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

11 In the Matter of the Accusation Against:

Case No. 4904

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

ACCUSATION

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

17 **and**

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

20 **Pharmacist License No. RPH 50765**

21 **and**

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

24 **Pharmacist License No. RPH 27345**

25 Respondents.

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.

1 7. Section 4011 of the Code provides that the Board shall administer and enforce both
2 the Pharmacy Law [Bus. & Prof. Code, § 4000 et seq.] and the Uniform Controlled Substances
3 Act [Health & Safety Code, § 11000 et seq.].

4 8. Section 4300(a) of the Code provides that every license issued by the Board may be
5 suspended or revoked.

6 9. Section 4300.1 of the Code states:

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

11 **STATUTORY PROVISIONS**

12 10. Section 4022 of the Code states:

13 "Dangerous drug" or "dangerous device" means any drug or device unsafe for
14 self-use in humans or animals, and includes the following:

15 (a) Any drug that bears the legend: "Caution: federal law prohibits
16 dispensing without prescription," "Rx only," or words of similar import.

17 (b) Any device that bears the statement: "Caution: federal law restricts this
18 device to sale by or on the order of a _____," "Rx only," or words of similar import,
19 the blank to be filled in with the designation of the practitioner licensed to use or
20 order use of the device.

21 (c) Any other drug or device that by federal or state law can be lawfully
22 dispensed only on prescription or furnished pursuant to Section 4006.

23 11. Section 4052.1 of the Code states:

24 (a) Notwithstanding any other provision of law, a pharmacist may perform
25 the following procedures or functions in a licensed health care facility in
26 accordance with policies, procedures, or protocols developed by health
27 professionals, including physicians, pharmacists, and registered nurses, with the
28 concurrence of the facility administrator:

 (1) Ordering or performing routine drug therapy-related patient assessment
procedures including temperature, pulse, and respiration.

 (2) Ordering drug therapy-related laboratory tests.

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

17

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.

. . . .

REGULATORY PROVISIONS

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

. . . .

(b) Each pharmacy licensed by the board shall maintain its facilities, space,
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.¹ 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 ¹ "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 liothyroine 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 **TENTH CAUSE FOR DISCIPLINE**

2 **(Against Respondent Kim, Respondent Piwonka, and Respondent Heritage)**

3 **(Variation from Prescription)**

4 52. Respondent Kim, Respondent Piwonka and Respondent Heritage are subject to
5 disciplinary action under Code sections 4301(o), for violating California Code of Regulations,
6 title 16, sections 1716, for deviating from the requirements of a prescription for dispensing RX
7 18476 with the wrong strength of medication, liothyronine (T3) 12.5 mcg SR capsules instead of
8 liothyronine (T3) 125 mcg SR, as set forth in paragraph 33 through 42, which are incorporated
9 herein by reference.

10 **ELEVENTH CAUSE FOR DISCIPLINE**

11 **(Against Respondent Kim, Respondent Piwonka, and Respondent Heritage)**

12 **(Administering Drugs by Injection)**

13 53. Respondent Kim, Respondent Piwonka and Respondent Heritage are subject to
14 disciplinary action under Code sections 4301(o), for violating Code section 4052.1, in that
15 Respondents administered Vitamin B-12 injections to patients at Respondent Heritage even
16 though Respondent Heritage is not a licensed health care facility, as set forth in paragraphs 33
17 through 42, which are incorporated herein by reference.

18 **TWELFTH CAUSE FOR DISCIPLINE**

19 **(Against Respondent Kim)**

20 **(General Unprofessional Conduct)**

21 54. Respondent Kim is subject to disciplinary action under Code sections 4301 for
22 general unprofessional conduct for creating prescriptions under a fictitious physician name in
23 order to dispense controlled substances and dangerous drugs without a valid prescription,
24 providing the Department of Justice with false CURES information, tampering with computer
25 files so that the records falsely represent the nonexistence of a fact, and allowing a pharmacy
26 technician to administer Vitamin B-12 injections to customers, which is outside the scope of a
27 pharmacy technician's license, as set forth in paragraphs 33 through 42, which are incorporated
28 herein by reference.

1 **DISCIPLINARY CONSIDERATIONS**

2 55. To determine the degree of discipline, if any, to be imposed on Respondents,
3 Complainant alleges:

4 56. On or about May 1, 2008, the Board of Pharmacy issued Citation No. CI 2007 35772
5 to Respondent Heritage for violation of Business and Professions Code section 4342 for
6 maintaining within its inventory, outdated drugs and chemicals used for compounding that had
7 expired expiration dates and assessed a fine in the amount of \$750.00. Respondent Heritage
8 complied with Citation No. CI 2007 35772.

9 57. On or about May 1, 2008, the Board of Pharmacy issued Citation No. CI 2007 36124
10 to Respondent Kim for violation of Business and Professions Code section 4342 for maintaining
11 within its inventory, outdated drugs and chemicals used for compounding that had expired
12 expiration dates and assessed a fine in the amount of \$750.00. Respondent Kim complied with
13 Citation No. CI 2007 36124.

14 58. On or about April 1, 2011, the Board of Pharmacy issued Citation No. CI 2009 43880
15 to Respondent Heritage for violation of California Code of Regulations, title 16, section 1716.2,
16 subdivisions (a)(2) and (3) for failing to document the expiration date of all the ingredients used
17 to prepare compounds and assigning a 180 day expiration date to preparations which were
18 prepared from ingredients with a shorter expiration date, and assessed a fine in the amount of
19 \$1,000.00. Respondent Heritage complied with Citation No. CI 2009 43880.

20 59. On or about April 1, 2011, the Board of Pharmacy issued Citation No. CI 2010 47709
21 to Respondent Kim for violation of California Code of Regulations, title 16, sections 1716.2,
22 subdivisions (a)(2) and (3) for failing to document the expiration date of all the ingredients used
23 to prepare compounds and assigning a 180 day expiration date to preparations which were
24 prepared from ingredients with a shorter expiration date, and section 1751.7, subdivision (c) for
25 failing to quarantine and test for sterility or pyrogens compounded batches prior to dispensing,
26 and assessed a fine in the amount of \$2,000.00. Respondent Kim complied with Citation No. CI
27 2010 47709.

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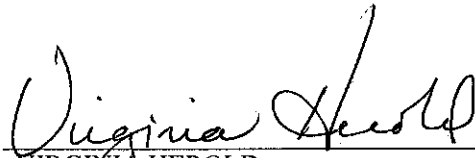
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PRAYER

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

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

DATED: 1/17/14



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

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