

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

In the Matter of the Accusation Against:

**PACIFIC HEALTHCARE INC. DBA
B & B PHARMACY, JANE E. HYUN, HYUN
JOON RO, OWNERS
10244 Rosecrans Ave.
Bellflower, CA 90706**

**Original Permit No. PHY 50799
Sterile Compounding Permit No. LSC 99714**

Respondent.

Case No. 6022

OAH No. 2017090416

**STIPULATED SURRENDER OF
LICENSE AND ORDER AS TO
RESPONDENT PACIFIC
HEALTHCARE INC. DBA B & B
PHARMACY, JANE E. HYUN, HYUN
JOON RO, OWNERS**

DECISION AND ORDER

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

This Decision shall become effective at 5:00 p.m. on March 15, 2018.

It is so ORDERED on February 13, 2018.

BOARD OF PHARMACY
DEPARTMENT OF CONSUMER AFFAIRS
STATE OF CALIFORNIA



By

Amy Gutierrez, Pharm.D.
Board President

1 XAVIER BECERRA
Attorney General of California
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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. 6022

11 **PACIFIC HEALTHCARE INC. DBA B &**
12 **B PHARMACY, JANE E. HYUN, HYUN**
13 **JOON RO, OWNERS**
10244 Rosecrans Ave.
14 Bellflower, CA 90706

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16 **Sterile Compounding Permit No. LSC 99714**

STIPULATED SURRENDER OF
LICENSE AND ORDER AS TO
RESPONDENT PACIFIC
HEALTHCARE INC. DBA B & B
PHARMACY, JANE E. HYUN, HYUN
JOON RO, OWNERS

17 Respondent.

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
23 by Xavier Becerra, Attorney General of the State of California, by Emily Y. Wada, Deputy
24 Attorney General.

25 2. Pacific Healthcare Inc. dba B & B Pharmacy, Jane E. Hyun, Hyun Joon Ro, owners
26 ("Respondent") is represented in this proceeding by attorney Herb L. Weinberg, Esq., whose
27 address is Fenton Law Group, LLP, 1990 S. Bundy Drive, Suite 777, Los Angeles, CA 90025
28 (Telephone (310) 444-5244).

3. On or about December 22, 2011, the Board issued Original Permit No. PHY 50799 to Respondent. The Original Permit expired on April 15, 2016, and has not been renewed.

4. On or about January 21, 2012, the Board issued Sterile Compounding Permit No. LSC 99714 to Respondent. The Sterile Compounding Permit expired on August 26, 2015, and has not been renewed.

JURISDICTION

5. Accusation No. 6022 was filed before the Board and is currently pending against Respondent. The Accusation and all other statutorily required documents were properly served on Respondent on July 12, 2017. Respondent timely filed its Notice of Defense contesting the Accusation. A copy of Accusation No. 6022 is attached as Exhibit A and incorporated by reference.

ADVISEMENT AND WAIVERS

6. Respondent has carefully read, fully discussed with counsel, and understands the charges and allegations in Accusation No. 6022. Respondent also has carefully read, fully discussed with counsel, and understands the effects of this Stipulated Surrender of License and Order.

7. Respondent is fully aware of its legal rights in this matter, including the right to a hearing on the charges and allegations in the Accusation; the right to confront and cross-examine the witnesses against them; the right to present evidence and to testify on its own behalf; the right to the issuance of subpoenas to compel the attendance of witnesses and the production of documents; the right to reconsideration and court review of an adverse decision; and all other rights accorded by the California Administrative Procedure Act and other applicable laws.

8. Respondent voluntarily, knowingly, and intelligently waives and gives up each and every right set forth above.

CULPABILITY

9. Respondent understands that the charges and allegations in Accusation No. 6022, if proven at a hearing, constitute cause for imposing discipline upon their Original Permit as well as on their Sterile Compounding Permit.

10. For the purpose of resolving the Accusation without the expense and uncertainty of further proceedings, Respondent agrees that, at a hearing, Complainant could establish a factual basis for the charges in the Accusation and that those charges constitute cause for discipline. Respondent hereby gives up their right to contest that cause for discipline exists based on those charges.

11. Respondent understands that by signing this stipulation Entity enables the Board to issue an order accepting the surrender of their Original Permit without further process.

12. Respondent understands that by signing this stipulation Entity enables the Board to issue an order accepting the surrender of their Sterile Compounding Permit without further process.

CONTINGENCY

13. This stipulation shall be subject to approval by the Board. Respondent understands and agrees that counsel for Complainant and the staff of the Board may communicate directly with the Board regarding this stipulation and surrender, without notice to or participation by Respondent or its counsel. By signing the stipulation, Respondent understands and agrees that they may not withdraw its agreement or seek to rescind the stipulation prior to the time the Board considers and acts upon it. If the Board fails to adopt this stipulation as its Decision and Order, the Stipulated Surrender and Disciplinary Order shall be of no force or effect, except for this paragraph, it shall be inadmissible in any legal action between the parties, and the Board shall not be disqualified from further action by having considered this matter.

14. The parties understand and agree that Portable Document Format (PDF) and facsimile copies of this Stipulated Surrender of License and Order, including Portable Document Format (PDF) and facsimile signatures thereto, shall have the same force and effect as the originals.

15. This Stipulated Surrender of License and Order is intended by the parties to be an integrated writing representing the complete, final, and exclusive embodiment of their agreement. It supersedes any and all prior or contemporaneous agreements, understandings, discussions, negotiations, and commitments (written or oral). This Stipulated Surrender of License and Order

1 may not be altered, amended, modified, supplemented, or otherwise changed except by a writing
2 executed by an authorized representative of each of the parties.

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

5 **ORDER**

6 IT IS HEREBY ORDERED that Original Permit No. PHY 50799 and Sterile Compounding
7 Permit No. LSC 99714 issued to Respondent Pacific Healthcare Inc., dba B & B Pharmacy, Jane
8 E. Hyun, Hyun Joon Ro, owners, are surrendered and accepted by the Board of Pharmacy.

9 1. The surrender of Respondent's Original Permit and Sterile Compounding Permit, and
10 the acceptance of the surrendered licenses by the Board shall constitute the imposition of
11 discipline against Respondent. This stipulation constitutes a record of the discipline and shall
12 become a part of Respondent's license history with the Board of Pharmacy.

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

15 3. Respondent shall cause to be delivered to the Board its pocket licenses and, if one
16 was issued, its wall certificates on or before the effective date of the Decision and Order.

17 4. If Respondent ever applies for licensure or petitions for reinstatement in the State of
18 California, the Board shall treat it as a new application for licensure. Respondent must comply
19 with all the laws, regulations and procedures for licensure in effect at the time the application or
20 petition is filed, and all of the charges and allegations contained in Accusation No. 6022 shall be
21 deemed to be true, correct and admitted by Respondent when the Board determines whether to
22 grant or deny the application or petition.

23 5. Respondent shall pay the agency its costs of investigation and enforcement in the
24 amount of \$3,799.75 prior to issuance of a new or reinstated license.


25 6. If Respondent should ever apply or reapply for a new license or certification, or
26 petition for reinstatement of a license, by any other health care licensing agency in the State of
27 California, all of the charges and allegations contained in Accusation, No. 6022 shall be deemed
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1 to be true, correct, and admitted by Respondent for the purpose of any Statement of Issues or any
2 other proceeding seeking to deny or restrict licensure.


3 7. Respondent shall not apply for licensure or petition for reinstatement for three (3)
4 years from the effective date of the Board's Decision and Order.

5 ACCEPTANCE

6 I have carefully read the above Stipulated Surrender of License and Order and have fully
7 discussed it with my attorney, Herb L. Weinberg. I understand the stipulation and the effect it
8 will have on my Original Permit, and Sterile Compounding Permit. I enter into this Stipulated
9 Surrender of License and Order voluntarily, knowingly, and intelligently, and agree to be bound
10 by the Decision and Order of the Board of Pharmacy.

11
12 DATED: 11/28/17 
13 PACIFIC HEALTHCARE INC., DBA B & B
14 PHARMACY, JANE E. HYUN, HYUN JOON
15 RO, OWNERS
16 Respondent

17 I have read and fully discussed with Respondent Pacific Healthcare Inc., dba B & B
18 Pharmacy, Jane E. Hyun, Hyun Joon Ro, owners, the terms and conditions and other matters
19 contained in this Stipulated Surrender of License and Order. I approve its form and content.

20
21 DATED: 11/28/17 
22 Herb L. Weinberg
23 Attorney for Respondent
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ENDORSEMENT

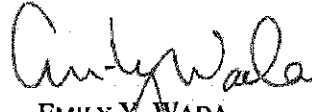
The foregoing Stipulated Surrender of License and Order is hereby respectfully submitted
for consideration by the Board of Pharmacy of the Department of Consumer Affairs.

Dated:

December 27, 2017

Respectfully submitted,

XAVIER BECERRA
Attorney General of California
THOMAS L. RINALDI
Supervising Deputy Attorney General


EMILY Y. WADA
Deputy Attorney General
Attorneys for Complainant

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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:
11 **PACIFIC HEALTHCARE INC. DBA B&B**
12 **PHARMACY, JANE E. HYUN, HYUN**
JOON RO, OWNERS

13 10244 Rosecrans Ave.
Bellflower, CA 90706
14 Original Permit No. PHY 50799
Sterile Compounding Permit No. LSC 99714,

15 **SUZY MICHEL MORKOS**
6222 Forester Dr.
16 Huntington Beach, CA 92648
Pharmacist License No. RPH 47817

17
18 Respondents.

Case No. 6022

ACCUSATION

19 Complainant alleges:

20 **PARTIES**

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

23 2. On or about December 22, 2011, the Board of Pharmacy issued Original Permit
24 Number PHY 50799 to Pacific Healthcare Inc., dba B&B Pharmacy, Jane E. Hyun, Hyun Joon Ro
25 ("B&B Pharmacy"). The Original Permit expired on April 15, 2016, and has not been renewed.

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27 ///

3. On or about January 31, 2012, the Board of Pharmacy issued Sterile Compounding Permit Number LSC 99714 to B&B Pharmacy. The Sterile Compounding Permit expired on August 26, 2015, and has not been renewed.

4. On or about March 8, 1995, the Board of Pharmacy issued Pharmacist License Number RPH 47817 to Suzy Michel Morkos ("Morkos"). The Pharmacist License was in full force and effect at all times relevant to the charges brought herein and will expire on July 31, 2018, unless renewed. Morkos has been the Pharmacist-in-Charge of B&B Pharmacy since May 1, 2015.

JURISDICTION

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

6. Section 118, subdivision (b), of the Code provides that the suspension, expiration, surrender, or cancellation of a license shall not deprive the Board of jurisdiction to proceed with a disciplinary action during the period within which the license may be renewed, restored, reissued or reinstated.

7. Section 4011 of the Code provides that the Board shall administer and enforce both the Pharmacy Law, Business and Professions Code, § 4000, *et seq.*, and the Uniform Controlled Substances Act, Health and Safety Code, § 11000, *et seq.*

8. Section 4300.1 of the Business and Professions Code ("Code") states:

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

STATUTORY PROVISIONS

9. Health and Safety Code section 111330 provides that, “Any drug or device is misbranded if its labeling is false or misleading in any particular.”

10. Health and Safety Code section 111440 provides that, "It is unlawful for any person to manufacture, sell, deliver, hold, or offer for sale any drug or device that is misbranded."

11. Section 4059.5, subdivision (e), provides, in pertinent part, that:

(e) A dangerous drug or dangerous device shall not be transferred, sold, or delivered to a person outside this state, whether foreign or domestic, unless the transferor, seller, or deliverer does so in compliance with the laws of this state and of the United States and of the state or country to which the dangerous drugs or dangerous devices are to be transferred, sold, or delivered. . . .

12. Section 4113, subdivision (c), provides that, "The pharmacist-in-charge shall be responsible for a pharmacy's compliance with all state and federal laws and regulations pertaining to the practice of pharmacy."

13. Section 4169, subdivision (a)(3), of the Code provides that:

(a) A person or entity shall 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. . . .

14. Section 4301, subdivision (o), provides, that:

The board shall take action against any holder of a license who is guilty of unprofessional conduct or whose license has been issued by mistake. Unprofessional conduct shall include, but is not limited to, any of the following:

(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.

15. Section 4307 provides, in relevant part, that:

(a) Any person who has been denied a license or whose license has been revoked or is under suspension, or who has failed to renew his or her license while it was under suspension, or who has been a manager, administrator, owner, member, officer, director, associate, partner, or any other person with management or control of any partnership, corporation, trust, firm, or association whose application for a license has been denied or revoked, is under suspension or has been placed on probation, and while acting as the manager, administrator, owner, member, officer, director, associate, partner, or any other person with management or control had knowledge of or knowingly participated in any conduct for which the license was denied, revoked, suspended, or placed on probation, shall be prohibited from serving as a manager, administrator, owner, member, officer, director, associate, partner, or any other person with management or control of a licensee as follows:

(1) Where a probationary license is issued or where an existing license is placed on probation, this prohibition shall remain in effect for a period not to exceed five years.

(2) Where the license is denied or revoked, the prohibition shall continue until the license is issued or reinstated.

(b) "Manager, administrator, owner, member, officer, director, associate, partner, or any other person with management or control of a license" as used in this section and Section 4308, may refer to a pharmacist or to any other person who serves in such capacity in or for a licensee. . . .

REGULATORY PROVISIONS

16. California Code of Regulations, title 16, section 1735.2, provides, in pertinent part,

that:

(d) A drug product shall not be compounded until the pharmacy has first prepared a written master formula record that includes at least the following elements:

- (1) Active ingredients to be used.
- (2) Inactive ingredients to be used.
- (3) Process and/or procedure used to prepare the drug.
- (4) Quality reviews required at each step in preparation of the drug.
- (5) Post-compounding process or procedures required, if any.
- (6) Expiration dating requirements.

.....
(h) Every compounded drug product shall be given an expiration date representing the date beyond which, in the professional judgment of the pharmacist performing or supervising the compounding, it should not be used. This "beyond use date" of the compounded drug product shall not exceed 180 days from preparation or the shortest expiration date of any component in the compounded drug product, unless a longer date is supported by stability studies of finished drugs or compounded drug products using the same components and packaging. Shorter dating than set forth in this subsection may be used if it is deemed appropriate in the professional judgment of the responsible pharmacist.

17. California Code of Regulations, title 16, section 1735.6, subdivision (b), provides that,

"Any equipment used to compound drug products shall be stored, used, and maintained in accordance with manufacturers' specifications."

18. California Code of Regulations, title 16, section 1751.4, subdivision (d), provides that:

Exterior workbench surfaces and other hard surfaces in the designated area, such as walls, floors, ceilings, shelves, tables, and stools, must be disinfected weekly and after any unanticipated event that could increase the risk of contamination.

19. California Code of Regulations, title 16, section 1751.7, subdivision (c), provides that:

Batch-produced sterile injectable drug products compounded from one or more non-sterile ingredients shall be subject to documented

1 end product testing for sterility and pyrogens and shall be
2 quarantined until the end product testing confirms sterility and
3 acceptable levels of pyrogens.

4 OTHER PROVISIONS

5 20. Arizona Administrative Code section R4-23-607, subdivision (A)(1), provides that:

6 A. Permit. A person who is not a resident of Arizona shall not sell
7 or distribute any narcotic or other controlled substance,
8 prescription-only drug or device, nonprescription drug, precursor
9 chemical, or regulated chemical into Arizona without:

10 1. Processing a current Board-issued nonresident pharmacy
11 permit, nonresident manufacturer permit, nonresident full-service or
12 nonprescription drug wholesale permit, or nonresident
13 nonprescription drug permit;

14 COST RECOVERY

15 21. Section 125.3 of the Code provides, in pertinent part, that the Board may request the
16 administrative law judge to direct a licentiate found to have committed a violation or violations of
17 the licensing act to pay a sum not to exceed the reasonable costs of the investigation and
18 enforcement of the case, with failure of the licentiate to comply subjecting the license to not being
19 renewed or reinstated. If a case settles, recovery of investigation and enforcement costs may be
20 included in a stipulated settlement.

21 FIRST CAUSE FOR DISCIPLINE

22 (Failure to Clean)

23 Against Respondents B&B Pharmacy and Morkos

24 22. Respondents B&B Pharmacy and Morkos are subject to disciplinary action under
25 California Code of Regulations, title 16, section 1751.4, subdivision (d), in that all of the exterior
26 workbench surfaces and other hard surfaces in the designated sterile compounding area of the
27 pharmacy had not been disinfected on a weekly basis according to the pharmacy's own cleaning
28 logs.

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26 SECOND CAUSE FOR DISCIPLINE

27 (Misbranded Drugs)

28 Against Respondents B&B Pharmacy and Morkos

23. Respondents B&B Pharmacy and Morkos are subject to disciplinary action under Code section 4169, subdivision (a)(3), and Health and Safety Code sections 111330 and 111440 on the grounds that they manufactured, sold, delivered, held, and/or offered for sale misbranded drugs. The circumstances are as follows:

24. On or around October 27, 2015, Morkos provided pharmacy documents to a Board inspector that showed several lots of compounded drug products had been assigned improper beyond-use-dates ("BUDs"). For example, pharmacy documents showed that Lot No. 06022015@4 of Papaverine HCL Injection 33mg/mL Solution had been given a BUD of May 27, 2016, but one of its components, Lot No. C162544 of Chlorobutanol NF Anhydrous, had an earlier BUD of November 16, 2015. As another example, pharmacy documents showed that Lot No. 06302015@6 of Phentolamine 20mg/mL Injectable had been given a BUD of June 24, 2016, but one of its components, Lot No. 111930/K of Phentolamine Mesylate USP Powder had an earlier BUD of April 1, 2016. As yet another example, pharmacy documents showed that Lot No. 05062015@12 of Alprostadil Alcohol Stock 500mcg/mL Solution had been given a BUD of April 30, 2016, but one of its components, Lot No. 98231/D of Alprostadil USP Powder had an earlier BUD of March 31, 2016.

THIRD CAUSE FOR DISCIPLINE

(Failure to Use Equipment In Accordance With Manufacturer's Specifications)

Against Respondents B&B Pharmacy and Morkos

25. Respondents B&B Pharmacy and Morkos are subject to disciplinary action under California Code of Regulations, title 16, section 1735.6, subdivision (b), on the grounds that they used certain equipment outside of the manufacturers' specifications to compound drugs. Specifically, Respondents used a Sharp convection microwave model R-390Ak/R-930AW and an Emerson 900W microwave oven model number MW8889SB during the compounding process to sterilize glassware or heat non-sterile drug preparations although both microwaves are only intended for household use.

FOURTH CAUSE FOR DISCIPLINE

(Failure to Prepare Master Formulas)

1 **Against Respondents B&B Pharmacy and Morkos**

2 26. Respondents B&B Pharmacy and Morkos are subject to disciplinary action under
3 California Code of Regulations, title 16, section 1735.2, subdivision (d), on the grounds that they
4 compounded drug products without complete written master formulas. The circumstances are as
5 follows:

6 27. On or around October 27, 2015, Morkos provided pharmacy documents to a Board
7 inspector that showed several lots of compounded drug products did not have complete written
8 master formulas. For example, there were no formula instructions or compounding steps to
9 prepare Lot No. 05062015@12 of Alprostadil Alcohol Stock 500mcg/mL Solution, Lot No.
10 06022015@4 of Papaverine HCL Injection 33mg/mL Solution, and Lot No. 08032015@2 of
11 Papaverine+PGE1+Phentolamine Injection 30mg:20mcg/mL Injectable. As another example, the
12 only formula instructions or compounding steps for Lot No. 06182013@16 of
13 Papaverine+PGE1+Phentolamine Injection 30mg:20mcg/mL Injectable was to "combine all
14 ingredients in sterile vial and seal."

15 **FIFTH CAUSE FOR DISCIPLINE**

16 **(Failure to Assign Valid Beyond Use Dates)**

17 **Against Respondents B&B Pharmacy and Morkos**

18 28. Respondents B&B Pharmacy and Morkos are subject to disciplinary action under
19 California Code of Regulations, title 16, section 1735.2, subdivision (h), on the grounds that they
20 assigned improper BUDs to compounded drug products without the appropriate supporting
21 stability analyses. Complainant refers to and hereby incorporates the allegations contained within
22 paragraph 24, above, as though fully set forth herein.

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25 **SIXTH CAUSE FOR DISCIPLINE**

26 **(Failure to Have Valid Sterility Testing)**

27 **Against Respondents B&B Pharmacy and Morkos**

1 29. Respondents B&B Pharmacy and Morkos are subject to disciplinary action under
2 California Code of Regulations, title 16, section 1751.7, subdivision (c), on the grounds that they
3 failed to obtain end product testing for sterility and/or pyrogens on all compounded drug products.
4 Specifically, Respondents failed to send a compliant sample size for sterility and pyrogens testing
5 on Lot No. 06022015@4 of Papaverine HCL Injection 33mg/mL Solution, Lot No. 06302015@6
6 of Phentolamine 20mg/mL Injectable, and Lot No. 05062015@12 of Alprostadil Alcohol Stock
7 500mcg/mL Solution, and, therefore, had no documented end product testing on those lots.

8 **SEVENTH CAUSE FOR DISCIPLINE**

9 **(Unprofessional Conduct)**

10 **Against Respondents B&B Pharmacy and Morkos**

11 30. Respondents B&B Pharmacy and Morkos are subject to disciplinary action under
12 Code section 4301, subdivision (o), on the grounds that they violated, either directly or indirectly,
13 or assisted in or abetted the violation of another state's laws and regulations governing
14 pharmacies. The circumstances are as follows:

15 31. Between March 2012 and September 2015, Respondents prepared and shipped
16 compounded drug products to an individual in Arizona on at least nine occasions. However, B&B
17 Pharmacy did not have a nonresident permit under Arizona Administrative Code section R4-23-
18 607, subdivision (A)(1), to sell or distribute drugs in Arizona.

19 **EIGHTH CAUSE FOR DISCIPLINE**

20 **(Unlicensed Shipping to Arizona)**

21 **Against Respondents B&B Pharmacy and Morkos**

22 32. Respondents B&B Pharmacy and Morkos are subject to disciplinary action under
23 Code section 4059.5, subdivision (e), on the grounds that they transferred, sold, and/or delivered a
24 dangerous drug to a person in Arizona without complying with all of the laws of the states of
25 California and Arizona before doing so. Complainant refers to and hereby incorporates the
26 allegations contained within paragraph 31, above, as though fully set forth herein.

27 **OTHER MATTERS**

28 33. Pursuant to Code section 4307, if discipline is imposed on Pharmacy Permit Number

1 PHY 50799 issued to Respondent B&B Pharmacy, then Respondent B&B Pharmacy shall be
2 prohibited from serving as a manager, administrator, owner, member, officer, director, associate,
3 or partner of a licensee for five years if Pharmacy Permit Number PHY 50799 is placed on
4 probation or until Pharmacy Permit Number PHY 50799 is reinstated if it is revoked.

5 34. Pursuant to Code section 4307, if discipline is imposed on Pharmacy Permit Number
6 PHY 50799 issued to Respondent B&B Pharmacy while Jane E. Hyun and/or Hyun Joon Ro,
7 Pharmacist License Number RPH 64426, have been officers and/or owners and had knowledge or
8 knowingly participated in any conduct for which the licensee was disciplined, then Jane E. Hyun
9 and/or Hyun Joon Ro shall be prohibited from serving as managers, administrators, owners,
10 members, officers, directors, associates, or partners of a licensee for five years if Pharmacy Permit
11 Number PHY 50799 is placed on probation or until Pharmacy Permit Number PHY 50799 is
12 reinstated if it is revoked.

13 DISCIPLINARY CONSIDERATIONS

14 35. To determine the degree of discipline, if any, to be imposed on Respondents,
15 Complainant alleges that, on or around August 13, 2012, Respondent B&B Pharmacy was issued
16 Citation No. CI 2011 50984 for violating Business and Professions Code section 4169, subdivision
17 (a)(4) [purchase, trade, sell, or transfer dangerous drugs or devices after or beyond use date on
18 label], in the amount of \$750, and California Code of Regulations, title 16, section 1751.7,
19 subdivision (a)(4) [written justification of the chosen expiration date for compounded sterile
20 injectable products], in the amount of \$500. Specifically, on or around January 6, 2012, during an
21 inspection of the pharmacy, it was discovered that B&B Pharmacy dispensed Amlodipine 5mg
22 beyond its labeled expiration date on multiple occasions between December 22, 2011, and January
23 6, 2012. It was also discovered that B&B Pharmacy did not have written justification for the
24 chosen expiration dates printed on the logged formula worksheets and stock bottle labels for
25 Apomorphine HCL 6mg/ml, dated November 2, 2011, and Baclofen Intrathecal 1mg/ml, dated
26 November 16, 2011, and that the chosen expiration dates did not correlate to the pharmacy's
27 master formulas.

36. To determine the degree of discipline, if any, to be imposed on Respondents, Complainant alleges that, on or around March 22, 2013, Respondent B&B Pharmacy was issued Citation No. CI 2011 51974 for violating Health and Safety Code section 11162.1, subdivision (a) [prescription forms for controlled substances; requirements], in the amount of \$5,000. Specifically, between March 26, 2012, and June 23, 2012, B&B Pharmacy dispensed the following prescriptions for controlled substances that were not printed in compliance with California security form requirements:

Dates	Drugs
6/23/12	Hydrocodone/acetaminophen (APAP) 5/500 #60
3/26/12	Carisoprodol 350mg #90
3/26/12	Alprazolam 5mg #60
3/26/12	Zolpidem 10mg #0
3/26/12	Hydrocodone (APAP) 10/325/ #60
3/26/12	Lorazepam 1mg #30
3/26/12	Hydrocodone (APAP) 10/325mg #60

37. To determine the degree of discipline, if any, to be imposed on Respondents, Complainant alleges that, on or around June 13, 2014, Respondent B&B Pharmacy was issued a letter of admonishment pursuant to Business and Professions Code section 4315 for failure to comply with the laws and regulations that govern the practice of pharmacy in California, including: (i) Business and Professions Code section 4315 and 4115, subdivision (f)(1) [ratio of pharmacists to pharmacy technicians]; (ii) California Code of Regulations, title 16, section 1751.7, subdivision (a)(4) [written justification on the chosen expiration date for compounded sterile injectable products]; (iii) California Code of Regulations, title 16, section 1751, subdivision (c) [batch produced sterile injectable drug products compounded from one or more non-sterile ingredients shall be subjected to documented end product testing and quarantined]; (iv) California Code of Regulations, title 16, section 1735.8, subdivision (c) [compounding quality assurance requires reports on integrity, potency, and quality]; (v) California Code of Regulations, title 16, sections 1735.6, subdivisions (b) and (c), 1735.5, subdivision (c), and 1735.3, subdivision (a)(7)

1 [compounding facilities and equipment, compounding policies and procedures, and records of
2 compounded drug products], (vi) Business and Professions Code section 4169, subdivision (a)(3),
3 in conjunction with California Code of Regulations, title 16, section 1735.2, subdivision (f)
4 [prohibited to purchase, trade, sell, or transfer dangerous drugs that a person knows or reasonably
5 should know are misbranded; pharmacist performing or supervising compounding is responsible
6 for the integrity, potency, quality, and labeled strength of a drug until it is dispensed]. Specifically,
7 on or around October 9, 2012, during an inspection of the pharmacy, multiple violations of
8 pharmacy law were observed under the aforementioned laws.

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 Original Permit Number PHY 50799, issued to Pacific
13 Healthcare Inc., dba B&B Pharmacy, Jane E. Hyun, Hyun Joon Ro;

14 2. Revoking or suspending Sterile Compounding Permit Number LSC 99714, issued to
15 Pacific Healthcare Inc., dba B&B Pharmacy, Jane E. Hyun, Hyun Joon Ro;

16 3. Revoking or suspending Pharmacist License Number RPH 47817, issued to Suzy
17 Michel Morkos;

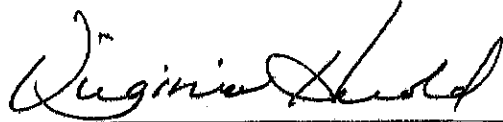
18 4. Prohibiting Jane E. Hyun from serving as a manager, administrator, owner, member,
19 officer, director, associate, partner, or any other person with management or control of a licensee
20 for five years if Pharmacy Permit Number PHY 50799 is placed on probation or until Pharmacy
21 Permit Number PHY 50799 is reinstated if it is revoked.

22 5. Prohibiting Hyun Joon Ro, Pharmacist License Number RPH 64426, from serving as a
23 manager, administrator, owner, member, officer, director, associate, partner, or any other person
24 with management or control of a licensee for five years if Pharmacy Permit Number PHY 50799 is
25 placed on probation or until Pharmacy Permit Number PHY 50799 is reinstated if it is revoked.

26 6. Ordering B&B Pharmacy and Suzy Michel Morkos to pay the Board of Pharmacy the
27 reasonable costs of the investigation and enforcement of this case, pursuant to Business and
28 Professions Code section 125.3; and,

1 7. Taking such other and further action as deemed necessary and proper.
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3

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5 DATED: 6/30/17



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

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