

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

In the Matter of the Accusation Against:

**KOVAC'S PHARMACY
14423 Gilmore Street
Van Nuys, CA 91401
Original Permit No. PHY 49968**

**IRINA PUSTILNIKOVA
4029 Madelia Avenue
Sherman Oaks, CA 91403
Registered Pharmacist No. RPH 57750**

Respondent.

Case No. 3943

OAH NO.: 2011090249

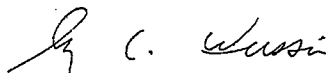
DECISION AND ORDER

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 May 18, 2012.

It is so ORDERED on April 18, 2012.

BOARD OF PHARMACY
DEPARTMENT OF CONSUMER AFFAIRS
STATE OF CALIFORNIA



By

STANLEY C. WEISSER
Board President

1 KAMALA D. HARRIS
Attorney General of California
2 KAREN B. CHAPPELLE
Supervising Deputy Attorney General
3 RENE JUDKIEWICZ
Deputy Attorney General
4 State Bar No. 141773
300 So. Spring Street, Suite 1702
5 Los Angeles, CA 90013
Telephone: (213) 897-2537
6 Facsimile: (213) 897-2804
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. 3943

11 **KOVAC'S PHARMACY; IRINA**
12 **PUSTILNIKOVA**
13 **14423 Gilmore Street**
Van Nuys, CA 91401
14 **Original Permit No. PHY No. 49968**
Registered Pharmacist No. RPH 57750

OAH No. 2011090249

STIPULATED SETTLEMENT AND
DISCIPLINARY ORDER

15
16 Respondents.

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18 IT IS HEREBY STIPULATED AND AGREED by and between the parties to the above-
19 entitled proceedings that the following matters are true:

20 PARTIES

21 1. Virginia Herold (Complainant) is the Executive Officer of the Board of Pharmacy
22 (Board). She brought this action solely in her official capacity and is represented in this matter by
23 Kamala D. Harris, Attorney General of the State of California, by Rene Judkiewicz, Deputy
24 Attorney General.

25 2. Kovac's Pharmacy and Irina Pustilnikova (Respondents) are represented in this
26 proceeding by attorney Noah E. Jussim, whose address is: McGuireWoods LLP, 1800 Century
27 Park East, 8th Floor, Los Angeles, California 90067.

1 15. In consideration of the foregoing admissions and stipulations, the parties agree that
2 the Board may, without further notice or formal proceeding, issue and enter the following
3 Disciplinary Order:

4 **DISCIPLINARY ORDER**

5 IT IS HEREBY ORDERED that Original Permit No. PHY 49968 issued to Respondent-
6 Pharmacy Kovac's Pharmacy and that Registered Original Pharmacist License No. RPH 57750
7 issued to Respondent-Pharmacist Irina Pustilnikova are revoked. However, the revocation is
8 stayed, and Respondents are placed on probation for five (5) years on the following terms and
9 conditions.

10 **1. Community Services Program**

11 Within sixty (60) days of the effective date of this decision, Respondents shall submit to the
12 Board or its designee, for prior approval, a community service program in which Respondent-
13 Pharmacy shall provide free health-care related services on a regular basis to a community or
14 charitable facility or agency for at least fifty (50) hours per each year of probation, and
15 Respondent-Pharmacist shall provide free health-care related services on a regular basis to a
16 community or charitable facility or agency for at least ^{fifty (50) hours} ~~one hundred (100)~~ hours per each year of
17 probation. Within thirty (30) days of Board approval thereof, Respondents shall submit
18 documentation to the Board demonstrating commencement of the community service program. A
19 record of this notification must be provided to the Board upon request. Respondents shall report
20 on progress with the community service program in the quarterly reports. Failure to timely
21 submit, commence, or comply with the program shall be considered a violation of probation.

22 **2. Obey All Laws**

23 Respondents shall obey all state and federal laws and regulations.

24 Respondents shall report any of the following occurrences to the Board, in writing, within
25 seventy-two (72) hours of such occurrence:

- 26 an arrest or issuance of a criminal complaint for violation of any provision of the
27 Pharmacy Law, state and federal food and drug laws, or state and federal controlled
28 substances laws;

- 1 an arrest or issuance of a criminal complaint for violation of any state or federal law;
- 2 a plea of guilty or nolo contendere in any state or federal criminal proceeding to any
- 3 criminal complaint, information or indictment;
- 4 a conviction of any crime; and
- 5 discipline, citation, or other administrative action filed by any state or federal agency
- 6 which involves Respondents' Original Permit No. PHY 49968 or Registered Original
- 7 Pharmacist License No. RPH 57750, or which is related to the practice of pharmacy
- 8 or the manufacturing, obtaining, handling or distribution or billing or charging for of
- 9 any drug, device or controlled substance.

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

11 **3. Report to the Board**

12 Respondents shall report to the Board quarterly, on a schedule as directed by the Board or

13 its designee. The report shall be made either in person or in writing, as directed. Among other

14 requirements, Respondents shall state in each report under penalty of perjury whether there has

15 been compliance with all the terms and conditions of probation. Failure to submit timely reports

16 in a form as directed shall be considered a violation of probation. Any period(s) of delinquency

17 in submission of reports as directed may be added to the total period of probation. Moreover, if

18 the final probation report is not made as directed, probation shall be automatically extended until

19 such time as the final report is made and accepted by the Board.

20 **4. Interview with the Board**

21 Upon receipt of reasonable prior notice, Respondent-Pharmacist shall appear in person for

22 interviews with the Board or its designee, upon request at such intervals and locations as are

23 determined by the Board or its designee. Failure to appear for any scheduled interview without

24 prior notification to Board staff, or failure to appear for two (2) or more scheduled interviews

25 with the Board or its designee during the period of probation, shall be considered a violation of

26 probation.

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1 **5. Cooperate with Board Staff**

2 Respondents shall cooperate with the Board's inspection program and with the Board's
3 monitoring and investigation of Respondents' compliance with the terms and conditions of their
4 probation. Failure to cooperate shall be considered a violation of probation.

5 **6. Continuing Education**

6 Respondent-Pharmacist shall provide evidence of efforts to maintain skill and knowledge as
7 a pharmacist as directed by the Board or its designee.

8 **7. Notice to Employers**

9 During the period of probation, Respondent-Pharmacist shall notify all present and
10 prospective employers of the decision in Board Case Number 3943 and the terms, conditions and
11 restrictions imposed on Respondent-Pharmacist by the decision, as follows:

12 Within thirty (30) days of the effective date of this decision, and within fifteen (15) days of
13 Respondent-Pharmacist undertaking any new employment, Respondent-Pharmacist shall cause
14 her direct supervisor, pharmacist-in-charge (including each new pharmacist-in-charge employed
15 during Respondent-Pharmacist's tenure of employment) and owner to report to the Board in
16 writing acknowledging that the listed individual(s) has/have read the decision in Board Case
17 Number 3943, and terms and conditions imposed thereby. It shall be Respondent-Pharmacist's
18 responsibility to ensure that her employer(s) and/or supervisor(s) submit timely
19 acknowledgment(s) to the Board.

20 If Respondent-Pharmacist works for or is employed by or through a pharmacy employment
21 service, she must notify her direct supervisor, pharmacist-in-charge, and owner at every entity
22 licensed by the Board of the terms and conditions of the decision in Board Case Number 3943 in
23 advance of Respondent-Pharmacist commencing work at each licensed entity. A record of this
24 notification must be provided to the Board upon request.

25 Furthermore, within thirty (30) days of the effective date of this decision, and within fifteen
26 (15) days of Respondent-Pharmacist undertaking any new employment by or through a pharmacy
27 employment service, Respondent-Pharmacist shall cause her direct supervisor with the pharmacy
28 employment service to report to the Board in writing acknowledging that the supervisor has read

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1 the decision in Board Case Number 3943 and the terms and conditions imposed thereby. It shall
2 be Respondent-Pharmacist's responsibility to ensure that her employer(s) and/or supervisor(s)
3 submit timely acknowledgment(s) to the Board.

4 Failure to timely notify present or prospective employer(s) or to cause that/those
5 employer(s) to submit timely acknowledgments to the Board shall be considered a violation of
6 probation.

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

12 **8. No Supervision of Interns, Serving as Pharmacist-in-Charge (PIC), Serving as**
13 **Designated Representative-in-Charge, or Serving as a Consultant**

14 During the period of probation, Respondent-Pharmacist shall not supervise any intern
15 pharmacist, be the pharmacist-in-charge or designated representative-in-charge of any entity
16 licensed by the Board, and shall not serve as a consultant, except that Respondent-Pharmacist is
17 authorized to be the designated Pharmacist-in-Charge of Respondent-Pharmacy Kovac's
18 Pharmacy provided that Respondent-Pharmacist has a Board-approved consultant who provides
19 the Board or its designee with monthly reviews, as detailed in Probation Term 11 below.
20 Assumption of any such unauthorized supervision responsibilities shall be considered a violation
21 of probation.

22 **9. Consultant for Owner or Pharmacist-In-Charge**

23 During the period of probation, Respondent-Pharmacist shall not supervise any intern
24 pharmacist or serve as a consultant to any entity licensed by the Board. Respondent-Pharmacist
25 may be a pharmacist-in-charge of Respondent-Pharmacy Kovac's Pharmacy. However, if, during
26 the period of probation, Respondent-Pharmacist serves as a pharmacist-in-charge of Respondent-
27 Pharmacy Kovac's Pharmacy, Respondent-Pharmacist shall retain an independent consultant at
28 Respondents' own expense, and the independent consultant shall be responsible for reviewing

1 pharmacy operations on a monthly basis for compliance by Respondents with state and federal
2 laws and regulations governing the practice of pharmacy and for compliance by Respondent-
3 Pharmacist with the obligations of a pharmacist-in-charge. The consultant shall be a pharmacist
4 licensed by and not on probation with the Board and whose name shall be submitted to the Board
5 or its designee, for prior approval, within thirty (30) days of the effective date of this decision.
6 Respondent-Pharmacist shall not be a pharmacist-in-charge at more than one pharmacy or at any
7 pharmacy of which she is not the sole owner. Failure to timely retain, seek approval of, or ensure
8 timely reporting by the consultant shall be considered a violation of probation.

9 **10. Ethics Course**

10 Within sixty (60) calendar days of the effective date of this decision, Respondent-
11 Pharmacist shall enroll in a course in ethics, at Respondents' expense, approved in advance by the
12 Board or its designee. Failure to initiate the course during the first year of probation, and
13 complete it within the second year of probation, is a violation of probation.

14 Respondents shall submit a certificate of completion to the Board or its designee within five
15 (5) days after Respondent-Pharmacist completing the course.

16 **11. Remedial Education**

17 Within ninety (90) days of the effective date of this decision, Respondent-Pharmacist
18 submit to the Board or its designee, for prior approval, an appropriate program of remedial
19 education related the grounds for discipline. The program of remedial education shall consist of
20 at least eight (8) hours, which shall be completed within twenty-four (24) months of the effective
21 date of the decision, at Respondents' own expense. All remedial education shall be in addition to,
22 and shall not be credited toward, continuing education (CE) courses used for license renewal
23 purposes.

24 Failure to timely submit or complete the approved remedial education shall be considered a
25 violation of probation. The period of probation will be automatically extended until such
26 remedial education is successfully completed and written proof, in a form acceptable to the
27 Board, is provided to the Board or its designee.

28 **12. Separate File of Records**

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1 Respondents shall maintain and make available for inspection a separate file of all records
2 pertaining to the acquisition or disposition of all controlled substances. Failure to maintain such
3 file or make it available for inspection shall be considered a violation of probation.

4 **13. No Ownership of Licensed Premises**

5 Respondent-Pharmacist shall not own, have any legal or beneficial interest in, or serve as a
6 manager, administrator, member, officer, director, trustee, associate, or partner of any business,
7 firm, partnership, or corporation currently or hereinafter licensed by the Board, with the exception
8 of Respondent-Pharmacy pursuant to the probation terms and conditions set forth in the herein
9 Disciplinary Order. Except for with respect to Respondent-Pharmacy, Respondent-Pharmacist
10 shall sell or transfer any legal or beneficial interest in any entity licensed by the Board within
11 ninety (90) days following the effective date of this decision, and shall immediately thereafter
12 provide written proof thereof to the Board. Failure to timely divest any legal or beneficial
13 interest(s) or provide documentation thereof shall be considered a violation of probation.

14 Respondent-Pharmacist shall not acquire any new ownership, legal or beneficial interest,
15 nor serve as a manager, administrator, member, officer, director, trustee, associate, or partner of
16 any additional business, firm, partnership, or corporation licensed by the Board. If Respondent-
17 Pharmacist currently owns or has any legal or beneficial interest in, or serves as a manager,
18 administrator, member, officer, director, trustee, associate, or partner of any business, firm,
19 partnership, or corporation currently or hereinafter licensed by the board, Respondent may
20 continue to serve in such capacity or hold that interest, but only to the extent of that position or
21 interest as of the effective date of this decision. Violation of this restriction shall be considered a
22 violation of probation.

23 **14. Notice to Employees**

24 Respondent-Pharmacy shall, upon or before the effective date of this decision, ensure that
25 all employees involved in permit operations are made aware of all the terms and conditions of
26 probation, either by posting a notice of the terms and conditions, circulating such notice, or both.
27 If the notice required by this provision is posted, it shall be posted in a prominent place and shall
28 remain posted throughout the probation period. Respondent-Pharmacy shall ensure that any

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1 employees hired or used after the effective date of this decision are made aware of the terms and
2 conditions of probation by posting a notice, circulating a notice, or both. Additionally,
3 Respondent-Pharmacy shall submit written notification to the Board, within fifteen (15) days of
4 the effective date of this decision, that this term has been satisfied. Failure to submit such
5 notification to the Board shall be considered a violation of probation.

6 "Employees" as used in this provision includes all full-time, part-time,
7 volunteer, temporary and relief employees and independent contractors employed or
8 hired at any time during probation.

9 **15. Posted Notice of Probation**

10 Respondent-Pharmacy shall prominently post a probation notice provided by the Board in a
11 place conspicuous and readable to the public. The probation notice shall remain posted during
12 the entire period of probation.

13 Respondent-Pharmacy shall not, directly or indirectly, engage in any conduct or make any
14 statement which is intended to mislead or is likely to have the effect of misleading any patient,
15 customer, member of the public, or other person(s) as to the nature of and reason for the probation
16 of the licensed entity.

17 Failure to post such notice shall be considered a violation of probation.

18 **16. Reimbursement of Board Costs**

19 As a condition precedent to successful completion of probation, Respondents shall pay to
20 the Board its costs of investigation and prosecution in the amount of \$8,518.00. Respondents are
21 jointly and severally liable for costs, to be paid in full within thirty (30) days of the effective date
22 of the Board's decision. There shall be no deviation from this schedule absent prior written
23 approval by the Board or its designee. Failure to pay costs by the deadline(s) as directed shall be
24 considered a violation of probation.

25 The filing of bankruptcy by Respondents shall not relieve Respondents of their
26 responsibility to reimburse the Board its costs of investigation and prosecution.

27 **17. Probation Monitoring Costs**

28 Respondents shall pay any costs associated with probation monitoring as determined by the

1 Board each and every year of probation. Such costs shall be payable to the Board on a schedule
2 as directed by the Board or its designee. Failure to pay such costs by the deadline(s) as directed
3 shall be considered a violation of probation.

4 **18. Status of Permit and License**

5 Respondents shall, at all times while on probation, maintain an active, current ~~designated~~
6 ^{pharmacy} representative permit and ^{pharmacist's} license with the Board, including any period during which suspension
7 or probation is tolled. Failure to maintain an active, current permit and license shall be
8 considered a violation of probation.

9 If Respondents' ~~designated~~ ^{pharmacy} representative permit or ^{pharmacist's} license expires or is cancelled by
10 operation of law or otherwise at any time during the period of probation, including any extensions
11 thereof due to tolling or otherwise, upon renewal or reapplication Respondents' permit or license
12 shall be subject to all terms and conditions of this probation not previously satisfied.

13 **19. License Surrender While on Probation/Suspension**

14 Following the effective date of this decision, should Respondent-Pharmacist cease work
15 due to retirement or health, or be otherwise unable to satisfy the terms and conditions of
16 probation, Respondent-Pharmacist may tender her ~~designated~~ ^{pharmacist's} representative license to the Board
17 for surrender. The Board or its designee shall have the discretion whether to grant the request for
18 surrender or take any other action it deems appropriate and reasonable. Upon formal acceptance
19 of the surrender of the license, Respondent-Pharmacist will no longer be subject to the terms and
20 conditions of probation. This surrender constitutes a record of discipline and shall become a part
21 of the Respondent-Pharmacist's license history with the Board.

22 Upon acceptance of the surrender, Respondents shall relinquish their ~~designated~~ ^{pharmacy}
23 ^{or pharmacist's} representative permit and license to the Board within ten (10) days of notification by the Board
24 that the surrender is accepted. Respondents may not reapply for any license, permit, or
25 registration from the board for three (3) years from the effective date of the surrender.

26 Respondents shall meet all requirements applicable to the permit and license sought as of the date
27 the application for that permit and/or license is submitted to the Board.

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1 **20. Notification of a Change in Name, Residence Address, Mailing Address or**
2 **Employment**

3 Respondent-Pharmacist shall notify the Board in writing within ten (10) days of any change
4 of employment. Said notification shall include the reasons for leaving and the address of the new
5 employer, supervisor and owner and work schedule, if known. Respondents shall further notify
6 the Board in writing within ten (10) days of a change in name, residence address and mailing
7 address, or phone number.

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

10 **21. Tolling of Probation**

11 Except during periods of suspension, Respondent-Pharmacist shall, at all times while on
12 probation, be employed as a designated representative in California for a minimum of forty (40)
13 hours per calendar month. Any month during which this minimum is not met shall toll the period
14 of probation, i.e., the period of probation shall be extended by one month for each month during
15 which this minimum is not met. During any such period of tolling of probation, Respondent-
16 Pharmacist must nonetheless comply with all terms and conditions of probation.

17 Should Respondent-Pharmacist, regardless of residency, for any reason (including vacation)
18 cease working as a ^{pharmacist} ~~designated representative~~ for a minimum of 40 hours in California,
19 Respondent-Pharmacist must notify the Board in writing within ten (10) days of cessation of
20 work and must further notify the Board in writing within ten (10) days of the resumption of work.
21 Any failure to provide such notification(s) shall be considered a violation of probation.

22 It is a violation of probation for Respondents' probation to remain tolled pursuant to the
23 provisions of this condition for a total period, counting consecutive and non-consecutive months,
24 exceeding thirty-six (36) months.

25 " Cessation of work " means any calendar month during which Respondent-
26 Pharmacist is not working as a designated representative for at least 40 hours as a
27 designated representative as defined by Business and Professions Code section 4053.

28 " Resumption of work " means any calendar month during which Respondent-

pharmacist

1 Pharmacist is working as a ~~designated representative~~ for at least 40 hours as a
2 designated representative as defined by Business and Professions Code section 4053.

3 **22. Violation of Probation**

4 If Respondents have not complied with any term or condition of probation, the Board shall
5 have continuing jurisdiction over Respondents, and probation shall automatically be extended
6 until all terms and conditions have been satisfied or the Board has taken other action as deemed
7 appropriate to treat the failure to comply as a violation of probation, to terminate probation, and
8 to impose the penalty that was stayed.

9 If Respondents violate probation in any respect, the Board, after giving Respondents notice
10 and an opportunity to be heard, may revoke probation and carry out the disciplinary order that
11 was stayed. Notice and opportunity to be heard are not required for those provisions stating that a
12 violation thereof may lead to automatic termination of the stay and/or revocation of the license. If
13 a petition to revoke probation or an accusation is filed against Respondents during probation, the
14 Board shall have continuing jurisdiction, and the period of probation shall be automatically
15 extended, until the petition to revoke probation or accusation is heard and decided.

16 **23. Completion of Probation**

17 Upon written notice by the Board indicating successful completion of probation,
18 Respondents' licenses will be fully restored.

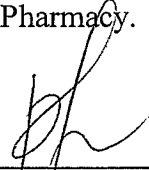
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ACCEPTANCE

I have carefully read the above Stipulated Settlement and Disciplinary Order and have fully discussed it with my attorney, Noah E. Jussim. I understand the stipulation and the effect it will have on both my pharmacy Kovac's Pharmacy's Original Permit and my Registered Original Pharmacist License. I enter into this Stipulated Settlement and Disciplinary Order voluntarily, knowingly, and intelligently, and agree that both my pharmacy Kovac's Pharmacy and I are to be bound by the Decision and Order of the Board of Pharmacy.

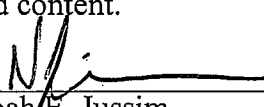
DATED: 2-17-12



IRINA PUSTILNIKOVA
In my individual capacity and as Pharmacist-in-Charge
of Kovac's Pharmacy
Respondents

I have read and fully discussed with Respondent-Pharmacist Irina Pustilnikova in her individual capacity and as the Pharmacist-in-Charge of Respondent-Pharmacy Kovac's Pharmacy the terms and conditions and other matters contained in the above Stipulated Settlement and Disciplinary Order. I approve its form and content.

DATED: 2/17/12



Noah E. Jussim
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 of the Department of Consumer Affairs.

Dated: 2/17/12

Respectfully submitted,

KAMALA D. HARRIS
Attorney General of California
KAREN B. CHAPPELLE
Supervising Deputy Attorney General



RENE JUDKIEWICZ
Deputy Attorney General
Attorneys for Complainant

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Exhibit A

Accusation No. 3943

1 KAMALA D. HARRIS
Attorney General of California
2 KAREN B. CHAPPELLE
Supervising Deputy Attorney General
3 RENE JUDKIEWICZ
Deputy Attorney General
4 State Bar No. 141773
300 So. Spring Street, Suite 1702
5 Los Angeles, CA 90013
Telephone: (213) 897-2537
6 Facsimile: (213) 897-2804
Attorneys for Complainant

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

11 In the Matter of the Accusation Against:

Case No. 3943

12 **KOVAC'S PHARMACY**
1423 Gilmore Street
13 Van Nuys, CA 91401
Original Permit No. PHY 49968,

A C C U S A T I O N

14 **and**

15 **IRINA PUSTILNIKOVA**
14844 Dickens St., #101
16 Los Angeles, CA 91403
17 Registered Pharmacist No. RPH 57750

18 Respondents.

19
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 (Board), Department of Consumer Affairs.
- 24 2. On or about August 19, 2009, the Board issued Original Permit Number PHY 49968
25 to Kovac's Pharmacy (Respondent-Pharmacy). The Original Permit was in full force and effect
26 at all times relevant to the charges brought herein and will expire on August 1, 2011, unless
27 renewed.

STATUTORY AND REGULATORY LAW

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2 7. Section 4022 of the Code defines the term “dangerous drug” as “any drug . . . unsafe
3 for self-use in humans or animals, and includes the following:

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

6

7 “(c) Any other drug . . . that by federal or state law can be lawfully dispensed only on
8 prescription”

9 8. Section 4037, subdivision (a) of the Code defines the term “pharmacy” as meaning
10 “an area, place, or premises licensed by the board in which the profession of pharmacy is
11 practiced and where prescriptions are compounded. ‘Pharmacy’ includes, but is not limited to,
12 any area, place, or premises described in a license issued by the board wherein controlled
13 substances, dangerous drugs, or dangerous devices are stored, possessed, prepared, manufactured,
14 derived, compounded, or repackaged, and from which the controlled substances, dangerous drugs,
15 or dangerous devices are furnished, sold, or dispensed at retail.”

16 9. Section 4076 of the Code states, in pertinent part:

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

19

20 “(11)(A) Commencing January 1, 2006, the physical description of the dispensed
21 medication, including its color, shape, and any identification code that appears on the tablets or
22 capsules”

23 10. Section 4104, subdivision (b) of the Code states: “Every pharmacy shall have written
24 policies and procedures for addressing chemical, mental, or physical impairment, as well as theft,
25 diversion, or self-use of dangerous drugs, among licensed individuals employed by or with the
26 pharmacy.”

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11. Section 4169, subdivision (a) of the Code states, in pertinent part:

“A person or entity may not do any of the following:

....

“(3) Purchase, trade, sell, or transfer dangerous drugs that the person knew or reasonably should have known were misbranded, as defined in Section 111335 of the Health and Safety Code.”

12. Section 4301 of the Code states, in pertinent part:

“The board shall take action against any holder of a license who is guilty of unprofessional conduct. Unprofessional conduct shall include, but is not limited to, any of the following:

....

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

....

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

13. Section 4342, subdivision (a) of the Code states, “The board may institute any action or actions as may be provided by law and that, in its discretion, are necessary, to prevent the sale of pharmaceutical preparations and drugs that do not conform to the standard and tests as to quality and strength, provided in the latest edition of the United States Pharmacopoeia or the National Formulary, or that violate any provision of the Sherman Food, Drug and Cosmetic Law (Part 5 (commencing with Section 109875) of Division 104 of the Health and Safety Code).”

14. Section 110290 of the Health and Safety Code states, in pertinent part: “In determining whether the labeling or advertisement of a . . . drug . . . is misleading, all representations made or suggested by statement, word, design, device, sound, or any combination of these, shall be taken into account. The extent that the labeling or advertising fails to reveal

1 facts concerning the . . . drug . . . or consequences of customary use of the . . . drug . . . shall also
2 be considered.”

3 15. Section 111335 of the Health and Safety Code states, in pertinent part: “Any drug . . .
4 is misbranded if its labeling or packaging does not conform to the requirements of Chapter 4
5 (commencing with Section 110290).”

6 16. California Code of Regulations, title 16, section 1715, states, in pertinent part:

7 “(a) The pharmacist-in-charge of each pharmacy as defined under . . . section 4037 . . . shall
8 complete a self-assessment of the pharmacy’s compliance with federal and state pharmacy law.
9 The assessment shall be performed before July 1 of every odd-numbered year. The primary
10 purpose of the self-assessment is to promote compliance through self-examination and education.

11 “(b) In addition to the self-assessment required in subdivision (a) of this section, the
12 pharmacist-in-charge shall complete a self-assessment within 30 days whenever:

13 “(1) A new pharmacy permit has been issued”

14 17. California Code of Regulations, title 16, section 1717, states, in pertinent part:

15

16 “(b) [T]he following information shall be maintained for each prescription on file and shall
17 be readily retrievable:

18

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

21 18. Code of Federal Regulations, title 21, section 1306.22, subdivision (f) authorizes use
22 of a computer application “for the storage and retrieval of refill information for original paper
23 prescription orders for controlled substances in Schedule III and IV” subject to enumerated
24 conditions including:

25 “(3) Documentation of the fact that the refill information entered into the computer each
26 time a pharmacist refills an original paper, fax, or oral prescription order for a Schedule III or IV
27 controlled substance is correct must be provided by the individual pharmacist who makes use of
28 such an application. If such an application provides a hard-copy printout of each day’s controlled

1 substance prescription order refill data, that printout shall be verified, dated, and signed by the
2 individual pharmacist who refilled such a prescription order. The individual pharmacist must
3 verify that the data indicated are correct and then sign this document in the same manner as he
4 would sign a check or legal document (e.g., J.H. Smith, or John H. Smith). . . . This printout of
5 the day's controlled substance prescription order refill data must be provided to each pharmacy
6 using such a computerized application within 72 hours of the date on which the refill was
7 dispensed. It must be verified and signed by each pharmacist who is involved with such
8 dispensing. In lieu of such a printout, the pharmacy shall maintain a bound log book, or separate
9 file, in which each individual pharmacist involved in such dispensing shall sign a statement (in
10 the manner previously described) each day, attesting to the fact that the refill information entered
11 into the computer that day has been reviewed by him and is correct as shown. . . ."²

12 REASONABLE COSTS

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

17 FIRST CAUSE FOR DISCIPLINE

18 (Failure to Complete Self-Assessment Prior to Inspection Date)

19 20. Respondents are subject to disciplinary action under Code sections 4300 and 4301
20 and under subdivisions (a) and (b)(1) of section 1715 of title 16 of the California Code of
21 Regulations in that Respondents failed to complete a timely self-assessment of Respondent-
22 Pharmacy's compliance with federal and state pharmacy laws. The circumstances are as
23 follows:

24 a. On or about May 19, 2010, a Board inspection was conducted at
25 Respondent-Pharmacy. The Board inspector requested Respondent-Pharmacist to give the
26 inspector a completed self-assessment form, which Respondent-Pharmacist had been required to

27 ² Section 11056 of the Health and Safety Code lists Schedule III controlled substances,
28 and section 11057 of the Health and Safety Code lists Schedule IV controlled substances.

1 fill out when she had received her new permit for Respondent-Pharmacy. Respondent-Pharmacist
2 did not complete the form, and, instead, during the inspection, Respondent-Pharmacy's office
3 manager began to fill out the form which Respondent-Pharmacist was required to complete.

4 SECOND CAUSE FOR DISCIPLINE

5 (Misbranded Bubble-Packed Dangerous Drugs)

6 21. Respondents are subject to disciplinary action under Code sections 4300 and 4301 in
7 that Respondents had misbranded bubble-packed dangerous drugs, in violation of Health and
8 Safety Code sections 111335 and 110290. The circumstances are as follows:

9 a. On or about May 19, 2010, Respondents allowed their staff to repackage drugs from
10 labeled stock containers into unlabeled bubble packs that failed to have the complete facts
11 concerning the drugs as they relate to the drug name, strength, lot number, expiration date or
12 manufacturer.

13 THIRD CAUSE FOR DISCIPLINE

14 (Allowing Staff to Dispense Repackage Drugs from Misbranded Bubble Packs)

15 22. Respondents are subject to disciplinary action under Code sections 4300, 4301, 4169,
16 subdivision (a)(3), and 4342, subdivision (a) in that Respondents allowed their staff to dispense
17 repackaged drugs from unlabeled bubble packs that did not have the complete facts concerning
18 the drugs as they relate to the drug name, strength, lot number, expiration date or manufacturer.
19 The circumstances are alleged in paragraphs 21 through subparagraph (a), above, inclusive, and
20 are incorporated by reference as though fully set forth therein.

21 FOURTH CAUSE FOR DISCIPLINE

22 (Lack of Written Policy for Theft or Impairment)

23 23. Respondents are subject to disciplinary action under Code sections 4104, subdivision
24 (b), 4300 and 4301 in that, on or about May 19, 2010, Respondents did not have a written policy
25 and procedures for theft or impairment by a licensed employee.

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1 FIFTH CAUSE FOR DISCIPLINE

2 (Failure to Issue Daily Reports and Timely Controlled Substance Printouts)

3 24. Respondents are subject to disciplinary action under Code sections 4300 and 4301
4 and subdivision (b)(3) of section 1717 of title 16 of the California Code of Regulations in that
5 Respondents did not properly document refilled prescriptions, in violation of subdivision (f)(3) of
6 section 1306.22 of the Code of Federal Regulations. The circumstances are as follows:

7 a. On or about May 19, 2010, Respondent-Pharmacist did not print out daily reports or
8 controlled substance printouts within 72 hours for prescription refills dispensed at Respondent-
9 Pharmacy.

10 SIXTH CAUSE FOR DISCIPLINE

11 (Misabeled Prescription Containers)

12 25. Respondents are subject to disciplinary action under Code sections 4076, subdivision
13 (a)(11)(A), 4300 and 4301 in that Respondents had mislabeled prescription containers. The
14 circumstances are as follows:

15 a. On or about May 19, 2010, Respondent-Pharmacist dispensed the following sixteen
16 (16) prescriptions of dangerous drugs with the wrong identification codes:

- 17 i. RX 6087435, five (5) milligrams Metolazone, brand name Zaroxolyn, labeled
18 Blue Round 644/5 but dispensed as M & 173 Orange Round;
- 19 ii. RX 6076795, twenty (20) milligrams Paroxetine, brand name Paxil, labeled
20 Oval APO/083 but dispensed as White Round ZC/16;
- 21 iii. RX 4008798, one (1) milligram of controlled substance Clonazepam, brand
22 name Klonopin, labeled Blue Round 274 & 1 but dispensed as Blue Round A
23 & 2531;
- 24 iv. RX 6088335, five (5) milligrams Oxybutynin, brand name Ditropan, labeled
25 Blue Round 4853 V but dispensed as Light Blue PLIA 456;
- 26 v. RX 6088606, twelve and a half (12.5) milligrams Carvedilol, brand name
27 Coreg, labeled R & 254 but dispensed as G & 164;
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- vi. RX 6084299, twenty-five (25) milligrams Bethanechol, brand name Urecholine, labeled Yellow Round Pliva 325 but dispensed as Yellow Oval W967;
- vii. RX 6080656, three hundred (300) milligrams Gabapentin, brand name Neurontin, labeled Yellow/Brown Oblong logo/2666 but dispensed as Yellow Capsule 138/138;
- viii. RX 6076213, three hundred and fifty (350) milligrams Carisoprodol, brand name Soma, labeled White Round MP/58 but dispensed as White Round 2410/V;
- ix. RX 6071087, five (5) milligrams Warfarin, brand name Coumadin, labeled Peach Oval 833/5 & barr but dispensed as Peach 5 & TARO;
- x. RX 6084081, ten (10) milligrams Haloperidol, brand name Haldol, labeled Green Round GG/126 but dispensed as Light Green ZC/08;
- xi. RX 6076213, three hundred and fifty (350) milligrams Carisoprodol labeled White Round MP/58 but dispensed as White Round V/2410;
- xii. RX 6071578, three hundred (300) milligrams Ranitidine, brand name Zantac, labeled Peach Oval par/545 but dispensed as White Oval APO & RAN/300;
- xiii. RX 6059485, three hundred (300) milligrams Lithium Carbonate, brand name Eskalith, labeled Flesh Oblong APO 300 but dispensed as Yellow & Grey Westward 3189;
- xiv. RX 6086654, twenty-five (25) milligrams Amitriptyline, brand name Elavil, labeled Green Round GG/44 but dispensed as Yellow V;
- xv. RX 6075710, seventy (70) milligrams Alendronate, brand name Fosamax, with different NDC numbers, 00591-3173-04 and 41616-638-68, on the labeled package;
- xvi. Mometasone Furoate Cream with different NDC numbers on the labeled box.

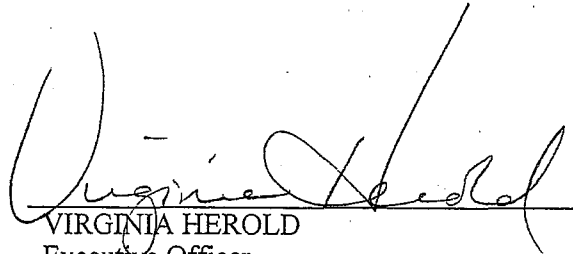
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1 PRAYER

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 Original Permit Number PHY 49968, issued to Respondent-
5 Pharmacy Kovac's Pharmacy;
- 6 2. Revoking or suspending Registered Original Pharmacist License Number RPH
7 57750, issued to Respondent-Pharmacist Irina Pustilnikova;
- 8 3. Ordering Respondents to pay the Board the reasonable costs of the investigation and
9 enforcement of this case, pursuant to section 125.3; and
- 10 4. Taking such other and further action as deemed necessary and proper.

11
12
13 DATED: 4/21/11


14 VIRGINIA HEROLD
15 Executive Officer
16 Board of Pharmacy
17 Department of Consumer Affairs
18 State of California
19 Complainant

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