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

In the Matter of the Accusation Against:

Case No. 5785

ALERE HOME MONITORING INC.

OAH No. 2016100938

6465 National Drive Livermore, CA 94550

Wholesale Permit No. WLS 6079

And

THEODORE LLOYD WALKER

6465 National Drive Livermore, CA 94550

Designated Representative License No. EXC 22009

Respondents.

DECISION AND ORDER

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

This Decision shall become effective at 5:00 p.m. on June 8, 2017.

It is so ORDERED on May 9, 2017.

BOARD OF PHARMACY DEPARTMENT OF CONSUMER AFFAIRS STATE OF CALIFORNIA

By

Amy Gutierrez, Pharm.D. Board President

1 2 3 4 5	XAVIER BECERRA Attorney General of California DIANN SOKOLOFF Supervising Deputy Attorney General SUSANA A. GONZALES Deputy Attorney General State Bar No. 253027 1515 Clay Street, 20th Floor P.O. Box 70550 Oakland, CA 94612-0550 Telephone: (510) 879-0266							
7	Facsimile: (510) 622-2270 Attorneys for Complainant							
8 9 10	BEFORE THE BOARD OF PHARMACY DEPARTMENT OF CONSUMER AFFAIRS STATE OF CALIFORNIA							
11	In the Matter of the Accusation Against:	Case No. 5785						
12 13 14 15 16 17 18 19	ALERE HOME MONITORING INC. 6465 National Drive Livermore, CA 94550 Wholesale Permit No. WLS 6079 and THEODORE LLOYD WALKER 6465 National Drive Livermore, CA 94550 Designated Representative License No. EXC 22009	STIPULATED SETTLEMENT AND DISCIPLINARY ORDER FOR PUBLIC REPROVAL [ALERE HOME MONITORING INC., Wholesale Permit No. WLS 6079 ONLY] [Bus. & Prof. Code § 495]						
20	Respondents.							
21 22 23 24 25 26 27 28	IT IS HEREBY STIPULATED AND AGREED by and between the parties to the above- entitled proceedings that the following matters are true: PARTIES 1. Virginia Herold ("Complainant") is the Executive Officer of the Board of Pharmac ("Board"). She brought this action solely in her official capacity and is represented in this matter.							

by Xavier Becerra, Attorney General of the State of California, by Susana A. Gonzales, Deputy Attorney General.

- 2. Theodore Lloyd Walker ("Respondent Walker") is represented in this proceeding by attorney Lara D. Compton, whose address is 633 W. Fifth Street, Suite 1700, Los Angeles, CA 90071.
- 3. On or about November 8, 2012, the Board of Pharmacy issued Designated Representative License Number EXC 22009 to Theodore Lloyd Walker ("Respondent Walker"). The Designated Representative License expired on November 1, 2014, and was cancelled on April 8, 2015. Respondent Walker was the Designated Representative-in-Charge of Respondent Alere from May 16, 2013, through August 5, 2015.

JURISDICTION

4. Accusation No. 5785 was filed before the Board of Pharmacy ("Board"), Department of Consumer Affairs, and is currently pending against Respondent. The Accusation and all other statutorily required documents were properly served on Respondent on August 3, 2016.

Respondent timely filed its Notice of Defense contesting the Accusation. A copy of Accusation No. 5785 is attached as Exhibit A and incorporated by reference.

ADVISEMENT AND WAIVERS

- 5. Respondent has carefully read, fully discussed with counsel, and understands the charges and allegations in Accusation No. 5785. Respondent has also carefully read, fully discussed with counsel, and understands the effects of this Stipulated Settlement and Disciplinary Order for Public Reproval.
- 6. Respondent is fully aware of its legal rights in this matter, including the right to a hearing on the charges and allegations in the Accusation; the right to be represented by counsel at its own expense; the right to confront and cross-examine the witnesses against it; the right to present evidence and to testify on its own behalf; the right to the issuance of subpoenas to compel the attendance of witnesses and the production of documents; the right to reconsideration and court review of an adverse decision; and all other rights accorded by the California Administrative Procedure Act and other applicable laws.

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

CULPABILITY

- 8 Respondent understands that the charges and allegations in Accusation No. 5785, if proven at hearing, constitute cause for imposing discipline against its Wholesale Permit Number WLS 6079.
- 9. For the purpose of resolving the Accusation without the expense and uncertainty of further proceedings, Respondent agrees that, at a hearing, Complainant could establish a factual basis for the charges in the Accusation, and that Respondent hereby gives up his right to contest those charges.
- 10. Respondent agrees that its Original Wholesale Permit is subject to discipline and it agrees to be bound by the Disciplinary Order below.

CIRCUMSTANCES IN MITIGATION

11. Respondent Alere has never been the subject of any disciplinary action. It is accepting responsibility at an early stage in the proceedings.

CONTINGENCY

- 12. This stipulation shall be subject to approval by the Board of Pharmacy. Respondent understands and agrees that counsel for Complainant and the staff of the Board of Pharmacy may communicate directly with the Board regarding this stipulation and settlement, without notice to or participation by Respondent or his counsel. By signing the stipulation, Respondent understands and agrees that it may not withdraw its agreement or seek to rescind the stipulation prior to the time the Board considers and acts upon it. If the Board fails to adopt this stipulation as its Decision and Order, the Stipulated Settlement and Disciplinary Order for Public Reproval shall be of no force or effect, except for this paragraph, it shall be inadmissible in any legal action between the parties, and the Board shall not be disqualified from further action by having considered this matter.
- The parties understand and agree that Portable Document Format (PDF) and facsimile copies of this Stipulated Settlement and Disciplinary Order for Public Reproval, including

ACCEPTANCE

I have carefully read the above Stipulated Settlement and Disciplinary Order for Public Reproval and have fully discussed it with my attorney, Lara Compton. I understand the stipulation and the affect it will have on my Original Wholesale Permit. I enter into this Stipulated Settlement and Disciplinary Order for Public Reproval voluntarily, knowingly, and intelligently, and agree to be bound by the Decision and Order of the Board of Pharmacy.

DATED: 3/8/26/7 Saturd Sing.

ALERE HOME MONITORING INC.

Respondent Alere

I have read and fully discussed with Respondent Alere Home Monitoring Inc. the terms and conditions and other matters contained in the above Stipulated Settlement and Disciplinary Order for Public Reproval. I approve its form and content.

DATED: 3/8/2017

Attorney for Respondent

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ENDORSEMENT The foregoing Stipulated Settlement and Disciplinary Order for Public Reproval is hereby respectfully submitted for consideration by the Board of Pharmacy of the Department of Consumer Affairs. Dated: Respectfully submitted, XAVIER BECERRA Attorney General of California DIANN SOKOLOFF Supervising Deputy Attorney General Deputy Attorney General Attorneys for Complainant SF2016900269 90767224.docx

Exhibit A

Accusation No. 5785

	1				
1	Kamala D, Harris	·			
2	Attorney General of California DIANN SOKOLOFF				
3	Supervising Deputy Attorney General SUSANA A. GONZALES				
4	Deputy Attorney General State Bar No. 253027				
5	1515 Clay Street, 20th Floor P.O. Box 70550				
	Oakland, CA 94612-0550				
6	Telephone: (510) 622-2221 Facsimile: (510) 622-2270				
7	Attorneys for Complainant				
8	BEFORE THE BOARD OF PHARMACY				
9	DEPARTMENT OF C	CONSUMER AFFAIRS CALIFORNIA			
10		1			
11	In the Matter of the Accusation Against:	Case No. 5785			
12	ALERE HOME MONITORING INC.				
13	6465 National Drive Livermore, CA 94550	ACCUSATION			
14	Wholesale Permit No. WLS 6079				
15	and				
16	THEODORE LLOYD WALKER	·			
17	6465 National Drive Livermore, CA 94550				
18	Designated Representative License No. EXC 22009				
19	Respondents.				
20					
21 22	Complainant alleges:				
23	PAR	TIES			
24	 Virginia Herold ("Complainant") brit 	ngs this Accusation solely in her official capacity			
25	as the Executive Officer of the Board of Pharmacy, Department of Consumer Affairs.				
	2. On or about May 16, 2013, the Board	of Pharmacy issued Wholesale Permit Number			
26	WLS 6079 to Alere Home Monitoring Inc. ("Res	pondent Alere"). The Wholesale Permit expired			
27	on May 1, 2016, and is currently delinquent.				
28	•				
	1				
	(ALERE HOME MONITORING IN	C. and THEODORE LLOYD WALKER) ACCUSATION			

3. On or about November 8, 2013, the Board of Pharmacy issued Designated Representative License Number EXC 22009 to Theodore Lloyd Walker ("Respondent Walker"). The Designated Representative License expired on November 1, 2014, and was cancelled on April 8, 2015. Respondent Walker was the Designated Representative-in-Charge of Respondent Alere from May 16, 2013, through August 5, 2015.

JURISDICTION

- 4. This Accusation is brought before the Board of Pharmacy ("Board"), Department of Consumer Affairs, under the authority of the following laws. All section references are to the Business and Professions Code unless otherwise indicated.
- 5. Section 4011 of the Code provides that the Board shall administer and enforce both the Pharmacy Law [Bus. & Prof. Code, § 4000 et seq.] and the Uniform Controlled Substances Act [Health & Safety Code, § 11000 et seq.].
- 6. Section 4300, subdivision (a), of the Code provides that every license issued by the Board may be suspended or revoked.
 - 7. Section 4300.1 of the Code states:

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

8. Section 118, subdivision (b), of the Code provides, in pertinent part, that the expiration of a license shall not deprive the Registrar of jurisdiction to proceed with a disciplinary action during the period within which the license may be renewed, restored, reissued or reinstated.

Under Code section 7076.1, the Registrar may reinstate a cancelled license if the licensee pays all of the fees and meets all of the qualifications and requirements for obtaining an original license.

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STATUTORY AND REGULATORY PROVISIONS

9. Code section 4301, states, in pertinent part:

"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 misrepresentation or issued by mistake.

Unprofessional conduct shall include, but is not limited to, any of the following:

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

- 10. Section 4043 of the Code, in pertinent part, defines "wholesaler" to mean and include "a person who acts as a wholesale merchant, broker, jobber, customs broker, reverse distributor, agent, or a nonresident wholesaler, who sells for resale, or negotiates for distribution, or takes possession of, any drug or device included in Section 4022."
 - 11. Code section 4053, subdivision (a), states:

"Notwithstanding Section 4051, the board may issue a license as a designated representative to provide sufficient and qualified supervision in a wholesaler or veterinary food-animal drug retailer. The designated representative shall protect the public health and safety in the handling, storage, and shipment of dangerous drugs and dangerous devices in the wholesaler or veterinary food-animal drug retailer."

- 12. Section 4160 of the Code states, in pertinent part:
- "(a) A person shall not act as a wholesaler or third-party logistics provider of any dangerous drug or dangerous device unless he or she has obtained a license from the board.

"(o)(1) A separate license shall be required for each place of business owned or operated by a wholesaler or third-party logistics provider. Each place of business may only be issued a single license by the board, except as provided in paragraph (2). Each license shall be renewed annually and shall not be transferable. At all times during which a place of business is open for business,

 at least one designated representative, in the case of a wholesaler, or designated representative-3PL in the case of a third-party logistics provider, shall be present.

"(d) Every wholesaler shall be supervised or managed by a designated representative-in-charge. The designated representative-in-charge shall be responsible for the wholesaler's compliance with state and federal laws governing wholesalers. As part of its initial application for a license, and for each renewal, each wholesaler shall, on a form designed by the board, provide identifying information and the California license number for a designated representative or pharmacist proposed to serve as the designated representative-in-charge. The proposed designated representative-in-charge shall be subject to approval by the board. The board shall not issue or renew a wholesaler license without identification of an approved designated representative-in-charge for the wholesaler. The designated representative-in-charge shall maintain an active license as a designated representative with the board at all times during which he or she is designated as the designated representative-in-charge.

"(f) A wholesaler shall notify the board in writing, on a form designed by the board, within 30 days of the date when a designated representative-in-charge ceases to act as the designated representative-in-charge, and shall on the same form propose another designated representative or pharmacist to take over as the designated representative-in-charge. The proposed replacement designated representative-in-charge shall be subject to approval by the board. If disapproved, the wholesaler shall propose another replacement within 15 days of the date of disapproval, and shall continue to name proposed replacements until a designated representative-in-charge is approved by the board."

13. Code section 4101, subdivision (b), states:

"A designated representative or a pharmacist may take charge of, and act as, the designated representative-in-charge of a wholesaler or veterinary food-animal drug retailer upon application by the wholesaler or veterinary food-animal drug retailer and approval by the board. A designated representative-in-charge who ceases to act as the designated representative-in-charge at that entity shall notify the board in writing within 30 days of the date of that change in status."

14. California Code of Regulations, title 16, section 1784 states, in pertinent part:

"(a) The designated representative-in-charge of each wholesaler as defined under section 4160 of the Business and Professions Code shall complete a self-assessment of the wholesaler's compliance with federal and state pharmacy law. The assessment shall be performed before July 1 of every odd-numbered year. The primary purpose of the self-assessment is to promote compliance through self-examination and education.

"(d) Bach self-assessment shall be kept on file in the licensed wholesale premises for three years after it is completed.

"(e) The wholesaler is jointly responsible with the designated representative-in-charge for compliance with this section."

COST RECOVERY

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

FACTUAL ALLEGATIONS

16. Prior to May 1, 2015, the Board received a permit renewal application and fee payment from Respondent Alere for the renewal of their Wholesale Permit. The Board flagged the renewal application and determined that the renewal could not be processed because the designated representative license of Respondent Alere's designated representative, Respondent Walker, was expired. Respondent Walker's license expired on November 1, 2014, and after failing to respond to communication from the Board, Respondent Walker's license was cancelled on April 8, 2015. The Board did not receive any communication from Respondent Alere requesting approval of a new designated representative. The Board could not process Respondent Alere's renewal application because it lacked a valid designated representative, and, therefore, its Wholesale Permit expired on May 1, 2015.

17. On or about August 10, 2015, the Board received a "Change of Representative In
Charge" form from Respondent Alere. The form identified a new designated representative,
effective August 5, 2015. The Board processed Respondent Alere's Wholesale Permit renewal
and approved its new designated representative.
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18. On or about September 18, 2015, a Board inspector conducted a complaint-related inspection at Respondent Alere's place of business. The inspector requested and received documentation related to Respondent Alere's sales activity for prescription items sold between November 1, 2014, and September 18, 2015. The report showed 85 sales transactions for items requiring a wholesale permit between November 1, 2014, through May 15, 2015. There was no sales activity for the prescription items requiring a wholesale permit after May 15, 2015.

RESPONDENT ALERE

FIRST CAUSE FOR DISCIPLINE

(Bus. & Prof. Code, §§ 4301, subd. (o), 4160, subd. (a)) (Engaging in Wholesaler Activity Without an Active License)

19. Respondent Alere has subjected its Wholesale Permit to disciplinary action in that it engaged in wholesaler activity after its license expired on May 1, 2015. (Bus. & Prof. Code, §§ 4301, subd. (o), 4160, subd. (a).) Respondent Alere's sales transactions report indicated at least three sales transactions requiring a wholesale permit between May 1, 2015, and May 15, 2015, after Respondent Alere's wholesale permit had expired. The circumstances are set forth in further detail in paragraphs 16 through 18, above.

SECOND CAUSE FOR DISCIPLINE

(Bus. & Prof. Code, §§ 4301, subd. (o), 4160, subd. (c)(1)) (Acting as a Wholesaler Without a Designated Representative Present)

20. Respondent Alere has subjected its Wholesale Permit to disciplinary action in that it was open for business and engaged in wholesaler activity during a time in which it did not have a currently licensed designated representative present. (Bus. & Prof. Code, §§ 4301, subd. (o), 4160, subd. (o)(1).) Specifically, Respondent Walker's license expired on November 1, 2014. Respondent Alere did not identify a new designated representative until August 2015. The circumstances are set forth in further detail in paragraphs 16 through 18, above.

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III

THIRD CAUSE FOR DISCIPLINE

(Bus. & Prof. Code, §§ 4301, subd. (o), 4160, subd. (d)) (Operating as a Wholesaler Without a DRIC)

21. Respondent Alere has subjected its Wholesale Permit to disciplinary action in that it operated as a wholesaler without a designated representative. (Bus. & Prof. Code, §§ 4301, subd. (o), 4160, subd. (d).) Specifically, Respondent Walker's license expired on November 1, 2014. Respondent Alere did not identify a new designated representative until August 2015. The circumstances are set forth in further detail in paragraphs 16 through 18, above.

FOURTH CAUSE FOR DISCIPLINE

(Bus. & Prof. Code, §§ 4301, subd. (o), 4160, subd. (f)) (Failure to Notify Board of No Designated Representative)

22. Respondent Alere has subjected its Wholesale Permit to disciplinary action in that it failed to notify the Board within 30 days of the date in which Respondent Walker was no longer the designated representative. (Bus. & Prof. Code, §§ 4301, subd. (o), 4160, subd. (f).) Specifically, Respondent Walker's license expired on November 1, 2014. Respondent Alere did not identify a new designated representative until August 2015. The circumstances are set forth in further detail in paragraphs 16 through 18, above.

FIFTH CAUSE FOR DISCIPLINE

(Cal. Code Regs., tit. 16, sec 1784, subds. (a), (d), (e))
(Failure of Designated Representative to Complete Required Self-Assessment)

23. Respondent Alere has subjected its Wholesale Permit to disciplinary action in that it failed to cause Respondent Walker, its designated representative, to submit the required self-assessment of its compliance with federal and state pharmacy law. (Cal. Code Regs., tit. 16, see 1784, subds. (a), (d), (e).) Specifically, Respondent Alere failed to have Respondent Walker complete a self-assessment on July 1, 2015. Respondent Alere was educated of its need to complete a self-assessment every odd year during a prior inspection in 2013.

RESPONDENT WALKER

FIRST CAUSE FOR DISCIPLINE

(Bus. & Prof. Code, §§ 4301, subd. (o), 4160, subds. (a), (d)) (Engaging in Wholesaler Activity Without an Active License)

24. Respondent Walker has subjected his Designated Representative License to disciplinary action in that Respondent Alere engaged in wholesaler activity after its license expired on May 1, 2015. (Bus. & Prof. Code, §§ 4301, subd. (o), 4160, subds. (a), (d).) Respondent Alere's sales transactions report indicated at least three sales transactions requiring a wholesale permit between May 1, 2015, and May 15, 2015, after Respondent Alere's wholesale permit had expired. The circumstances are set forth in further detail in paragraphs 16 through 18, above.

SECOND CAUSE FOR DISCIPLINE

(Bus. & Prof. Code, § 4160, subds. (c)(1), (d))
(Acting as a Wholesaler Without a Designated Representative Present)

25. Respondent Walker has subjected his Designated Representative License to disciplinary action in that between November 1, 2014, the date Respondent Walker's license expired, and May 15, 2015, the date of Respondent Alere's last pharmaceutical sales transaction, Alere was open for business and engaged in wholesaler activity without a valid designated representative present. (Bus. & Prof. Code, § 4160, subds. (c)(1), (d).) Specifically, Respondent Walker's license expired on November 1, 2014. Respondent Alere did not identify a new designated representative until August 2015. The circumstances are set forth in further detail in paragraphs 16 through 18, above.

THIRD CAUSE FOR DISCIPLINE

(Bus. & Prof. Code, §§ 4301, subd. (o), 4160, subd. (d)) (Failure to Maintain an Active License While DRIC)

26. Respondent Walker has subjected his Designated Representative License to disciplinary action in that Respondent Walker failed to maintain an active license with the board during a time in which he was the designated representative-in-charge of Respondent Alere. (Bus. & Prof. Code, §§ 4301, subd. (o), 4160, subd. (d).) Respondent Walker allowed his license to expire on November 1, 2014, yet he was identified as the designated representative of

Respondent Alere until August 5, 2015. The circumstances are set forth in further detail in paragraphs 16 through 18, above.

FOURTH CAUSE FOR DISCIPLINE

(Bus. & Prof. Code, §§ 4301, subd. (o), 4160, subds. (c)(1), (f)) (Failure to Notify Board of No Designated Representative)

27. Respondent Walker has subjected his Designated Representative License to disciplinary action in that in that he and Respondent Alere failed to notify the Board within 30 days of the date in which Respondent Walker ceased to act as the designated representative-in-charge. (Bus. & Prof. Code, §§ 4301, subd. (o), 4160, subds. (c)(1), (f).) Specifically, Respondent Walker's license expired on November 1, 2014. Respondent Alere did not identify a new designated representative until August 2015. The circumstances are set forth in further detail in paragraphs 16 through 18, above.

FIFTH CAUSE FOR DISCIPLINE

(Bus. & Prof. Code, §§ 4301, subd. (o), 4101, subd. (b)) (Failure to Notify Board No Longer In Charge)

28. Respondent Walker has subjected his Designated Representative License to disciplinary action in that he failed to notify the Board within 30 days of his change in status as the designated representative of Respondent Alere. (Bus. & Prof. Code, §§ 4301, subd. (o), 4101, subd. (b).) Specifically, Respondent Walker's license expired on November 1, 2014. Respondent Alere did not identify a new designated representative until August 2015, and Respondent Walker never sent notification to the Board that he was no longer the designated representative of Respondent Alere. The circumstances are set forth in further detail in paragraphs 16 through 18, above.

SIXTH CAUSE FOR DISCIPLINE

(Cal. Code Regs., tit. 16, § 1784, subds. (a), (d), (e) (Failure of DRIC to Complete Required Self-Assessment)

29. Respondent Walker has subjected his Designated Representative License to disciplinary action in that he failed to submit the required self-assessment of Respondent Alere's compliance with federal and state pharmacy law. (Cal. Code Regs., tit. 16, sec 1784, subds. (a), (d), (e).) Specifically, Respondent Walker failed to complete a self-assessment on July 1, 2015, a

1	time in which he was still identified as the designated representative of Respondent Alere.						
2	Respondent Walker was educated of his need to complete a self-assessment every odd year durin						
3	a prior inspection in 2013.						
4	PRAYER						
5	WHBREFORE, Complainant requests that a hearing be held on the matters alleged in this						
6	Accusation, and that following the hearing, the Board of Pharmacy issue a decision:						
7	1. Revoking or suspending Original Wholesale Permit Number WLS 6079, issued to						
8	Alere Home Monitoring Inc.;						
9	2. Revoking or suspending Designated Representative License No. EXC 22009, issued						
10	to Theodore Lloyd Walker;						
11	3. Ordering Respondents to pay the Board of Pharmacy the reasonable costs of the						
12	investigation and enforcement of this case, pursuant to Business and Professions Code section						
13	125.3;						
14	4. Taking such other and further action as deemed necessary and proper.						
15							
16							
17	7/26/16 Original Level						
18	DATED:						
19.	VIRGINIA HEROLD Executive Officer						
20	Board of Pharmacy Department of Consumer Affairs						
21	State of California Complainant						
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- 1	tn						

(ALERE HOME MONITORING INC. and THEODORE LLOYD WALKER) ACCUSATION

1	XAVIER BECERRA						
2	Attorney General of California DIANN SOKOLOFF						
3	Supervising Deputy Attorney General SUSANA A. GONZALES						
4	Deputy Attorney General State Bar No. 253027						
5	1515 Clay Street, 20th Floor P.O. Box 70550						
6	Oakland, CA 94612-0550 Telephone: (510) 879-0266						
7	Facsimile: (510) 622-2270 Attorneys for Complainant						
8		RE THE					
9	BOARD OF PHARMACY DEPARTMENT OF CONSUMER AFFAIRS						
10	STATE OF C	CALIFORNIA					
11	In the Matter of the Accusation Against:	Case No. 5785					
12	ALERE HOME MONITORING INC.	OAH No. 2016100938					
13	6465 National Drive Livermore, CA 94550						
14	Wholesale Permit No. WLS 6079	STIPULATED SETTLEMENT AND DISCIPLINARY ORDER FOR PUBLIC DEPROVAL ITHEODORE I LOVE					
15	and	REPROVAL [THEODORE LLOYD WALKER, Designated Representative					
16	THEODORE LLOYD WALKER 6465 National Drive	License No. EXC 22009 ONLY]					
17	Livermore, CA 94550	[Bus. & Prof. Code § 495]					
18	Designated Representative License No. EXC 22009						
19	Respondents.						
20		,					
21							
22	IT IS HEREBY STIPULATED AND AGREED by and between the parties to the above-						
23	entitled proceedings that the following matters are true:						
24	<u>PARTIES</u>						
25	1. Virginia Herold ("Complainant") is the Executive Officer of the Board of Pharmacy						
26	(Board). She brought this action solely in her official capacity and is represented in this matter by						
27	Xavier Becerra, Attorney General of the State of California, by Susana A. Gonzales, Deputy						
28	Attorney General.	- ·					
		· 1					

- 2. Theodore Lloyd Walker ("Respondent Walker") is represented in this proceeding by attorney Lara D. Compton, whose address is 633 W. Fifth Street, Suite 1700, Los Angeles, CA 90071.
- 3. On or about November 8, 2012, the Board of Pharmacy issued Designated Representative License Number EXC 22009 to Theodore Lloyd Walker ("Respondent Walker"). The Designated Representative License expired on November 1, 2014, and was cancelled on April 8, 2015. Respondent Walker was the Designated Representative-in-Charge of Alere Home Monitoring, Inc. from May 16, 2013, through August 5, 2015.

JURISDICTION

4. Accusation No. 5785 was filed before the Board of Pharmacy ("Board"), Department of Consumer Affairs, and is currently pending against Respondent. The Accusation and all other statutorily required documents were properly served on Respondent on August 3, 2016.

Respondent timely filed his Notice of Defense contesting the Accusation. A copy of Accusation No. 5785 is attached as Exhibit A and incorporated by reference.

ADVISEMENT AND WAIVERS

- 5. Respondent has carefully read, fully discussed with counsel, and understands the charges and allegations in Accusation No. 5785. Respondent has also carefully read, fully discussed with counsel, and understands the effects of this Stipulated Settlement and Disciplinary Order for Public Reproval.
- 6. Respondent is fully aware of his legal rights in this matter, including the right to a hearing on the charges and allegations in the Accusation; the right to be represented by counsel at his own expense; the right to confront and cross-examine the witnesses against him; the right to present evidence and to testify on his own behalf; the right to the issuance of subpoenas to compel the attendance of witnesses and the production of documents; the right to reconsideration and court review of an adverse decision; and all other rights accorded by the California Administrative Procedure Act and other applicable laws.
- 7. Respondent voluntarily, knowingly, and intelligently waives and gives up each and every right set forth above.

CULPABILITY

- 8. Respondent understands and agrees that the charges and allegations in Accusation No. 5785, if proven at a hearing, constitute cause for imposing discipline upon his Designated Representative License No. EXC 22009.
- 9. For the purpose of resolving the Accusation without the expense and uncertainty of further proceedings, Respondent agrees that, at a hearing, Complainant could establish a factual basis for the charges in the Accusation, and that Respondent hereby gives up his right to contest those charges.
- 10. Respondent agrees that his Designated Representative License is subject to discipline and he agrees to be bound by the Disciplinary Order below.

<u>CIRCUMSTANCES IN MITIGATION</u>

11. Respondent Walker has never been the subject of any disciplinary action. He is accepting responsibility at an early stage in the proceedings.

CONTINGENCY

- 12. This stipulation shall be subject to approval by the Board of Pharmacy. Respondent understands and agrees that counsel for Complainant and the staff of the Board of Pharmacy may communicate directly with the Board regarding this stipulation and settlement, without notice to or participation by Respondent or his counsel. By signing the stipulation, Respondent understands and agrees that he may not withdraw his agreement or seek to rescind the stipulation prior to the time the Board considers and acts upon it. If the Board fails to adopt this stipulation as its Decision and Order, the Stipulated Settlement and Disciplinary Order for Public Reproval shall be of no force or effect, except for this paragraph, it shall be inadmissible in any legal action between the parties, and the Board shall not be disqualified from further action by having considered this matter.
- 13. The parties understand and agree that Portable Document Format (PDF) and facsimile copies of this Stipulated Settlement and Disciplinary Order for Public Reproval, including Portable Document Format (PDF) and facsimile signatures thereto, shall have the same force and effect as the originals.

- 14. This Stipulated Settlement and Disciplinary Order for Public Reproval is intended by the parties to be an integrated writing representing the complete, final, and exclusive embodiment of their agreement. It supersedes any and all prior or contemporaneous agreements, understandings, discussions, negotiations, and commitments (written or oral). This Stipulated Settlement and Disciplinary Order for Public Reproval may not be altered, amended, modified, supplemented, or otherwise changed except by a writing executed by an authorized representative of each of the parties.
- 15. In consideration of the foregoing admissions and stipulations, the parties agree that the Board may, without further notice or formal proceeding, issue and enter the following Disciplinary Order:

DISCIPLINARY ORDER

IT IS HEREBY ORDERED that Designated Representative License No. EXC 22009, issued Theodore Lloyd Walker ("Respondent Walker") shall be publicly reproved by the Board of Pharmacy under Business and Professions Code section 495 in resolution of Accusation No. 5785, attached as exhibit A.

ACCEPTANCE

I have carefully read the above Stipulated Settlement and Disciplinary Order for Public Reproval and have fully discussed it with my attorney, Lara Compton. I understand the stipulation and the effect it will have on Designated Representative License. I enter into this Stipulated Settlement and Disciplinary Order for Public Reproval voluntarily, knowingly, and intelligently, and agree to be bound by the Decision and Order of the Board of Pharmacy.

DATED:	3/8/2017	THEODORE LICOYD WALKER Respondent					

III

I have read and fully discussed with Respondent Theodore Lloyd Walker the terms and į conditions and other matters contained in the above Stipulated Settlement and Disciplinary Order 2 for Public Reproval. I approve its form and content. 3 4 3/8/2017 5 DATED: LARA COMPTON 6 Attorney for Respondent 8 **ENDORSEMENT** The foregoing Stipulated Settlement and Disciplinary Order for Public Reproval is hereby 9 respectfully submitted for consideration by the Board of Pharmacy of the Department of 10 Consumer Affairs. П 12 Dated: 318/H Respectfully submitted. 13 XAVIER BECERRA 14 Attorney General of California DIANN ŠOKOLOFF 15 Supervising Deputy Attorney General 16 17 Deputy Attorney General 18 Attorneys for Complainant 19 20 21 SF2016900269 22 90767244.docx 23 24 25 26 27 28

Exhibit Á

Accusation No. 5785

1	KAMALA D. HARRIS Attorney General of California						
2	DIANN ŠOKOLOFF Supervising Deputy Attorney General						
3	SUSANA A. GONZALES Deputy Attorney General						
4	State Bar No. 253027 1515 Clay Street, 20th Floor						
5	P.O. Box 70550 Oakland, CA 94612-0550						
6	Telephone: (510) 622-2221 Facsimile: (510) 622-2270						
7	Attorneys for Complainant						
8	BEFORE THE						
9	BOARD OF PHARMACY DEPARTMENT OF CONSUMER AFFAIRS STATE OF CALIFORNIA						
10	SIALLOF	ALIFORNIA					
11	In the Matter of the Accusation Against:	Case No. 5785					
12	ALERE HOME MONITORING INC.						
13	Livermore, CA 94550	ACCUSATION					
14	Wholesale Permit No. WLS 6079						
15	and						
16	THEODORE LLOYD WALKER 6465 National Drive						
17	Livermore, CA 94550	4					
18	Designated Representative License No. EXC 22009						
19	Respondents.						
20	nespondents.						
21	Complainant alleges:						
22	PARTIES						
23	,						
24	Se mis i record de la company						
25	as the Executive Officer of the Board of Pharmacy, Department of Consumer Affairs. 2. On or about May 16, 2013, the Board of Pharmacy issued Wholesale Permit Number						
26							
27	WLS 6079 to Alere Home Monitoring Inc. ("Res	poncent Alere"). The Wholesale Permit expired					
28	on May 1, 2016, and is currently delinquent.						

(ALERE HOME MONITORING INC. and THEODORE LLOYD WALKER) ACCUSATION

3. On or about November 8, 2013, the Board of Pharmacy issued Designated Representative License Number EXC 22009 to Theodore Lloyd Walker ("Respondent Walker"). The Designated Representative License expired on November 1, 2014, and was cancelled on April 8, 2015. Respondent Walker was the Designated Representative-in-Charge of Respondent Alere from May 16, 2013, through August 5, 2015.

JURISDICTION

- 4. This Accusation is brought before the Board of Pharmacy ("Board"), Department of Consumer Affairs, under the authority of the following laws. All section references are to the Business and Professions Code unless otherwise indicated.
- 5. Section 4011 of the Code provides that the Board shall administer and enforce both the Pharmacy Law [Bus. & Prof. Code, § 4000 et seq.] and the Uniform Controlled Substances Act [Health & Safety Code, § 11000 et seq.].
- 6. Section 4300, subdivision (a), of the Code provides that every license issued by the Board may be suspended or revoked.
 - 7. Section 4300.1 of the Code states:

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

8. Section 118, subdivision (b), of the Code provides, in pertinent part, that the expiration of a license shall not deprive the Registrar of jurisdiction to proceed with a disciplinary action during the period within which the license may be renewed, restored, reissued or reinstated.

Under Code section 7076.1, the Registrar may reinstate a cancelled license if the licensee pays all of the fees and meets all of the qualifications and requirements for obtaining an original license.

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STATUTORY AND REGULATORY PROVISIONS

9. Code section 4301, states, in pertinent part:

"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 misrepresentation or issued by mistake.

Unprofessional conduct shall include, but is not limited to, any of the following:

"(o) Violating or attempting to violate, directly or indirectly, or assisting in or abetting the violation of or conspiring to violate any provision or term of this chapter or of the applicable

federal and state laws and regulations governing pharmacy, including regulations established by

the board or by any other state or federal regulatory agency."

10. Section 4043 of the Code, in pertinent part, defines "wholesaler" to mean and include "a person who acts as a wholesale merchant, broker, jobber, customs broker, reverse distributor, agent, or a nonresident wholesaler, who sells for resale, or negotiates for distribution, or takes possession of, any drug or device included in Section 4022."

11. Code section 4053, subdivision (a), states:

"Notwithstanding Section 4051, the board may issue a license as a designated representative to provide sufficient and qualified supervision in a wholesaler or veterinary food-animal drug retailer. The designated representative shall protect the public health and safety in the handling, storage, and shipment of dangerous drugs and dangerous devices in the wholesaler or veterinary food-animal drug retailer."

12. Section 4160 of the Code states, in pertinent part:

"(a) A person shall not act as a wholesaler or third-party logistics provider of any dangerous drug or dangerous device unless he or she has obtained a license from the board.

"(c)(1) A separate license shall be required for each place of business owned or operated by

a wholesaler or third-party logistics provider. Each place of business may only be issued a single license by the board, except as provided in paragraph (2). Each license shall be renewed annually and shall not be transferable. At all times during which a place of business is open for business,

at least one designated representative, in the case of a wholesaler, or designated representative-3PL in the case of a third-party logistics provider, shall be present.

"(d) Every wholesaler shall be supervised or managed by a designated representative-in-charge. The designated representative-in-charge shall be responsible for the wholesaler's compliance with state and federal laws governing wholesalers. As part of its initial application for a license, and for each renewal, each wholesaler shall, on a form designed by the board, provide identifying information and the California license number for a designated representative or pharmacist proposed to serve as the designated representative-in-charge. The proposed designated representative-in-charge shall be subject to approval by the board. The board shall not issue or renew a wholesaler license without identification of an approved designated representative-in-charge for the wholesaler. The designated representative-in-charge shall maintain an active license as a designated representative with the board at all times during which he or she is designated as the designated representative-in-charge.

. .

"(f) A wholesaler shall notify the board in writing, on a form designed by the board, within 30 days of the date when a designated representative-in-charge ceases to act as the designated representative-in-charge, and shall on the same form propose another designated representative or pharmacist to take over as the designated representative-in-charge. The proposed replacement designated representative-in-charge shall be subject to approval by the board. If disapproved, the wholesaler shall propose another replacement within 15 days of the date of disapproval, and shall continue to name proposed replacements until a designated representative-in-charge is approved by the board."

13. Code section 4101, subdivision (b), states:

"A designated representative or a pharmacist may take charge of, and act as, the designated representative-in-charge of a wholesaler or veterinary food-animal drug retailer upon application by the wholesaler or veterinary food-animal drug retailer and approval by the board. A designated representative-in-charge who ceases to act as the designated representative-in-charge at that entity shall notify the board in writing within 30 days of the date of that change in status."

14.	California	Code	of Regulations,	title 16	, section	1784	states,	ın	pertinent	part:
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"(a) The designated representative-in-charge of each wholesaler as defined under section 4160 of the Business and Professions Code shall complete a self-assessment of the wholesaler's compliance with federal and state pharmacy law. The assessment shall be performed before July 1 of every odd-numbered year. The primary purpose of the self-assessment is to promote compliance through self-examination and education."

"(d) Each self-assessment shall be kept on file in the licensed wholesale premises for three years after it is completed.

"(e) The wholesaler is jointly responsible with the designated representative-in-charge for compliance with this section."

COST RECOVERY

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

FACTUAL ALLEGATIONS

16. Prior to May 1, 2015, the Board received a permit renewal application and fee payment from Respondent Alere for the renewal of their Wholesale Permit. The Board flagged the renewal application and determined that the renewal could not be processed because the designated representative license of Respondent Alere's designated representative, Respondent Walker, was expired. Respondent Walker's license expired on November 1, 2014, and after failing to respond to communication from the Board, Respondent Walker's license was cancelled on April 8, 2015. The Board did not receive any communication from Respondent Alere requesting approval of a new designated representative. The Board could not process Respondent Alere's renewal application because it lacked a valid designated representative, and, therefore, its Wholesale Permit expired on May 1, 2015.

- 17. On or about August 10, 2015, the Board received a "Change of Representative In Charge" form from Respondent Alere. The form identified a new designated representative, effective August 5, 2015. The Board processed Respondent Alere's Wholesale Permit renewal and approved its new designated representative.
- 18. On or about September 18, 2015, a Board inspector conducted a complaint-related inspection at Respondent Alere's place of business. The inspector requested and received documentation related to Respondent Alere's sales activity for prescription items sold between November 1, 2014, and September 18, 2015. The report showed 85 sales transactions for items requiring a wholesale permit between November 1, 2014, through May 15, 2015. There was no sales activity for the prescription items requiring a wholesale permit after May 15, 2015.

RESPONDENT ALERE

FIRST CAUSE FOR DISCIPLINE

(Bus. & Prof. Code, §§ 4301, subd. (o), 4160, subd. (a)) (Engaging in Wholesaler Activity Without an Active License)

19. Respondent Alere has subjected its Wholesale Permit to disciplinary action in that it engaged in wholesaler activity after its license expired on May 1, 2015. (Bus. & Prof. Code, §§ 4301, subd. (o), 4160, subd. (a).) Respondent Alere's sales transactions report indicated at least three sales transactions requiring a wholesale permit between May 1, 2015, and May 15, 2015, after Respondent Alere's wholesale permit had expired. The circumstances are set forth in further detail in paragraphs 16 through 18, above.

SECOND CAUSE FOR DISCIPLINE

(Bus. & Prof. Code, §§ 4301, subd. (o), 4160, subd. (c)(1)) (Acting as a Wholesaler Without a Designated Representative Present)

20. Respondent Alere has subjected its Wholesale Permit to disciplinary action in that it was open for business and engaged in wholesaler activity during a time in which it did not have a currently licensed designated representative present. (Bus. & Prof. Code, §§ 4301, subd. (o), 4160, subd. (e)(1).) Specifically, Respondent Walker's license expired on November 1, 2014. Respondent Alere did not identify a new designated representative until August 2015. The circumstances are set forth in further detail in paragraphs 16 through 18, above.

THIRD CAUSE FOR DISCIPLINE

(Bus. & Prof. Code, §§ 4301, subd. (o), 4160, subd. (d)) (Operating as a Wholesaler Without a DRIC)

21. Respondent Alere has subjected its Wholesale Permit to disciplinary action in that it operated as a wholesaler without a designated representative. (Bus. & Prof. Code, §§ 4301, subd. (o), 4160, subd. (d).) Specifically, Respondent Walker's license expired on November 1, 2014. Respondent Alere did not identify a new designated representative until August 2015. The circumstances are set forth in further detail in paragraphs 16 through 18, above.

FOURTH CAUSE FOR DISCIPLINE

(Bus. & Prof. Code, §§ 4301, subd. (o), 4160, subd. (f)) (Failure to Notify Board of No Designated Representative)

22. Respondent Alere has subjected its Wholesale Permit to disciplinary action in that it failed to notify the Board within 30 days of the date in which Respondent Walker was no longer the designated representative. (Bus. & Prof. Code, §§ 4301, subd. (o), 4160, subd. (f).) Specifically, Respondent Walker's license expired on November 1, 2014. Respondent Alere did not identify a new designated representative until August 2015. The circumstances are set forth in further detail in paragraphs 16 through 18, above.

FIFTH CAUSE FOR DISCIPLINE

(Cal. Code Regs., tit. 16, sec 1784, subds. (a), (d), (e))
(Failure of Designated Representative to Complete Required Self-Assessment)

23. Respondent Alere has subjected its Wholesale Permit to disciplinary action in that it failed to cause Respondent Walker, its designated representative, to submit the required self-assessment of its compliance with federal and state pharmacy law. (Cal. Code Regs., tit. 16, see 1784, subds. (a), (d), (e).) Specifically, Respondent Alere failed to have Respondent Walker complete a self-assessment on July 1, 2015. Respondent Alere was educated of its need to complete a self-assessment every odd year during a prior inspection in 2013.

RESPONDENT WALKER

FIRST CAUSE FOR DISCIPLINE

(Bus. & Prof. Code, §§ 4301, subd. (o), 4160, subds. (a), (d)) (Engaging in Wholesaler Activity Without an Active License)

24. Respondent Walker has subjected his Designated Representative License to disciplinary action in that Respondent Alere engaged in wholesaler activity after its license expired on May 1, 2015. (Bus. & Prof. Code, §§ 4301, subd. (o), 4160, subds. (a), (d).) Respondent Alere's sales transactions report indicated at least three sales transactions requiring a wholesale permit between May 1, 2015, and May 15, 2015, after Respondent Alere's wholesale permit had expired. The circumstances are set forth in further detail in paragraphs 16 through 18, above.

SECOND CAUSE FOR DISCIPLINE

(Bus. & Prof. Code, § 4160, subds. (c)(1), (d))
(Acting as a Wholesaler Without a Designated Representative Present)

25. Respondent Walker has subjected his Designated Representative License to disciplinary action in that between November 1, 2014, the date Respondent Walker's license expired, and May 15, 2015, the date of Respondent Alere's last pharmaceutical sales transaction, Alere was open for business and engaged in wholesaler activity without a valid designated representative present. (Bus. & Prof. Code, § 4160, subds. (c)(1), (d).) Specifically, Respondent Walker's license expired on November 1, 2014. Respondent Alere did not identify a new designated representative until August 2015. The circumstances are set forth in further detail in paragraphs 16 through 18, above.

THIRD CAUSE FOR DISCIPLINE

(Bus. & Prof. Code, §§ 4301, subd. (o), 4160, subd. (d)) (Failure to Maintain an Active License While DRIC)

26. Respondent Walker has subjected his Designated Representative License to disciplinary action in that Respondent Walker failed to maintain an active license with the board during a time in which he was the designated representative-in-charge of Respondent Alere.

(Bus. & Prof. Code, §§ 4301, subd. (o), 4160, subd. (d).) Respondent Walker allowed his license to expire on November 1, 2014, yet he was identified as the designated representative of

Respondent Alere until August 5, 2015. The circumstances are set forth in further detail in paragraphs 16 through 18, above.

FOURTH CAUSE FOR DISCIPLINE

(Bus. & Prof. Code, §§ 4301, subd. (o), 4160, subds. (c)(1), (f)) (Failure to Notify Board of No Designated Representative)

27. Respondent Walker has subjected his Designated Representative License to disciplinary action in that in that he and Respondent Alere failed to notify the Board within 30 days of the date in which Respondent Walker ceased to act as the designated representative-incharge. (Bus. & Prof. Code, §§ 4301, subd. (o), 4160, subds. (c)(1), (f).) Specifically, Respondent Walker's license expired on November 1, 2014. Respondent Alere did not identify a new designated representative until August 2015. The circumstances are set forth in further detail in paragraphs 16 through 18, above.

FIFTH CAUSE FOR DISCIPLINE

(Bus. & Prof. Code, §§ 4301, subd. (o), 4101, subd. (b)) (Failure to Notify Board No Longer In Charge)

28. Respondent Walker has subjected his Designated Representative License to disciplinary action in that he failed to notify the Board within 30 days of his change in status as the designated representative of Respondent Alere. (Bus. & Prof. Code, §§ 4301, subd. (o), 4101, subd. (b).) Specifically, Respondent Walker's license expired on November 1, 2014. Respondent Alere did not identify a new designated representative until August 2015, and Respondent Walker never sent notification to the Board that he was no longer the designated representative of Respondent Alere. The circumstances are set forth in further detail in paragraphs 16 through 18, above.

SIXTH CAUSE FOR DISCIPLINE

(Cal. Code Regs., tit. 16, § 1784, subds. (a), (d), (e) (Failure of DRIC to Complete Required Self-Assessment)

29. Respondent Walker has subjected his Designated Representative License to disciplinary action in that he failed to submit the required self-assessment of Respondent Alere's compliance with federal and state pharmacy law. (Cal. Code Regs., tit. 16, sec 1784, subds. (a), (d), (e).) Specifically, Respondent Walker failed to complete a self-assessment on July 1, 2015, a