

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

In the Matter of the Accusation Against:

**INNOVATIVE COMPOUNDING SOLUTIONS,  
DBA HERITAGE COMPOUNDING PHARMACY  
2903 Saturn Street, Unit A  
Brea, CA 92821**

**Pharmacy Permit No. PHY 47098  
Sterile Compounding License No. LSC 99303**

and

**ESTHER J. KIM  
Cedarglen Court  
Fullerton, CA 92835**

**Pharmacist License No. RPH 50765**

and

**ALLAN MICHAEL PIWONKA  
8440 E. Chapman Avenue  
Orange, CA 92869**

**Pharmacist License No. RPH 27345**

Respondents.

Case No. 4904

OAH No. 2014020492

**STIPULATED SURRENDER OF  
LICENSE AND ORDER AS TO  
INNOVATIVE COMPOUNDING  
SOLUTIONS, DBA HERITAGE  
COMPOUNDING PHARMACY AND  
ESTHER KIM ONLY**

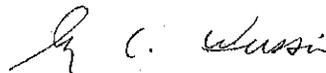
**DECISION AND ORDER**

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

This decision shall become effective on January 28, 2015.

It is so ORDERED on January 21, 2015.

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 JAMES M. LEDAKIS  
Supervising Deputy Attorney General  
3 NICOLE R. TRAMA  
Deputy Attorney General  
4 State Bar No. 263607  
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*Attorneys for Complainant*

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

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12 In the Matter of the Accusation Against:  
13 **INNOVATIVE COMPOUNDING**  
14 **SOLUTIONS, DBA HERITAGE**  
**COMPOUNDING PHARMACY**  
15 **2903 Saturn Street, Unit A**  
**Brea, CA 92821**  
16 **Pharmacy Permit No. PHY 47098**  
**Sterile Compounding License No. LSC**  
17 **99303**  
18 **and**  
19 **ESTHER J. KIM**  
**Cedarglen Court**  
20 **Fullerton, CA 92835**  
21 **Pharmacist License No. RPH 50765**  
22 **and**  
23 **ALLAN MICHAEL PIWONKA**  
**8440 E Chapman Avenue**  
24 **Orange, CA 92869**  
25 **Pharmacist License No. RPH 27345**  
26 **Respondents.**

Case No. 4904  
OAH No. 2014020492  
**STIPULATED SURRENDER OF**  
**LICENSE AND ORDER AS TO**  
**INNOVATIVE COMPOUNDING**  
**SOLUTIONS, DBA HERITAGE**  
**COMPOUNDING PHARMACY AND**  
**ESTHER KIM ONLY**

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

3 PARTIES

4 1. Virginia Herold (Complainant) is the Executive Officer of the Board of Pharmacy.  
5 She brought this action solely in her official capacity and is represented in this matter by Kamala  
6 D. Harris, Attorney General of the State of California, by Nicole R. Trama, Deputy Attorney  
7 General.

8 2. Innovative Compounding Solutions, Inc., doing business as Heritage Compounding  
9 Pharmacy and Esther J. Kim (Respondents) are represented in this proceeding by attorney Tony  
10 Park, Esq., whose address is 6789 Quail Hill Parkway, #405, Irvine, CA 92603.

11 3. On or about April 29, 2005, the Board of Pharmacy issued Pharmacy Permit Number  
12 PHY 47098 to Innovative Compounding Solutions, doing business as Heritage Compounding  
13 Pharmacy (Respondent Heritage), with Esther J. Kim, as President and Pharmacist-in- Charge.  
14 The Pharmacy Permit was in full force and at all times relevant to the charges brought in  
15 Accusation No. 4904 and will expire on April 1, 2015, unless renewed.

16 4. On or about June 9, 2005, the Board of Pharmacy issued Licensed Sterile  
17 Compounding Permit Number LSC 99303 to Innovative Compounding Solutions, doing business  
18 as Heritage Compounding Pharmacy (Respondent Heritage). The Sterile Compounding License  
19 was in full force and effect at all times relevant to the charges brought in Accusation No. 4904  
20 and will expire on April 1, 2015, unless renewed.

21 5. On or about March 31, 1999, the Board of Pharmacy issued Pharmacist License  
22 Number RPH 50765 to Esther J. Kim (Respondent Kim). The Pharmacy Permit was in full force  
23 and effect at all times relevant to the charges brought in Accusation No. 4904 and will expire on  
24 July 31, 2016, unless renewed.

25 JURISDICTION

26 6. Accusation No. 4904 was filed before the Board of Pharmacy (Board), Department of  
27 Consumer Affairs, and is currently pending against Respondents. The Accusation and all other  
28 statutorily required documents were properly served on Respondents on January 29, 2014.

1 Respondents timely filed their Notices of Defense contesting the Accusation. A copy of  
2 Accusation No. 4904 is attached as Exhibit A and incorporated by reference.

3 ADVISEMENT AND WAIVERS

4 7. Respondents have carefully read, fully discussed with counsel, and understand the  
5 charges and allegations in Accusation No. 4904. Respondents also have carefully read, fully  
6 discussed with counsel, and understand the effects of this Stipulated Surrender of License and  
7 Order.

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

14 9. Respondents voluntarily, knowingly, and intelligently waive and give up each and  
15 every right set forth above.

16 CULPABILITY

17 10. Respondents understands that the charges and allegations in Accusation No. 4904, if  
18 proven at a hearing, constitute cause for imposing discipline upon Pharmacy Permit Number PHY  
19 47098, Pharmacy Permit, Licensed Sterile Compounding Permit Number LSC 99303, and  
20 Pharmacist License Number RPH 50765.

21 11. For the purpose of resolving the Accusation without the expense and uncertainty of  
22 further proceedings, Respondents agree that, at a hearing, Complainant could establish a factual  
23 basis for the charges in the Accusation and that those charges constitute cause for discipline.  
24 Respondents hereby gives up their right to contest that cause for discipline exists based on those  
25 charges.

26 12. Respondents understand that by signing this stipulation they enable the Board to issue  
27 an order accepting the surrender of Pharmacy Permit Number PHY 47098, Pharmacy Permit,  
28

1 Licensed Sterile Compounding Permit Number LSC 99303, and Pharmacist License Number  
2 RPH 50765.

3 CONTINGENCY

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

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

17 15. This Stipulated Surrender of License and Order is intended by the parties to be an  
18 integrated writing representing the complete, final, and exclusive embodiment of their agreement.  
19 It supersedes any and all prior or contemporaneous agreements, understandings, discussions,  
20 negotiations, and commitments (written or oral). This Stipulated Surrender of License and Order  
21 may not be altered, amended, modified, supplemented, or otherwise changed except by a writing  
22 executed by an authorized representative of each of the parties.

23 16. Respondent Kim stipulates and agrees that as of January 2, 2015, Respondent Kim  
24 will not work in any capacity, including Pharmacist-in-Charge, at Respondent Heritage. In  
25 addition, Respondents also stipulate and agree that Respondents shall select a new Pharmacist-in-  
26 Charge for Respondent Heritage and submit the "Change in Pharmacist-in-Charge" form 17A-14  
27 to the Board for approval by January 2, 2015.

28



1           7. Respondents shall cause to be delivered to the Board their pocket licenses and, if one  
2 was issued, their wall certificates on or before the effective date of the Decision and Order.

3           8. If Respondents ever apply for licensure or petition for reinstatement in the State of  
4 California, the Board shall treat it as a new application for licensure. Respondents must comply  
5 with all the laws, regulations and procedures for licensure in effect at the time the application or  
6 petition is filed, and all of the charges and allegations contained in Accusation No. 4904 shall be  
7 deemed to be true, correct and admitted by Respondents when the Board determines whether to  
8 grant or deny the application or petition.

9           9. Respondents shall pay the agency its costs of investigation and enforcement in the  
10 amount of \$13,000.00. Respondents shall pay \$9,000.00 in costs within thirty (30) days of the  
11 effective date of the Decision and Order. Respondents shall pay the remaining \$4,000.00 in costs  
12 prior to issuance of a new or reinstated license. Respondents shall be jointly and severally liable  
13 for the payment of these costs.

14           10. If Respondents should ever apply or reapply for a new license or certification, or  
15 petition for reinstatement of a license, by any other health care licensing agency in the State of  
16 California, all of the charges and allegations contained in Accusation, No. 4904 shall be deemed  
17 to be true, correct, and admitted by Respondents for the purpose of any Statement of Issues or any  
18 other proceeding seeking to deny or restrict licensure.

19           11. In the event that Respondent Heritage is not sold by March 1, 2015, Respondent  
20 Heritage shall, within ten (10) days of the stayed effective date of the Board's order, arrange for  
21 the destruction of, the transfer to, sale of or storage in a facility licensed by the Board of all  
22 controlled substances and dangerous drugs and devices. Respondent Heritage shall further  
23 provide written proof of such disposition and submit a completed Discontinuance of Business  
24 form according to Board guidelines.

25           12. Respondents may not apply, reapply, or petition for any licensure or registration of  
26 the Board for three (3) years from the effective date of the Decision and Order.

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2 I have carefully read the above Stipulated Surrender of License and Order and have fully  
3 discussed it with my attorney, Tony Park, Esq. I understand the stipulation and the effect it will  
4 have on my Pharmacy Permit, Sterile Compounding License, and Pharmacist License. I enter  
5 into this Stipulated Surrender of License and Order voluntarily, knowingly, and intelligently, and  
6 agree to be bound by the Decision and Order of the Board of Pharmacy.

7  
8 DATED: 12/31/14

  
ESTHER J. KIM

As an individual and as the President and  
authorized agent on behalf of INNOVATIVE  
COMPOUNDING SOLUTIONS, INC. DBA  
HERITAGE COMPOUNDING PHARMACY  
Respondents

9  
10  
11  
12 I have read and fully discussed with Respondents the terms and conditions and other  
13 matters contained in this Stipulated Surrender of License and Order. I approve its form and  
14 content.

15 DATED:

16 TONY PARK, ESQ.  
17 Attorney for Respondent

18 ENDORSEMENT

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

21 Dated:

Respectfully submitted,

22 KAMALA D. HARRIS  
23 Attorney General of California  
24 JAMES M. LEDAKIS  
25 Supervising Deputy Attorney General

26 NICOLE R. TRAMA  
27 Deputy Attorney General  
28 Attorneys for Complainant

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**Exhibit A**

**Accusation No. 4904**

1 KAMALA D. HARRIS  
Attorney General of California  
2 JAMES M. LEDAKIS  
Supervising Deputy Attorney General  
3 NICOLE R. TRAMA  
Deputy Attorney General  
4 State Bar No. 263607  
110 West "A" Street, Suite 1100  
5 San Diego, CA 92101  
P.O. Box 85266  
6 San Diego, CA 92186-5266  
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13 **DBA HERITAGE COMPOUNDING PHARMACY**  
2903 Saturn Street, Unit A  
14 Brea, CA 92821

**A C C U S A T I O N**

15 Pharmacy Permit No. PHY 47098  
Sterile Compounding License No. LSC 99303

16 and

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18 **ESTHER J. KIM**  
Cedarglen Court  
Fullerton, CA 92835

19 Pharmacist License No. RPH 50765

20 and

21 **ALLAN MICHAEL PIWONKA**  
22 8440 E Chapman Avenue  
Orange, CA 92869

23 Pharmacist License No. RPH 27345

24 Respondents.  
25  
26  
27  
28

1 Complainant alleges:

2 **PARTIES**

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

5 2. On or about April 29, 2005, the Board of Pharmacy issued Pharmacy Permit Number  
6 PHY 47098 to Innovative Compounding Solutions, doing business as Heritage Compounding  
7 Pharmacy (Respondent Heritage), with Esther J. Kim, as President and Pharmacist-in- Charge  
8 (Respondents). The Pharmacy Permit was in full force and effect at all times relevant to the  
9 charges brought herein and will expire on April 1, 2014, unless renewed.

10 3. On or about June 9, 2005, the Board of Pharmacy issued Licensed Sterile  
11 Compounding Permit Number LSC 99303 to Innovative Compounding Solutions, doing business  
12 as Heritage Compounding Pharmacy (Respondent Heritage). The Licensed Sterile Compounding  
13 Permit was in full force and effect at all times relevant to the charges brought herein and will  
14 expire on April 1, 2014, unless renewed.

15 4. On or about March 31, 1999, the Board of Pharmacy issued Pharmacist License  
16 Number RPH 50765 to Esther J. Kim (Respondent Kim). The Pharmacy Permit was in full force  
17 and effect at all times relevant to the charges brought herein and will expire on April 1, 2014,  
18 unless renewed.

19 5. On or about August 5, 1971, the Board of Pharmacy issued Pharmacist License  
20 Number RPH 27345 to Allan Michael Piwonka (Respondent Piwonka). The Pharmacy Permit  
21 was in full force and effect at all times relevant to the charges brought herein and will expire on  
22 March 31, 2014, unless renewed.

23 **JURISDICTION**

24 6. This Accusation is brought before the Board of Pharmacy (Board), Department of  
25 Consumer Affairs, under the authority of the following laws. All section references are to the  
26 Business and Professions Code unless otherwise indicated.  
27  
28



1 (3) Administering drugs and biologicals by injection pursuant to a  
prescriber's order.

2 (4) Initiating or adjusting the drug regimen of a patient pursuant to an order  
3 or authorization made by the patient's prescriber and in accordance with the  
policies, procedures, or protocols of the licensed health care facility.

4 (b) Prior to performing any procedure authorized by this section, a  
5 pharmacist shall have received appropriate training as prescribed in the policies  
6 and procedures of the licensed health care facility.

7 12. Section 4059 of the Code states:

8 (a) A person may not furnish any dangerous drug, except upon the  
9 prescription of a physician, dentist, podiatrist, optometrist, veterinarian, or  
naturopathic doctor pursuant to Section 3640.7. A person may not furnish any  
10 dangerous device, except upon the prescription of a physician, dentist, podiatrist,  
optometrist, veterinarian, or naturopathic doctor pursuant to Section 3640.7.

11 (b) This section does not apply to the furnishing of any dangerous drug or  
12 dangerous device by a manufacturer, wholesaler, or pharmacy to each other or to a  
13 physician, dentist, podiatrist, optometrist, veterinarian, or naturopathic doctor  
pursuant to Section 3640.7, or to a laboratory under sales and purchase records that  
14 correctly give the date, the names and addresses of the supplier and the buyer, the  
drug or device, and its quantity. This section does not apply to the furnishing of  
15 any dangerous device by a manufacturer, wholesaler, or pharmacy to a physical  
therapist acting within the scope of his or her license under sales and purchase  
16 records that correctly provide the date the device is provided, the names and  
addresses of the supplier and the buyer, a description of the device, and the  
17 quantity supplied.

18 . . . .

19  
20 13. Section 4113, subdivision (c) of the Code states: "The pharmacist-in-charge shall be  
21 responsible for a pharmacy's compliance with all state and federal laws and regulations pertaining  
22 to the practice of pharmacy."

23 14. Section 4116 of the Code states in pertinent part:

24 (a) No person other than a pharmacist, an intern pharmacist, an authorized  
25 officer of the law, or a person authorized to prescribe shall be permitted in that  
area, place, or premises described in the license issued by the board wherein  
26 controlled substances or dangerous drugs or dangerous devices are stored,  
possessed, prepared, manufactured, derived, compounded, dispensed, or  
27 repackaged. However, a pharmacist shall be responsible for any individual who  
enters the pharmacy for the purposes of receiving consultation from the pharmacist  
28 or performing clerical, inventory control, housekeeping, delivery, maintenance, or

1 similar functions relating to the pharmacy if the pharmacist remains present in the  
2 pharmacy during all times as the authorized individual is present.

3 . . . .

4 15. Section 4301 of the Code states in pertinent part:

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

9 . . . .

10 (c) Gross negligence.

11 . . . .

12 (f) The commission of any act involving moral turpitude, dishonesty, fraud,  
13 deceit, or corruption, whether the act is committed in the course of relations as a  
14 licensee or otherwise, and whether the act is a felony or misdemeanor or not.

15 (g) Knowingly making or signing any certificate or other document that  
16 falsely represents the existence or nonexistence of a state of facts.

17 . . . .

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

20 . . . .

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

26 . . . .

27 (q) Engaging in any conduct that subverts or attempts to subvert an  
28 investigation of the board.

. . . .

16. Health and Safety Code section 11200 states:

(a) No person shall dispense or refill a controlled substance prescription  
more than six months after the date thereof.

1 (b) No prescription for a Schedule III or IV substance may be refilled more  
2 than five times and in an amount, for all refills of that prescription taken together,  
3 exceeding a 120-day supply.

4 (c) No prescription for a Schedule II substance may be refilled.

5 17. Health and Safety Code section 11150 states:

6 No person other than a physician, dentist, podiatrist, or veterinarian, or  
7 naturopathic doctor acting pursuant to Section 3640.7 of the Business and  
8 Professions Code, or pharmacist acting within the scope of a project authorized  
9 under Article 1 (commencing with Section 128125) of Chapter 3 of Part 3 of  
10 Division 107 or within the scope of either Section 4052.1 or 4052.2 of the  
11 Business and Professions Code, a registered nurse acting within the scope of a  
12 project authorized under Article 1 (commencing with Section 128125) of Chapter  
13 3 of Part 3 of Division 107, a certified nurse-midwife acting within the scope of  
14 Section 2746.51 of the Business and Professions Code, a nurse practitioner acting  
15 within the scope of Section 2836.1 of the Business and Professions Code, a  
16 physician assistant acting within the scope of a project authorized under Article 1  
17 (commencing with Section 128125) of Chapter 3 of Part 3 of Division 107 or  
18 Section 3502.1 of the Business and Professions Code, a naturopathic doctor acting  
19 within the scope of Section 3640.5 of the Business and Professions Code, or an  
20 optometrist acting within the scope of Section 3041 of the Business and  
21 Professions Code, or an out-of-state prescriber acting pursuant to Section 4005 of  
22 the Business and Professions Code shall write or issue a prescription.

23 18. Health and Safety Code section 11152 provides that no person shall write, issue, fill,  
24 compound, or dispense a prescription that does not conform to this division.

25 19. Health and Safety Code section 11157 provides that no person shall issue a  
26 prescription that is false or fictitious in any respect.

27 20. Health and Safety Code section 11165 states in pertinent part:

28 (a) To assist law enforcement and regulatory agencies in their efforts to  
control the diversion and resultant abuse of Schedule II, Schedule III, and  
Schedule IV controlled substances, and for statistical analysis, education, and  
research, the Department of Justice shall, contingent upon the availability of  
adequate funds from the Contingent Fund of the Medical Board of California, the  
Pharmacy Board Contingent Fund, the State Dentistry Fund, the Board of  
Registered Nursing Fund, and the Osteopathic Medical Board of California  
Contingent Fund, maintain the Controlled Substance Utilization Review and  
Evaluation System (CURES) for the electronic monitoring of, and Internet access  
to information regarding, the prescribing and dispensing of Schedule II, Schedule

1 III, and Schedule IV controlled substances by all practitioners authorized to  
2 prescribe or dispense these controlled substances.

3  
4 (d) For each prescription for a Schedule II, Schedule III, or Schedule IV  
5 controlled substance, as defined in the controlled substances schedules in federal  
6 law and regulations, specifically Sections 1308.12, 1308.13, and 1308.14,  
7 respectively, of Title 21 of the Code of Federal Regulations, the dispensing  
8 pharmacy or clinic shall provide the following information to the Department of  
9 Justice on a weekly basis and in a format specified by the Department of Justice:

10 (1) Full name, address, and the telephone number of the ultimate user or  
11 research subject, or contact information as determined by the Secretary of the  
12 United States Department of Health and Human Services, and the gender, and date  
13 of birth of the ultimate user.

14 (2) The prescriber's category of licensure and license number; federal  
15 controlled substance registration number; and the state medical license number of  
16 any prescriber using the federal controlled substance registration number of a  
17 government-exempt facility.

18 (3) Pharmacy prescription number, license number, and federal controlled  
19 substance registration number.

20 (4) NDC (National Drug Code) number of the controlled substance  
21 dispensed.

22 (5) Quantity of the controlled substance dispensed.

23 (6) ICD-9 (diagnosis code), if available.

24 (7) Number of refills ordered.

25 (8) Whether the drug was dispensed as a refill of a prescription or as a first-  
26 time request.

27 (9) Date of origin of the prescription.

28 (10) Date of dispensing of the prescription.

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REGULATORY PROVISIONS

21. California Code of Regulations, title 16, section 1714 states in pertinent part:

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27 (b) Each pharmacy licensed by the board shall maintain its facilities, space,  
28 fixtures, and equipment so that drugs are safely and properly prepared, maintained,

1 secured and distributed. The pharmacy shall be of sufficient size and unobstructed  
2 area to accommodate the safe practice of pharmacy.

3 .....  
4 (d) Each pharmacist while on duty shall be responsible for the security of the  
5 prescription department, including provisions for effective control against theft or  
6 diversion of dangerous drugs and devices, and records for such drugs and devices.  
7 Possession of a key to the pharmacy where dangerous drugs and controlled  
8 substances are stored shall be restricted to a pharmacist.

9 .....  
10 22. California Code of Regulations, title 16, section 1716 provides that pharmacists  
11 shall not deviate from the requirements of a prescription except upon the prior consent of the  
12 prescriber or to select the drug product in accordance with Section 4073 of the Business and  
13 Professions Code.

14 23. California Code of Regulations, title 16, section 1735, subdivision (a) states in  
15 pertinent part:

16 "Compounding" means any of the following activities occurring in a  
17 licensed pharmacy, by or under the supervision of a licensed pharmacist, pursuant to  
18 a prescription:

- 19 (1) Altering the dosage form or delivery system of a drug
- 20 (2) Altering the strength of a drug
- 21 (3) Combining components or active ingredients
- 22 (4) Preparing a drug product from chemicals or bulk drug substances

23 .....  
24 24. California Code of Regulations, title 16, section 1761, subdivision (a) states:

25 (a) No pharmacist shall compound or dispense any prescription which  
26 contains any significant error, omission, irregularity, uncertainty, ambiguity or  
27 alteration. Upon receipt of any such prescription, the pharmacist shall contact the  
28 prescriber to obtain the information needed to validate the prescription.

1 **COST RECOVERY**

2 25. Section 125.3 of the Code provides, in pertinent part, that the Board may request the  
3 administrative law judge to direct a licentiate found to have committed a violation or violations of  
4 the licensing act to pay a sum not to exceed the reasonable costs of the investigation and  
5 enforcement of the case, with failure of the licentiate to comply subjecting the license to not being  
6 renewed or reinstated. If a case settles, recovery of investigation and enforcement costs may be  
7 included in a stipulated settlement.

8 **DRUGS**

9 26. Clindamycin is a dangerous drug pursuant to Business and Professions Code section  
10 4022 and is used to treat infections.

11 27. Clobetasol is a dangerous drug pursuant to Business and Professions Code section  
12 4022 and is used to treat scalp and skin conditions.

13 28. Hydroquinone is a dangerous drug pursuant to Business and Professions Code section  
14 4022 and is used to treat hyperpigmentation and melisma.

15 29. Ketoprofen is a dangerous drug pursuant to Business and Professions Code section  
16 4022 and is used for the treatment of pain.

17 30. Liothyronine is a dangerous drug pursuant to Business and Professions Code section  
18 4022 and is used to treat hypothyroidism.

19 31. Progesterone is a dangerous drug pursuant to Business and Professions Code section  
20 4022 and is used as a part of hormone replacement therapy in women.

21 32. Testosterone is a Schedule III controlled substance pursuant to Health and Safety  
22 Code section 11056, subdivision (f), and a dangerous drug pursuant to Business and Professions  
23 Code section 4022.

24 **FACTUAL ALLEGATIONS**

25 33. At all times mentioned herein and since April 29, 2005, Esther J. Kim (Respondent  
26 Kim), has been the President and Pharmacist-in-Charge (PIC) of Innovation Compounding  
27 Solutions, doing business as Heritage Compounding Pharmacy, (Respondent Heritage). At all  
28 times mentioned herein and since June 2011, Allan Piwonka (Respondent Piwonka) was

1 employed as a registered pharmacist at Respondent Heritage. Respondent Heritage is not, and  
2 has never been, a licensed health care facility or clinic.

3 34. In December 2011, the Board received a complaint from a pharmacy technician who  
4 was employed at Respondent Heritage, alleging that Respondent Heritage was violating  
5 Pharmacy Laws.

6 35. Based on the complaint, the Board initiated an investigation. On February 22, 2012,  
7 Board inspectors conducted an inspection of Respondent Heritage. The Board inspectors arrived  
8 at Respondent Heritage at approximately 8:30 a.m., before Respondent Heritage opened for  
9 business. At or about 9:15 a.m., a Board inspector observed S.K. (who is Respondent Kim's  
10 husband) unlock and enter the front door of Respondent Heritage. Five minutes later, the  
11 inspectors entered Respondent Heritage, and observed S.K. come out of the back room. S.K.  
12 informed the Board inspectors that he was the pharmacy manager and not a pharmacist. There  
13 was no one else on the premises at that time. The Board inspectors instructed S.K. to step outside  
14 and lock the front door of Respondent Heritage with S.K.'s key until Respondent Piwonka, who  
15 was scheduled to work at 10:00 a.m., arrived at Respondent Heritage. After Respondent Piwonka  
16 arrived, the Board inspectors conducted their inspection of Respondent Heritage. During the  
17 inspection, the Board inspectors observed that the back room had cabinets which stored  
18 dangerous drugs and that sterile compounding was performed in that area.<sup>1</sup> The Board inspectors  
19 also discovered that the door to the room that stored controlled substances and dangerous drugs  
20 was open.

21 36. During the inspection, Board inspectors discovered that Respondent Kim wrote  
22 prescriptions for dangerous drugs and controlled substances under the name of a fictitious  
23 physician, "Dr. Heritage," located at 2903 Saturn Street, Unit A, Brea, California 92821, with a  
24 DEA number of BH9242099, which are the address and DEA number for Respondent Heritage.

25 <sup>1</sup> "Sterile" compounds require sterility and are typically in the form of injectables for the  
26 direct administration into a sterile organ or fluid in the body. It is imperative these products  
27 contain little to no contaminants for the safety of the patient.  
28

1 The Board inspectors discovered that the following fraudulent prescriptions were filled and  
2 dispensed by Respondent Heritage:

3 a. RX 14171 for 30 gm of testosterone 2% cream filled and dispensed to JG on  
4 October 28, 2010 and then refilled on January 25, 2011, February 22, 2011, March 30, 2011,  
5 April 28, 2011 and January 5, 2012.

6 b. RX 14172 for 30 gm of progesterone 10% cream filled and dispensed to JG on  
7 October 28, 2010, and then refilled on January 25, 2011, February 22, 2011, March 20, 2011,  
8 April 28, 2011 and January 5, 2012.

9 c. RX 7800 for 30 gm of testosterone 2% VC Cream filled and dispensed to JG on  
10 March 22, 2010 and then refilled on July 8, 2010, August 17, 2010, and October 4, 2010.

11 d. RX 7799 for 30 gm of testosterone 2% cream filled and dispensed to JG on  
12 March 22, 2010, and then refilled on July 8, 2010, August 7, 2010, and October 4, 2010.

13 e. RX 8102 for 30 gm of ketoprofen 10% gel filled and dispensed to PP on April  
14 4, 2009.

15 37. In addition, after reviewing the Controlled Substance Utilization Review and  
16 Evaluation System (CURES) report, the Board inspectors discovered that the following eleven  
17 controlled substance prescriptions were dispensed under the prescriber name of "Dr. Heritage" by  
18 Respondent Heritage:

19

	RX No.	Date Dispensed	Patient's Name	Drug	Quantity	
20	1	18142	10/27/2011	AC	Testosterone	60
21	2	6115	8/13/2008	JG	Compounded	30
22	3	6115	10/6/2008	JG	Compounded	30
23	4	6115	12/2/2008	JG	Compounded	30
24	5	6115	12/29/2008	JG	Compounded	30
25	6	7489	2/11/2009	JG	Compounded	30
26	7	7489	3/3/2009	JG	Compounded	30
27	8	7800	3/16/2009	JG	Compounded	30
28	9	7800	4/20/2009	JG	Compounded	30
	10	7800	6/10/2009	JG	Compounded	30
	11	8196	4/22/2009	CR	Compounded	60

1 Based on the CURES report, Board inspectors determined that Respondent Kim provided the  
2 Department of Justice with false CURES information by providing a fictitious physician name for  
3 the aforementioned prescriptions.

4 38. During the first inspection on February 22, 2012, the Board inspectors received from  
5 Respondent Kim, a Doctor Usage Report covering the dates of January 1, 2012 through February  
6 1, 2012, which showed that Respondent Heritage had filled prescriptions under the prescriber  
7 name of "Dr. Heritage." At the Board's follow-up inspection on February 28, 2012, Respondent  
8 Kim provided Board inspectors with another Doctor Usage Report covering the period of January  
9 1, 2010 through December 30, 2010, which did not show any prescriptions filled by Respondent  
10 Heritage under the prescriber name of "Dr. Heritage's" name. When questioned by the Board  
11 inspector, Respondent Kim admitted that after her first inspection (on February 22, 2012), she  
12 voided or deleted all prescriptions under Dr. Heritage's name, including prescriptions that had  
13 been filled under the prescriber name of "Dr. Heritage."

14 39. On April 11, 2012, January 30, 2013, and February 26, 2013, Board inspectors  
15 conducted additional follow-up inspections of Respondent Heritage. At the conclusion of their  
16 investigation and after reviewing compounding logs, the Board inspectors determined that  
17 Respondent Heritage dispensed liothyronine 12.5 mcg SR capsules instead of liothyronine 125  
18 mcg SR capsules as follows:

19 a. RX 17263 for 30 capsules of liothyronine 125 mcg SR was dispensed to  
20 TB on August 5, 2011, September 6, 2011, September 29, 2011, and October 28, 2011. On  
21 August 5, 2011, the prescription was filled with a compounded medication liothyronine 125 mcg  
22 SR lot number 08052011@10, compounded on August 5, 2011, and verified by Respondent Kim.  
23 The compounding log for liothyronine 125 mcg SR lot number 08052011@10 showed the  
24 compounded product was prepared using liothyronine (T3) 1:100 lot number 06152011@9.  
25 However, the compounding log for lot number 06152011@9 was a formulation for liothyronine  
26 (T3) 1:1000 instead of liothyronine (T3) 1:100. Thus, Respondent Heritage dispensed RX 17263  
27 with a compounded product containing 12.5 mcg of liothyronine (T3) instead of 125 mcg of  
28 liothyronine (T3).

1           b.     RX 18476 for 30 capsules of liothyronine 125 mcg SR was dispensed on  
2 December 1, 2011 and subsequently refilled on January 3, 2012 and February 1, 2012. The  
3 prescription was dispensed with liothyronine 125 mcg SR lot number 12011211@7, compounded  
4 on December 1, 2011, and verified by Respondent Piwonka. The compounding log for  
5 liothyronine 125 mcg SR lot number 12011211@7 showed that the medication was prepared  
6 using liothyronine (T3) 1:100 aliquot log number 11222011@5. However, the compounding log  
7 for lot number 11222011@5 was a formulation for liothyronine (T3) 1:1000 instead of  
8 liothyronine (T3) 1:100. Thus, Respondent Heritage dispensed RX 18476 with the wrong  
9 strength of medication, liothyronine (T3) 12.5 mcg SR capsules instead of liothyronine (T3) 125  
10 mcg SR.

11           40.    The Board inspectors also discovered that Respondent Kim and Respondent Piwonka  
12 were administering Vitamin B-12 injections to patients at Respondent Heritage. Respondent Kim  
13 admitted to Board inspectors that both Respondent Kim and Respondent Piwonka had been  
14 administering Vitamin B-12 injections at Respondent Heritage since January 2011. The Board  
15 inspector also determined that Respondent Kim allowed a pharmacy technician to administer  
16 Vitamin B-12 injections to a customer.

17           41.    At the conclusion of the investigation, the Board inspectors determined that  
18 Respondent Kim wrote the following eight prescriptions for controlled substances and/or  
19 dangerous drugs:

20           a.     On October 28, 2010, a prescription for JG processed under RX 14171 for 30  
21 gm of testosterone 2% cream.

22           b.     On October 28, 2010, a prescription for JG processed under RX 14172 for 30  
23 gm of progesterone 10% cream.

24           c.     On March 22, 2010, a prescription for JG processed under RX 7800 for 30 gm  
25 of testosterone 2% VC Cream.

26           d.     On March 22, 2010, a prescription for JG processed under RX 7799 for 30 gm  
27 of testosterone 2% cream.

28

1 e. On October 27, 2011, a prescription for AC processed under RX 18142 for 60  
2 gm of testosterone.

3 f. On August 13, 2008, a prescription for JG processed under RX 6115 for 30 gm  
4 of a compounded product.

5 g. On February 11, 2009, a prescription for JG processed under RX 7489 for 30  
6 gm of a compounded product.

7 h. On April 22, 2009, a prescription for CR processed under RX 8196 for 60 gm  
8 of a compounded product.

9 42. Board inspectors also discovered that on January 5, 2012, Respondent Kim  
10 compounded, filled and dispensed a refill on prescription RX 14171 (prescribed on October 28,  
11 2010) for JG for 30 gm of testosterone 2% cream, a controlled substance.

12 **FIRST CAUSE FOR DISCIPLINE**

13 **(Against Respondent Kim and Respondent Heritage)**

14 **(Possession of Key to Pharmacy & Access to Dangerous Drugs and Controlled Substances)**

15 43. Respondent Kim and Respondent Heritage are subject to disciplinary action under  
16 Code section 4301(o), for violating Code section 4116(a) and California Code of Regulations,  
17 title 16, section 1714(d) for allowing S.K., who is not a pharmacist, to have possession of a key to  
18 the pharmacy and access to an area where dangerous drugs and/or controlled substances are  
19 stored, as set forth in paragraphs 33 through 42, which are incorporated herein by reference.

20 **SECOND CAUSE FOR DISCIPLINE**

21 **(Against Respondent Kim and Respondent Heritage)**

22 **(Furnishing Dangerous Drugs without a Prescription)**

23 44. Respondent Kim and Respondent Heritage are subject to disciplinary action under  
24 Code sections 4301(j) and (o), for violating Code section 4059(a) for furnishing dangerous drugs  
25 without a valid prescription, as set forth in paragraphs 33 through 42, which are incorporated  
26 herein by reference.



1 information (fictitious physician with the address of 2903 Saturn Street, Unit A, Brea, CA 92821,  
2 DEA Registration Number BH9242099) to CURES, as set forth in paragraphs 33 through 42,  
3 which are incorporated herein by reference.

4 **SEVENTH CAUSE FOR DISCIPLINE**

5 **(Against Respondent Kim and Respondent Heritage)**

6 **(Act Involving Dishonesty, Fraud, Deceit)**

7 49. Respondent Kim and Respondent Heritage are subject to disciplinary action under  
8 Code sections 4301(f), for committing acts involving dishonest, fraud or deceit, in that  
9 Respondent Kim wrote prescriptions under a fictitious physician name (“Dr. Heritage”),  
10 Respondent Kim submitted false CURES information to the Department of Justice, and  
11 Respondent Kim tampered with computer files by voiding/deleting information about the  
12 prescriptions under “Dr. Heritage’s” name, as set forth in paragraphs 33 through 42, which are  
13 incorporated herein by reference.

14 **EIGHTH CAUSE FOR DISCIPLINE**

15 **(Against Respondent Kim and Respondent Heritage)**

16 **(Making a Document that Falsely Represents the Existence of a Fact)**

17 50. Respondent Kim and Respondent Heritage are subject to disciplinary action under  
18 Code sections 4301(g), for making documents that falsely represented the existence of a fact, in  
19 that Respondent Kim wrote prescriptions under a fictitious physician name (“Dr. Heritage”), as  
20 set forth in paragraphs 33 through 42, which are incorporated herein by reference.

21 **NINTH CAUSE FOR DISCIPLINE**

22 **(Against Respondent Kim and Respondent Heritage)**

23 **(Engaging in Conduct that Subverts or Attempts to Subvert a Board Investigation)**

24 51. Respondent Kim and Respondent Heritage are subject to disciplinary action under  
25 Code sections 4301(q), for engaging in conduct that subverts or attempts to subvert a Board  
26 investigation, in that Respondent Kim tampered with computer files by voiding/deleting  
27 information about the prescriptions under “Dr. Heritage’s” name after the Board’s first  
28 inspection, as set forth in paragraphs 33 through 42, which are incorporated herein by reference.



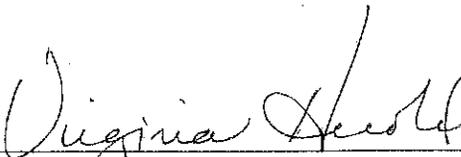


1 PRAYER

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 Pharmacy Permit Number PHY 47098, issued to Innovative  
5 Compounding Solutions, doing business as Heritage Compounding Pharmacy;
- 6 2. Revoking or suspending Sterile Compounding License Number LSC 99303, issued to  
7 Innovative Compounding Solutions, doing business as Heritage Compounding Pharmacy;
- 8 3. Revoking or suspending Pharmacist License Number RPH 50765, issued to Esther J.  
9 Kim;
- 10 4. Revoking or suspending Pharmacist License Number RPH 27345, issued to Allan  
11 Michael Piwonka;
- 12 5. Ordering Respondents to pay the Board of Pharmacy the reasonable costs of the  
13 investigation and enforcement of this case, pursuant to Business and Professions Code section  
14 125.3;
- 15 6. Taking such other and further action as deemed necessary and proper.

16  
17  
18 DATED: 1/17/14

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

23 SD2013705747  
24 70754840.doc