

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

In the Matter of the Accusation Against:

Case No. 4248

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

Pharmacy License No. PHY 46847

and

FRANK TSOLAKIS
P.O. Box 1126
San Carlos, CA 94070-1126

Pharmacist License No. RPH 49416

Respondents.

DECISION AND ORDER

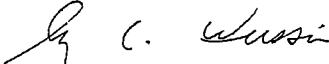
The attached Stipulated Settlement and Disciplinary Order is hereby adopted by the Board of Pharmacy, Department of Consumer Affairs, as its Decision in this matter.

This decision shall become effective on July 9, 2014.

It is so ORDERED on July 2, 2014.

BOARD OF PHARMACY
DEPARTMENT OF CONSUMER AFFAIRS
STATE OF CALIFORNIA

By



STAN C. WEISSER
Board President

1 KAMALA D. HARRIS
Attorney General of California
2 FRANK H. PACOE
Supervising Deputy Attorney General
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Attorneys for Complainant

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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**

STIPULATED SETTLEMENT AND
DISCIPLINARY ORDER

14 **Pharmacy License No. PHY 46847**

15 **and**

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

18 **Pharmacist License No. RPH 49416**

19 Respondents.

20 In the interest of a prompt and speedy settlement of this matter, consistent with the public
21 interest and the responsibility of the Board of Pharmacy of the Department of Consumer Affairs,
22 the parties hereby agree to the following Stipulated Settlement and Disciplinary Order which will
23 be submitted to the Board for approval and adoption as the final disposition of the Accusation.

24 **PARTIES**

25 1. Virginia Herold ("Complainant"), Executive Officer, Board of Pharmacy, brought this
26 action solely in her official capacity and is represented herein by Kamala D. Harris, Attorney
27 General of the State of California, by Joshua A. Room, Supervising Deputy Attorney General.

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1 2. Respondents Mills Square Pharmacy and Frank Tsolakis (Respondents) are
2 represented in this proceeding by attorney Lucy S. McAllister, whose address is: 255 North
3 Market Street, Suite 100, San Jose, CA 95110 (telephone (408) 291-8686; fax (408) 291-0187).

4 3. On or about August 3, 2004, the Board of Pharmacy issued Pharmacy License No.
5 PHY 46847 to Medicross Pharmaceutical Services dba Mills Square Pharmacy, Gary Toy, CEO,
6 Frank Tsolakis, Vice President (Respondent Mills Square). Beginning on or about November 27,
7 2009, Frank Tsolakis became CEO, President, and Secretary of the ownership entity. The
8 Pharmacy License expired on August 1, 2011, and has not been renewed.

9 4. On or about April 19, 1997, the Board of Pharmacy issued Pharmacist License No.
10 RPH 49416 to Frank Tsolakis (Respondent Tsolakis). The Pharmacist License was in full force
11 and effect at all times relevant to the charges herein and will expire on September 30, 2014,
12 unless renewed. Since on or about August 3, 2004, and for all time periods relevant to the
13 charges in Accusation No. 4248, Respondent Tsolakis served and/or was reflected in Board
14 records as the Pharmacist in Charge (PIC) for Respondent Mills Square.

15 JURISDICTION

16 5. Accusation No. 4248 was filed before the Board of Pharmacy (Board) , Department
17 of Consumer Affairs, and is currently pending against Respondents. The Accusation and all other
18 statutorily required documents were properly served on Respondents on October 2, 2013.
19 Respondents timely filed a Notice of Defense contesting the Accusation. A copy of Accusation
20 No. 4248 is attached as exhibit A and incorporated herein by reference.

21 ADVISEMENT AND WAIVERS

22 6. Respondents have carefully read, discussed with counsel, and understand the charges
23 and allegations in Accusation No. 4248. Respondents have also carefully read, fully discussed
24 with counsel, and understand the effects of this Stipulated Settlement and Disciplinary Order.

25 7. Respondents are fully aware of their legal rights in this matter, including the right to a
26 hearing on the charges and allegations in the Accusation; the right to be represented by counsel at
27 their own expense; the right to confront and cross-examine the witnesses against them; the right
28 to present evidence and to testify on their own behalf; the right to the issuance of subpoenas to

1 compel the attendance of witnesses and the production of documents; the right to reconsideration
2 and court review of an adverse decision; and all other rights accorded by the California
3 Administrative Procedure Act and other applicable laws.

4 8. Respondents voluntarily, knowingly, and intelligently waive and give up each and
5 every right set forth above.

6 CULPABILITY

7 9. Respondents admit the truth of each and every charge and allegation in Accusation
8 No. 4248. Respondents agree that their respective licenses are subject to discipline and agree to
9 be bound by the Board's imposition of discipline as set forth in the Disciplinary Order below.

10 RESERVATION

11 10. Admissions made by Respondents herein are only for the purposes of this proceeding,
12 or any other proceedings in which the Board of Pharmacy or other professional licensing agency
13 is involved, and shall not be admissible in any other criminal or civil proceeding.

14 CONTINGENCY

15 11. This stipulation shall be subject to approval by the Board of Pharmacy. Respondents
16 understand and agree that counsel for Complainant and the staff of the Board may communicate
17 directly with the Board regarding this stipulation and settlement, without notice to or participation
18 by respondents or their counsel. By signing the stipulation, respondents understand and agree
19 that they may not withdraw their agreement or seek to rescind the stipulation prior to the time the
20 Board considers and acts upon it. If the Board fails to adopt this stipulation as its Decision and
21 Order, the Stipulated Settlement and Disciplinary Order shall be of no force or effect, except for
22 this paragraph, it shall be inadmissible in any legal action between the parties, and the Board shall
23 not be disqualified from further action by having considered this matter.

24 12. The parties understand and agree that Portable Document Format (PDF) and facsimile
25 copies of this Stipulated Settlement and Disciplinary Order, including Portable Document Format
26 (PDF) and facsimile signatures thereto, shall have the same force and effect as the originals.

27 13. This Stipulated Settlement and Disciplinary Order is intended by the parties to be an
28 integrated writing representing the complete, final, and exclusive embodiment of their agreement.

1 It supersedes any and all prior or contemporaneous agreements, understandings, discussions,
2 negotiations, and commitments (written or oral). This Stipulated Settlement and Disciplinary
3 Order may not be altered, amended, modified, supplemented, or otherwise changed except by a
4 writing executed by an authorized representative of each of the parties.

5 14. In consideration of the foregoing, the parties agree that the Board may, without
6 further notice or formal proceeding, issue and enter the following Disciplinary Order.

7 **DISCIPLINARY ORDER**

8 **AS TO RESPONDENT MILLS SQUARE**

9 IT IS HEREBY ORDERED that Pharmacy License No. PHY 46487, issued to Respondent
10 Mills Square, is revoked.

11 1. The revocation of respondent's Pharmacy License shall constitute the imposition of
12 discipline against respondent. This stipulation constitutes a record of the discipline and shall
13 become a part of respondent's license history with the Board of Pharmacy.

14 2. Respondent shall lose all rights and privileges as a Pharmacy in California as of the
15 effective date of the Board's Decision and Order.

16 3. Respondent shall cause to be delivered to the Board its pocket license and, if one was
17 issued, its wall certificate(s) on or before the effective date of the Decision and Order.

18 4. Respondent may not apply, reapply, or petition for any licensure or registration of the
19 Board for three (3) years from the effective date of the Decision and Order.

20 5. If Respondent ever files an application for licensure or a petition for reinstatement in
21 the State of California, the Board shall treat it as a petition for reinstatement. Respondent must
22 comply with all the laws, regulations and procedures for reinstatement of a revoked license in
23 effect at the time the petition is filed, and all of the charges and allegations contained in
24 Accusation No. 4248 shall be deemed to be true, correct and admitted by respondent when the
25 Board determines whether to grant or deny the petition.

26 6. Respondents shall be jointly and severally liable for paying the Board its costs of
27 investigation and enforcement in the amount of \$14,500.00. As to Respondent Mills Square, this
28 amount shall be paid in full prior to issuance of a new or reinstated license.

1 7. If respondent should ever apply or reapply for a new license or certification, or
2 petition for reinstatement of a license, by any other health care licensing agency in the State of
3 California, all of the charges and allegations contained in Accusation, No. 4248 shall be deemed
4 to be true, correct, and admitted by respondent for the purpose of any Statement of Issues or any
5 other proceeding seeking to deny or restrict licensure.

6 **AS TO RESPONDENT TSOLAKIS**

7 IT IS HEREBY ORDERED that Pharmacist License No. RPH 49416, issued to Respondent
8 Tsolakis, is revoked. However, the revocation is stayed and respondent is placed on probation for
9 five (5) years on the following terms and conditions.

10 1. **Obey All Laws**

11 Respondent shall obey all state and federal laws and regulations.

12 Respondent shall report any of the following occurrences to the board, in writing, within
13 seventy-two (72) hours of such occurrence:

- 14 • an arrest or issuance of a criminal complaint for violation of any provision of the
15 Pharmacy Law, state and federal food and drug laws, or state and federal controlled
16 substances laws
- 17 • a plea of guilty or nolo contendere in any state or federal criminal proceeding to any
18 criminal complaint, information or indictment
- 19 • a conviction of any crime
- 20 • discipline, citation, or other administrative action filed by any state or federal agency
21 which involves respondent's pharmacist license or which is related to the practice of
22 pharmacy or the manufacturing, obtaining, handling, distributing, billing, or charging
23 for any drug, device or controlled substance.

24 Failure to timely report such occurrence shall be considered a violation of probation.

25 2. **Cooperate with Board Staff**

26 Respondent shall cooperate with the board's inspection program and with the board's
27 monitoring and investigation of respondent's compliance with the terms and conditions of his
28 probation. Failure to cooperate shall be considered a violation of probation.

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3. Report to the Board

Respondent shall report to the board quarterly, on a schedule as directed by the board or its designee. The report shall be made either in person or in writing, as directed. Among other requirements, respondent shall state in each report under penalty of perjury whether there has been compliance with all the terms and conditions of probation. Failure to submit timely reports in a form as directed shall be considered a violation of probation. Any period(s) of delinquency in submission of reports as directed may be added to the total period of probation. Moreover, if the final probation report is not made as directed, probation shall be automatically extended until such time as the final report is made and accepted by the board.

4. Interview with the Board

Upon receipt of reasonable prior notice, respondent shall appear in person for interviews with the board or its designee, at such intervals and locations as are determined by the board or its designee. Failure to appear for any scheduled interview without prior notification to board staff, or failure to appear for two (2) or more scheduled interviews with the board or its designee during the period of probation, shall be considered a violation of probation.

5. Status of License

Respondent shall, at all times while on probation, maintain an active, current license with the board, including any period during which suspension or probation is tolled. Failure to maintain an active, current license shall be considered a violation of probation.

If respondent's license expires or is cancelled by operation of law or otherwise at any time during the period of probation, including any extensions thereof due to tolling or otherwise, upon renewal or reapplication respondent's license shall be subject to all terms and conditions of this probation not previously satisfied.

6. Continuing Education

Respondent shall provide evidence of efforts to maintain skill and knowledge as a pharmacist as directed by the board or its designee.

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1 **7. No Supervision of Interns, Serving as Pharmacist-in-Charge (PIC), Serving as**
2 **Designated Representative-in-Charge, or Serving as a Consultant**

3 During the period of probation, respondent shall not supervise any intern pharmacist, be the
4 pharmacist-in-charge or designated representative-in-charge of any entity licensed by the board,
5 nor serve as a consultant unless otherwise specified in this order. Assumption of any such
6 unauthorized supervision responsibilities shall be considered a violation of probation.

7 **8. Notification of Change in Employment, Name, Address(es), or Phone(s)**

8 Respondent shall notify the board in writing within ten (10) days of any change of
9 employment. Said notification shall include the reasons for leaving, the address of the new
10 employer, the name of the supervisor and owner, and the work schedule if known. Respondent
11 shall further notify the board in writing within ten (10) days of a change in name, residence
12 address, mailing address, or phone number.

13 Failure to timely notify the board of any change in employer(s), name(s), address(es), or
14 phone number(s) shall be considered a violation of probation.

15 **9. No Ownership of Licensed Premises**

16 Respondent shall not own, have any legal or beneficial interest in, or serve as a manager,
17 administrator, member, officer, director, trustee, associate, or partner of any business, firm,
18 partnership, or corporation currently or hereinafter licensed by the board. Respondent shall sell
19 or transfer any legal or beneficial interest in any entity licensed by the board within ninety (90)
20 days following the effective date of this decision and shall immediately thereafter provide written
21 proof thereof to the board. Failure to timely divest any legal or beneficial interest(s) or provide
22 documentation thereof shall be considered a violation of probation.

23 **10. Employment Requirement: Tolling of Probation**

24 Except during periods of suspension, respondent shall, at all times while on probation, be
25 employed as a pharmacist in California for a minimum of forty (40) hours per calendar month.
26 Any month during which this minimum is not met tolls the period of probation, i.e., the period of
27 probation is extended by one month for each month in which the minimum is not met. During
28 any such period of tolling, respondent must comply with all terms and conditions of probation.

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1 Should respondent, regardless of residency, for any reason (including vacation) cease
2 practicing as a pharmacist for a minimum of forty (40) hours per calendar month in California,
3 respondent must notify the board in writing within ten (10) days of the cessation of practice, and
4 must further notify the board in writing within ten (10) days of the resumption of practice. Any
5 failure to provide such notification(s) shall be considered a violation of probation.

6 It is a violation of probation for respondent's probation to remain tolled pursuant to the
7 provisions of this condition for a total period, counting consecutive and non-consecutive months
8 or smaller time periods, exceeding thirty-six (36) months.

9 "Cessation of practice" means any calendar month during which respondent is
10 not practicing as a pharmacist as defined by Business and Professions Code section
11 4000 et seq. for at least forty (40) hours. "Resumption of practice" means any
12 calendar month during which respondent is practicing as a pharmacist as defined by
13 Business and Professions Code section 4000 et seq. for at least forty (40) hours.

14 **11. Notice to Employers**

15 During the period of probation, respondent shall notify all present and prospective
16 employers of the decision in case number 4248 and the terms, conditions and restrictions imposed
17 on respondent by the decision, as follows:

18 Within thirty (30) days of the effective date of this decision, and within fifteen (15) days of
19 respondent undertaking any new employment, respondent shall cause his direct supervisor,
20 pharmacist-in-charge (including each new pharmacist-in-charge employed during respondent's
21 tenure of employment) and owner to report to the board in writing acknowledging that the listed
22 individual(s) has/have read the decision in case number 4248, and terms and conditions imposed
23 thereby. It shall be respondent's responsibility to ensure that his employer(s) and/or supervisor(s)
24 submit timely acknowledgment(s) to the board.

25 If respondent works for or is employed by or through a pharmacy employment service,
26 respondent must notify his direct supervisor, pharmacist-in-charge, and owner at every entity
27 licensed by the board of the terms and conditions of the decision in case number 4248 in advance
28 of the respondent commencing work at each licensed entity. A record of this notification must be
provided to the board upon request.

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1 Furthermore, within thirty (30) days of the effective date of this decision, and within fifteen
2 (15) days of respondent undertaking any employment by or through a pharmacy employment
3 service, respondent shall cause his direct supervisor with the pharmacy employment service to
4 report to the board in writing acknowledging that he has read the decision in case number 4248
5 and the terms and conditions imposed thereby. It shall be respondent's responsibility to ensure
6 that his employer(s) and/or supervisor(s) submit timely acknowledgment(s) to the board.

7 Failure to timely notify present or prospective employer(s) or to cause employer(s) to
8 submit timely acknowledgments to the board shall be considered a violation of probation.

9 "Employment" within the meaning of this provision shall include any full-time,
10 part-time, temporary, relief or pharmacy management service as a pharmacist or any
11 position for which a pharmacist license is a requirement or criterion for employment,
12 whether the respondent is an employee, independent contractor or volunteer.

12 12. Supervised Practice

13 During the period of probation, respondent shall practice only under the supervision of a
14 licensed pharmacist not on probation with the board. Upon and after the effective date of this
15 decision, respondent shall not practice pharmacy and his license shall be automatically suspended
16 until a supervisor is approved by the board or its designee. The supervision shall be, as required
17 by the board or its designee, either:

18 Continuous – At least 75% of a work week

19 Substantial - At least 50% of a work week

20 Partial - At least 25% of a work week

21 Daily Review - Supervisor's review of probationer's daily activities within 24 hours

22 Within thirty (30) days of the effective date of this decision, respondent shall have his
23 supervisor submit notification to the board in writing stating that the supervisor has read the
24 decision in case number 4248 and is familiar with the required level of supervision as determined
25 by the board or its designee. It shall be respondent's responsibility to ensure that his employer(s),
26 pharmacist-in-charge and/or supervisor(s) submit timely acknowledgment(s) to the board. Failure
27 to cause the direct supervisor and the pharmacist-in-charge to submit timely acknowledgements
28 to the board shall be considered a violation of probation.

1 If respondent changes employment, it shall be the respondent's responsibility to ensure that
2 his employer(s), pharmacist-in-charge and/or supervisor(s) submit timely acknowledgment(s) to
3 the board. Respondent shall have his new supervisor, within fifteen (15) days after employment
4 commences, submit notification to the board in writing stating the direct supervisor and
5 pharmacist-in-charge have read the decision in case number 4248 and are familiar with the level
6 of supervision as determined by the board.

7 In this circumstance, respondent shall not practice pharmacy and his license shall be
8 automatically suspended until the board or its designee approves a new supervisor. Failure to
9 cause the direct supervisor and the pharmacist-in-charge to submit timely acknowledgements to
10 the board shall be considered a violation of probation.

11 During any such suspension, respondent shall not enter any pharmacy area or any portion of
12 the licensed premises of a wholesaler, veterinary food-animal drug retailer or any other distributor
13 of drugs which is licensed by the board, or any manufacturer, or where dangerous drugs and
14 devices or controlled substances are maintained. Respondent shall not practice pharmacy nor do
15 any act involving drug selection, selection of stock, manufacturing, compounding, dispensing or
16 patient consultation; nor shall respondent manage, administer, or be a consultant to any licensee
17 of the board, or have access to or control ordering, manufacturing or dispensing of dangerous
18 drugs or controlled substances. Respondent shall not resume practice until notified by the board.

19 During any such suspension, respondent shall not engage in any activity that requires the
20 professional judgment of a pharmacist. Respondent shall not direct or control any aspect of the
21 practice of pharmacy. Respondent shall not perform the duties of a pharmacy technician or a
22 designated representative for any entity licensed by the board.

23 Failure to comply with any such suspension shall be considered a violation of probation.

24 **13. Probation Monitoring Costs**

25 Respondent shall pay any costs associated with probation monitoring as determined by the
26 board each and every year of probation. Such costs shall be payable to the board on a schedule as
27 directed by the board or its designee. Failure to pay such costs by the deadline(s) as directed shall
28 be considered a violation of probation.

1 **14. Reimbursement of Board Costs**

2 Respondents shall be jointly and severally liable for paying the Board its costs of
3 investigation and enforcement in the amount of \$14,500.00. As to Respondent Tsolakis, it shall
4 be a condition precedent to successful completion of probation that respondent pay this amount in
5 full. Respondent shall be permitted to pay these costs in a payment plan approved by the Board
6 or its designee, so long as full payment is made within fifty-four (54) months of the effective date
7 of this decision. There is to be no deviation from this schedule absent prior written approval by
8 the Board or its designee. Failure to pay costs by the deadline(s) as directed shall be considered a
9 violation of probation.

10 The filing of bankruptcy by respondent shall not relieve respondent of his responsibility to
11 reimburse the board its costs of investigation and prosecution.

12 **15. Community Services Program**

13 Within sixty (60) days of the effective date of this decision, respondent shall submit to the
14 board or its designee, for prior approval, a community service program in which respondent shall
15 provide free health-care related services on a regular basis to a community or charitable facility or
16 agency for at least fifty-six (56) hours per year for each year of probation (280 hours total).
17 Within thirty (30) days of board approval thereof, respondent shall submit documentation to the
18 board demonstrating commencement of the community service program. Respondent shall report
19 on progress with the community service program in the quarterly reports. Failure to timely
20 submit, commence, or comply with the program shall be considered a violation of probation.

21 With prior approval from the board or its designee, respondent may accelerate completion
22 of his community service hours by completing more than fifty (50) hours in any given year.

23 **16. Ethics Course**

24 Within sixty (60) calendar days of the effective date of this decision, respondent shall, at his
25 own expense, enroll in a course in ethics approved in advance by the board or its designee.
26 Respondent shall submit a certificate of completion to the board or its designee within five (5)
27 days after completing the course. Failure to initiate the course during the first year of probation,
28 and complete it within the second year of probation, shall be considered a violation of probation.

1 **17. License Surrender While on Probation/Suspension**

2 Following the effective date of this decision, should respondent cease practice due to
3 retirement or health, or be otherwise unable to satisfy the terms and conditions of probation,
4 respondent may tender his license to the board for surrender. The board or its designee shall have
5 the discretion whether to grant the request for surrender or take any other action it deems
6 appropriate and reasonable. Upon formal acceptance of the surrender of the license, respondent
7 will no longer be subject to the terms and conditions of probation. This surrender constitutes a
8 record of discipline and shall become a part of the respondent's license history with the board.

9 Upon acceptance of the surrender, respondent shall relinquish his pocket and wall license to
10 the board within ten (10) days of notification by the board that surrender is accepted. Respondent
11 may not reapply for any license from the board for three (3) years from the effective date of the
12 surrender. Respondent shall meet all requirements applicable to the license sought as of the date
13 the application for that license is submitted to the board, including any outstanding costs.

14 **18. Violation of Probation**

15 If a respondent has not complied with any term or condition of probation, the board shall
16 have continuing jurisdiction over respondent, and probation shall automatically be extended, until
17 all terms and conditions have been satisfied or the board has taken other action as deemed
18 appropriate to treat the failure to comply as a violation of probation, to terminate probation, and
19 to impose the penalty that was stayed.

20 If respondent violates probation in any respect, the board, after giving respondent notice
21 and an opportunity to be heard, may revoke probation and carry out the disciplinary order that
22 was stayed. If a petition to revoke probation or an accusation is filed against respondent during
23 probation, the board shall have continuing jurisdiction and the period of probation shall be
24 automatically extended until the petition to revoke probation or accusation is heard and decided.

25 **19. Completion of Probation**

26 Upon written notice by the board or its designee indicating successful completion of
27 probation, respondent's license will be fully restored.

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ACCEPTANCE

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I am authorized to sign for Respondent Mills Square. I have carefully read the above Stipulated Settlement and Disciplinary Order and have fully discussed it with my attorney, Lucy S. McAllister. I understand the stipulation and the effect it will have on my Pharmacy License. I enter into this Stipulated Settlement and Disciplinary Order voluntarily, knowingly, and intelligently, and agree to be bound by the Decision and Order of the Board of Pharmacy.

DATED: 5/14/2014 Frank Tsolakis
Frank Tsolakis, for
MILLS SQUARE PHARMACY
Respondent

I have carefully read the above Stipulated Settlement and Disciplinary Order and have fully discussed it with my attorney, Lucy S. McAllister. I understand the stipulation and the effect it will have on my Pharmacist License. I enter into this Stipulated Settlement and Disciplinary Order voluntarily, knowingly, and intelligently, and agree to be bound by the Decision and Order of the Board of Pharmacy.

DATED: 5/14/2014 Frank Tsolakis
FRANK TSOLAKIS
Respondent

I have read and fully discussed with Frank Tsolakis the terms and conditions and other matters contained in the above Stipulated Settlement and Disciplinary Order. I approve its form and content.

DATED: 5/15/2014 Lucy S. McAllister
LUCY S. MCALLISTER
Attorney for Respondents

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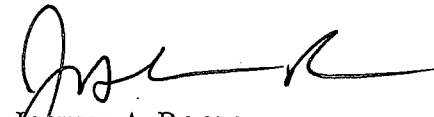
ENDORSEMENT

The foregoing Stipulated Settlement and Disciplinary Order is hereby respectfully submitted for consideration by the Board of Pharmacy.

Dated: 5/20/2014

Respectfully submitted,

KAMALA D. HARRIS
Attorney General of California
FRANK H. PACOE
Supervising Deputy Attorney General



JOSHUA A. ROOM
Supervising Deputy Attorney General
Attorneys for Complainant

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40966246.doc

Exhibit A

Accusation No. 4248

1 KAMALA D. HARRIS
Attorney General of California
2 FRANK H. PACOE
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3 JOSHUA A. ROOM
Supervising Deputy Attorney General
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Attorneys for Complainant

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12 11 S. San Mateo Drive	
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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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FOURTH CAUSE FOR DISCIPLINE

(Failure to Report Controlled Substance Prescriptions to CURES)

34. Respondents are subject to discipline under section(s) 4301(j) and/or (o), and/or 4113(c) of the Code, and/or Health and Safety Code section 11165, 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, between in or about March 2010 and February 9, 2011, the pharmacy had not successfully transmitted controlled substances dispensing data to CURES.

FIFTH CAUSE FOR DISCIPLINE

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

35. 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 1714, 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, at least three (3) non-pharmacist staff of the pharmacy were in possession of key(s) to the pharmacy.

SIXTH CAUSE FOR DISCIPLINE

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

36. 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 1715, 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 Respondent Tsolakakis failed to complete 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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1 TENTH CAUSE FOR DISCIPLINE

2 (Unprofessional Conduct)

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

5
6 **CAUSE FOR DISCIPLINE, SOLELY AS TO RESPONDENT MILLS SQUARE**

7 ELEVENTH CAUSE FOR DISCIPLINE

8 (Failure to Comply With/Pay Citation Fine)

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

13
14 DISCIPLINE CONSIDERATIONS

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

17 a. On or about November 15, 2007, Citation No. CI 2007 33797, with a \$2,250.00 fine
18 (subsequently reduced to zero), was issued to Respondent Mills Square, for: (1) failing to comply
19 with California Code of Regulations, title 16, section 1716, by varying from prescription; (2)
20 failing to comply with Health and Safety Code section 11165 by not reporting controlled
21 substance prescriptions dispensed to the Controlled Substance Utilization Review and Evaluation
22 System (CURES); (3) failing to comply with California Code of Regulations, title 16, section
23 1711, by failing to complete a quality assurance review relating to a prescription error; (4) failing
24 to comply with California Code of Regulations, title 16, section 1715.5, by failing to implement
25 an electronic monitoring system for Schedule II controlled substance prescriptions; and (5) failing
26 to comply with section 4076, subdivision (a)(11)(a) of the Code, by dispensing medication(s)
27 with a label lacking a physical description of the medication. A modified citation was issued on
28 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:

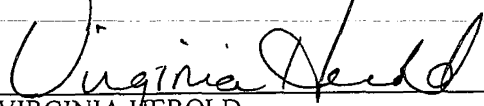
12 1. Revoking or suspending Pharmacy License No. PHY 46847, issued to Medicross
13 Pharmaceutical Services dba Mills Square Pharmacy (Respondent Mills Square);

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

25 SF2012401273
26 40737291.doc