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1	KAMALA D. HARRIS	
2	Attorney General of California JAMES M. LEDAKIS	
3	Supervising Deputy Attorney General MARICHELLE S. TAHIMIC	
4	Deputy Attorney General State Bar No. 147392	
5	600 West Broadway, Suite 1800 San Diego, CA 92101	
6	P.O. Box 85266 San Diego, CA 92186-5266	
7	Telephone: (619) 645-3154	
	Facsimile: (619) 645-2061 Attorneys for Complainant	
8		RE THE
9		PHARMACY CONSUMER AFFAIRS
10	STATE OF C	CALIFORNIA
11	In the Matter of the Accusation Against:	Case No. 5505
12	LEINA LE-HO YASUOKA, AKA LEINA UYEN LE-HO	
13	565 S. Parker Street, Unit A	ACCUSATION
14	Orange, CA 92868	ACCUSATION
15	Pharmacist License No. RPH 63410	
16	Respondent.	
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17	Complainant alleges:	
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18	PAR	TIES s this Accusation solely in her official capacity as
18 19	PAR	s this Accusation solely in her official capacity as
18 19 20	PAR 1. Virginia Herold (Complainant) brings the Executive Officer of the Board of Pharmacy,	s this Accusation solely in her official capacity as
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1	JURISDICTION
2	3. This Accusation is brought before the Board of Pharmacy (Board), Department of
3	Consumer Affairs, under the authority of the following laws. All section references are to the
4	Business and Professions Code unless otherwise indicated.
5	4. Section 4300 of the Code states:
6	(a) Every license issued may be suspended or revoked.
7 8	(b) The board shall discipline the holder of any license issued by the board, whose default has been entered or whose case has been heard by the board and found guilty, by any of the following methods:
9	(1) Suspending judgment.
10	(2) Placing him or her upon probation.
11	(3) Suspending his or her right to practice for a period not exceeding one
12	year.
13	(4) Revoking his or her license.(5) Taking one other setting in relation to dissiplining him on her setting the bound.
14	(5) Taking any other action in relation to disciplining him or her as the board in its discretion may deem proper.
15	
16	(e) The proceedings under this article shall be conducted in accordance with Chapter 5 (commencing with Section 11500) of Part 1 of Division 3 of the
17 18	Government Code, and the board shall have all the powers granted therein. The action shall be final, except that the propriety of the action is subject to review by the superior court pursuant to Section 1094.5 of the Code of Civil Procedure."
19	5. Section 4300.1 of the Code states:
20	The expiration, cancellation, forfeiture, or suspension of a board-issued license by
21	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
22	any investigation of, or action or disciplinary proceeding against, the licensee or to render a decision suspending or revoking the license.
23	Tender a decision suspending of revoking the needse.
24	STATUTORY AND REGULATORY PROVISIONS
25	6. Section 4301 of the Code states:
26	The board shall take action against any holder of a license who is guilty of unprofessional conduct or whose license has been procured by fraud or
27	misrepresentation or issued by mistake. Unprofessional conduct shall include, but is not limited to, any of the following:
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1 2	(j) The violation of any of the statutes of this state, or any other state, or of the United States regulating controlled substances and dangerous drugs.
3	
4	(o) Violating or attempting to violate, directly or indirectly, or assisting in or
5	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.
7	7. Code section 4306.5 states in part:
8	Unprofessional conduct for a pharmacist may include any of the following:
9 10	(a) Acts or omissions that involve, in whole or in part, the inappropriate exercise of his or her education, training, or experience as a pharmacist, whether or not the act or omission arises in the course of the practice of pharmacy or the ownership,
11	management, administration, or operation of a pharmacy or other entity licensed by the board.
12	
13	8. Title 16, California Code of Regulations ("CCR"), section 1716 states:
14	Pharmacists shall not deviate from the requirements of a prescription except upon
15	the prior consent of the prescriber or to select the drug product in accordance with Section 4073 of the Business and Professions Code.
16 17	Nothing in this regulation is intended to prohibit a pharmacist from exercising commonly-accepted pharmaceutical practice in the compounding or dispensing of a prescription.
18	9. Title 16, CCR, section 1761 states in part:
19	(a) No pharmacist shall compound or dispense any prescription which contains any
20	significant error, omission, irregularity, uncertainty, ambiguity or alteration. Upon receipt of any such prescription, the pharmacist shall contact the prescriber to
21	obtain the information needed to validate the prescription.
22	(b) Even after conferring with the prescriber, a pharmacist shall not compound or dispense a controlled substance prescription where the pharmacist knows or has
23	objective reason to know that said prescription was not issued for a legitimate medical purpose.
24	10. Health and Safety Code section 11162.1 states:
25	(a) The prescription forms for controlled substances shall be printed with the following features:
26	(1) A latent, repetitive "void" pattern shall be printed across the entire front
27	of the prescription blank; if a prescription is scanned or photocopied, the word "void" shall appear in a pattern across the entire front of the prescription.
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(2) A watermark shall be printed on the backside of the prescription blank; the watermark shall consist of the words "California Security Prescription."
(3) A chemical void protection that prevents alteration by chemical washing.
(4) A feature printed in thermochromic ink.
(5) An area of opaque writing so that the writing disappears if the prescription is lightened.
(6) A description of the security features included on each prescription form.
(7) (A) Six quantity check off boxes shall be printed on the form so that the prescriber may indicate the quantity by checking the applicable box where the following quantities shall appear:
1-24
25-49
50-74
75-100
101-150
151 and over.
(B) In conjunction with the quantity boxes, a space shall be provided to designate the units referenced in the quantity boxes when the drug is not in tablet or capsule form.
(8) Prescription blanks shall contain a statement printed on the bottom of the prescription blank that the "Prescription is void if the number of drugs prescribed is not noted."
(9) The preprinted name, category of licensure, license number, federal controlled substance registration number, and address of the prescribing practitioner.
(10) Check boxes shall be printed on the form so that the prescriber may indicate the number of refills ordered.
(11) The date of origin of the prescription.
(12) A check box indicating the prescriber's order not to substitute.
(13) An identifying number assigned to the approved security printer by the Department of Justice.
(14) (A) A check box by the name of each prescriber when a prescription form lists multiple prescribers.
(B) Each prescriber who signs the prescription form shall identify himself or herself as the prescriber by checking the box by his or her name.
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(b) Each batch of controlled substance prescription forms shall have the lot number printed on the form and each form within that batch shall be numbered sequentially beginning with the numeral one.

(c) (1) A prescriber designated by a licensed health care facility, a clinic specified in Section 1200, or a clinic specified in subdivision (a) of Section 1206 that has 25 or more physicians or surgeons may order controlled substance prescription forms for use by prescribers when treating patients in that facility without the information required in paragraph (9) of subdivision (a) or paragraph (3) of this subdivision.

(2) Forms ordered pursuant to this subdivision shall have the name, category of licensure, license number, and federal controlled substance registration number of the designated prescriber and the name, address, category of licensure, and license number of the licensed health care facility the clinic specified in Section 1200, or the clinic specified in Section 1206 that has 25 or more physicians or surgeons preprinted on the form. Licensed health care facilities or clinics exempt under Section 1206 are not required to preprint the category of licensure and license number of their facility or clinic.

(3) Forms ordered pursuant to this section shall not be valid prescriptions without the name, category of licensure, license number, and federal controlled substance registration number of the prescriber on the form.

(4) (A) Except as provided in subparagraph (B), the designated prescriber shall maintain a record of the prescribers to whom the controlled substance prescription forms are issued, that shall include the name, category of licensure, license number, federal controlled substance registration number, and quantity of controlled substance prescription forms issued to each prescriber. The record shall be maintained in the health facility for three years.

(B) Forms ordered pursuant to this subdivision that are printed by a computerized prescription generation system shall not be subject to subparagraph (A) or paragraph (7) of subdivision (a). Forms printed pursuant to this subdivision that are printed by a computerized prescription generation system may contain the prescriber's name, category of professional licensure, license number, federal controlled substance registration number, and the date of the prescription.

(d) This section shall become operative on January 1, 2012. Prescription forms not in compliance with this division shall not be valid or accepted after July 1, 2012.

11. Health and Safety Code section 11164 states:

Except as provided in Section 11167, no person shall prescribe a controlled substance, nor shall any person fill, compound, or dispense a prescription for a controlled substance, unless it complies with the requirements of this section.

(a) Each prescription for a controlled substance classified in Schedule II, III, IV, or V, except as authorized by subdivision (b), shall be made on a controlled substance prescription form as specified in Section 11162.1 and shall meet the following requirements:

(1) The prescription shall be signed and dated by the prescriber in ink and shall contain the prescriber's address and telephone number; the name of the ultimate user or research subject, or contact information as determined by the

Secretary of the United States Department of Health and Human Services; refill information, such as the number of refills ordered and whether the prescription is a 1 first-time request or a refill; and the name, quantity, strength, and directions for use 2 of the controlled substance prescribed. 3 (2) The prescription shall also contain the address of the person for whom the controlled substance is prescribed. If the prescriber does not specify this address on 4 the prescription, the pharmacist filling the prescription or an employee acting under the direction of the pharmacist shall write or type the address on the prescription or 5 maintain this information in a readily retrievable form in the pharmacy. 6 (1) Notwithstanding paragraph (1) of subdivision (a) of Section 11162.1, any (b)controlled substance classified in Schedule III, IV, or V may be dispensed upon an 7 oral or electronically transmitted prescription, which shall be produced in hard copy form and signed and dated by the pharmacist filling the prescription or by any other 8 person expressly authorized by provisions of the Business and Professions Code. Any person who transmits, maintains, or receives any electronically transmitted 9 prescription shall ensure the security, integrity, authority, and confidentiality of the prescription. 10(2) The date of issue of the prescription and all the information required for a 11 written prescription by subdivision (a) shall be included in the written record of the prescription; the pharmacist need not include the address, telephone number, license 12 classification, or federal registry number of the prescriber or the address of the patient on the hard copy, if that information is readily retrievable in the pharmacy. 13 (3) Pursuant to an authorization of the prescriber, any agent of the prescriber 14 on behalf of the prescriber may orally or electronically transmit a prescription for a controlled substance classified in Schedule III, IV, or V, if in these cases the written 15 record of the prescription required by this subdivision specifies the name of the agent of the prescriber transmitting the prescription. 16 (c) The use of commonly used abbreviations shall not invalidate an otherwise valid 17 prescription. 18 (d) Notwithstanding any provision of subdivisions (a) and (b), prescriptions for a controlled substance classified in Schedule V may be for more than one person in the same family with the same medical need. 19 20 (e) This section shall become operative on January 1, 2005. 21 12. Health and Safety Code section 11167 states: 22 Notwithstanding subdivision (a) of Section 11164, in an emergency where failure to 23 issue a prescription may result in loss of life or intense suffering, an order for a controlled substance may be dispensed on an oral order, an electronic data 24 transmission order, or a written order not made on a controlled substance form as specified in Section 11162.1, subject to all of the following requirements: 25 (a) The order contains all information required by subdivision (a) of Section 11164. 26 (b) Any written order is signed and dated by the prescriber in ink, and the pharmacy 27 reduces any oral or electronic data transmission order to hard copy form prior to dispensing the controlled substance. $\mathbf{28}$ 6

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1 2	(c) The prescriber provides a written prescription on a controlled substance prescription form that meets the requirements of Section 11162.1, by the seventh day following the transmission of the initial order; a postmark by the seventh day following transmission of the initial order shall constitute compliance.
3	(d) If the prescriber fails to comply with subdivision (c), the pharmacy shall so
4	notify the Department of Justice in writing within 144 hours of the prescriber's failure to do so and shall make and retain a hard copy, readily retrievable record of the prescription, including the date and method of notification of the Department of
5	Justice.
6	(e) This section shall become operative on January 1, 2005.
7	COST RECOVERY
8	13. Section 125.3 of the Code provides, in pertinent part, that the Board may request the
9	administrative law judge to direct a licentiate found to have committed a violation or violations of
10	the licensing act to pay a sum not to exceed the reasonable costs of the investigation and
11	enforcement of the case, with failure of the licentiate to comply subjecting the license to not being
12	renewed or reinstated. If a case settles, recovery of investigation and enforcement costs may be
13	included in a stipulated settlement.
14	DRUGS
15	14. <u>Duragesic patch</u> , a brand name for fentanyl patch, is a Schedule II controlled substance
16	pursuant to Health and Safety Code section 11055, subdivision (c), and a dangerous drug pursuant
17	to Business and Professions Code section 4022. It is used to manage severe, chronic pain.
18	FACTS
19	15. On February 22, 2011, R.M., an 88-year old female was transferred to a skilled
20	nursing facility after a hospital stay for evaluation. R.M. had been diagnosed with acute
21	myocardial infarction and left femoral artery occlusion with left foot gangrene, among other things.
22	R.M. was terminal and was on comfort measures only.
23	16. R.M. was medicated with Roxanol 2mg – 4mg every 4 hours as needed since February
24	22, 2011. This dose is equivalent to 25 mcg Duragesic patch.
25	17. On March 11, 2011, R.M.'s physician wrote a new order for Roxanol 4 mg SL every 6
26	hours with specific orders to hold the medication if R.M.'s respiratory rate fell below 8 breaths per
27	minute. The physician also wrote an order for Duragesic patch 12.5 mcg every 72 hours to the
28	chest wall.
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1	18. On or about March 11, 2011, Respondent, a pharmacist at Senior Care Pharmacy	
2	Services, Inc., received a faxed medication order from the facility for R.M. The medication order	
3	was not on a controlled substance prescription form pursuant to the requirements of Health and	
4	Safety Code section 11162.1, nor did it contain the prescriber's address and telephone number and	
5	the address of the person for whom the controlled substance is prescribed, among other things.	
6	19. Respondent dispensed five patches of Duragesic 75 mcg and five patches of Duragesic	
7	50 mcg total five doses of 125 mcg Duragesic patch for R.M. Duragesic patches come in doses of	
8	12.5 mcg, 25 mcg, 50 mcg, 75 mcg and 100 mcg per patch. The appropriate dose for R.M. should	
9	not exceed 25 mcg. Respondent failed to contact the prescribing physician to verify the dose of	
10	Duragesic patch. According to Respondent, a pharmacy technician at Senior Care Pharmacy	
11	Services, Inc. contacted a nurse at the facility and verified the medication order. The facility has	
12	no documentation of a call from Respondent or anyone at Senior Care Pharmacy Services, Inc. to	
13	clarify the medication order.	
14	20. R.M. was administered Duragesic patch at 9:00 a.m. on March 12, 2011. R.M.	
15	experience difficulty breathing and eventually stopped breathing. R.M. was pronounced dead at	
16	2:25 p.m. on March 13, 2011.	
17	FIRST CAUSE FOR DISCIPLINE	
18	(Variation from Prescription)	
19	21. Respondent is subject to disciplinary action under Code section 4301(o) for violating	
20	title 16, California Code of Regulations, section 1716, in that on or about March 11, 2011, while	
21	Respondent was on duty at Senior Care Pharmacy, Senior Care Pharmacy dispensed a total of 125	
22	mcg Duragesic patch instead of 12.5 mcg Duragesic patch to R.M., as more fully set forth in	
23	paragraphs 15 – 20 above and incorporated herein.	
24	///	
25	SECOND CAUSE FOR DISCIPLINE	
26	(Erroneous or Uncertain Prescription)	
27	22. Respondent is subject to disciplinary action under Code section 4301(o) for violating	
28	title 16, California Code of Regulations, section 1761, subdivision (a), in that on or about March	
	8	
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1	11, 2011, while Respondent was on duty at Senior Care Pharmacy, Respondent failed to note the
2	irregularity of a medication order for 125 mcg Duragesic patch and failed to contact the prescriber
3	to validate the prescription prior to dispensing a total of 125 mcg Duragesic patch to R.M, as more
4	fully set forth in paragraphs $15 - 20$ above and incorporated herein.
5	THIRD CAUSE FOR DISCIPLINE
6	(Unprofessional Conduct – Inappropriate Exercise
7	of Professional Training, Education, Experience)
8	23. Respondent is subject to disciplinary action under Code section 4306.5 for acts or
9	omissions that involve the inappropriate exercise of her education, training, or experience as a
10	pharmacist, in that on or about March 11, 2011, while Respondent was on duty at Senior Care
11	Pharmacy, Respondent failed to note the irregularity of a medication order for 125 mcg Duragesic
12	patch and failed to contact the prescriber to validate the prescription prior to dispensing a total of
13	125 mcg Duragesic patch to R.M, as more fully set forth in paragraphs $15 - 20$ above and
14	incorporated herein.
15	FOURTH CAUSE FOR DISCIPLINE
16	(Dispensed Controlled Substance Pursuant to Noncompliance Prescription)
17	24. Respondent is subject to disciplinary action under Code section 4301(j) for violating
18	California Health and Safety Code section 11164 in that on or about March 11, 2011, Respondent
19	dispensed Duragesic patch, a Schedule II controlled substance, pursuant to a prescription that
20	failed to comply with the requirements of Health and Safety Code sections 11162.1 and 11164, ,
21	as more fully set forth in paragraphs $15 - 20$ above and incorporated herein.
22	PRAYER
23	WHEREFORE, Complainant requests that a hearing be held on the matters herein alleged,
24	and that following the hearing, the Board of Pharmacy issue a decision:
25	1. Revoking or suspending Pharmacist License Number RPH 63410, issued to Leina Le-
26	Ho Yasuoka, aka Leina Uyen Le-Ho;
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28	
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Ordering Leina Le-Ho Yasuoka to pay the Board of Pharmacy the reasonable costs of 2. the investigation and enforcement of this case, pursuant to Business and Professions Code section 125.3; and, 3. Taking such other and further action as deemed necessary and proper. DATED: VIRGINIAH ROLD Executive-Officer Board of Pharmacy Department of Consumer Affairs State of California Complainant SD2015801309 81141232.doc (LEINA LE-HO YASUOKA, AKA LEINA UYEN LE-HO) ACCUSATION