federal Regulations, section 1305.13, subdivision (e), by failing to complete DEA 222 Order
23 Forms with the number of Schedule II controlled substance containers received and date received;
24 and (2) failing to comply with section 4342, by having expired drugs in the pharmacy's active
25 inventory. A modified citation reducing the fine to \$1,000.00 was issued on or about November
26 17, 2010. That citation is now final and is incorporated herein by reference.

1 e. On or about April 8, 2010, Citation No. CI 2009 41232, with no fine, was issued to
2 Respondent Mills Square, for violating California Code of Regulations, title 16, section 1716 by
3 varying from a prescription. That citation is now final and is incorporated herein by reference.

4 f. On or about April 8, 2010, Citation No. CI 2009 42903, with a fine of \$2,000.00, was
5 issued to Respondent Tsolakis, for violating California Code of Regulations, title 16, section 1716
6 by varying from a prescription. A modified citation reducing the fine to \$500.00 was issued on or
7 about November 17, 2010. That citation is now final and is incorporated herein by reference.

8
9 PRAYER

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

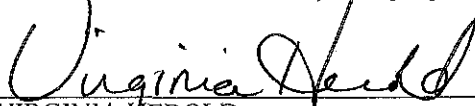
12 1. Revoking or suspending Pharmacy License No. PHY 46847, issued to Medicross
13 Pharmaceutical Services dba Mills Square Pharmacy (Respondent Mills Square);

14 2. Revoking or suspending Pharmacist License No. RPH 49416, issued to Frank
15 Tsolakis (Respondent Tsolakis);

16 3. Ordering Respondent Mills Square and Respondent Tsolakis to jointly and severally
17 be responsible to pay the Board of Pharmacy the reasonable costs of the investigation and
18 enforcement of this case, pursuant to Business and Professions Code section 125.3;

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

20 DATED: 9/19/13


21 VIRGINIA HEROLD
22 Executive Officer
23 Board of Pharmacy
24 Department of Consumer Affairs
25 State of California
26 Complainant

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