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	ARD OF P	PHARMACY
		ONSUMER AFFAIRS ALIFORNIA
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In the Matter of the Accusation Again	st:	Case No. 6945
HOFFMANN HOME CARE, INC., HOFFMANN HOMECARE; THO HOFFMANN, PRESIDENT; BETH HOFFMAN, VICE-PRESIDENT	MAS A.	DEFAULT DECISION AND ORDER
2225 E. Street, Suite 200 Bakersfield, CA 93301		[Gov. Code, §11520]
Pharmacy Permit No. PHY 37014,		
THOMAS ALAN HOFFMANN		
306 Penzance Dr., Bakersfield, CA 93312		
Registered Pharmacist License No. 38673	RPH	
and		
RENEE SUE BISCHOFF 4816 Planz Rd., #5		
Bakersfield, CA 93309 Pharmacy Technician Registration	No. TCH	
1061,		

FINDINGS OF FACT

- 1. On or about September 25, 2020, Complainant Anne Sodergren, in her official capacity as the Executive Officer of the Board of Pharmacy, Department of Consumer Affairs, filed Accusation No. 6945 against Hoffmann Home Care, Inc., dba Hoffmann Homecare; Thomas A. Hoffmann (Respondent) before the Board of Pharmacy. (Accusation attached as Exhibit A.)
- 2. On or about October 28, 1992, the Board of Pharmacy issued Pharmacy Technician Registration Number TCH 1061 to Renee Sue Bischoff (Respondent Bischoff). The Pharmacy Technician Registration expired on September 30, 2018, and has not been renewed.
- 3. On or about October 1, 2020, Respondent Bischoff was served by Certified and First Class Mail copies of the Accusation No. 6945, Statement to Respondent, Notice of Defense, Request for Discovery, and Discovery Statutes (Government Code sections 11507.5, 11507.6, and 11507.7) at Respondent Bischoff's address of record which, pursuant to Business and Professions Code section 4100, is required to be reported and maintained with the Board. Respondent's address of record was and is:
- Bakersfield, CA 93309.
- 4. Service of the Accusation was effective as a matter of law under the provisions of Government Code section 11505(c) and/or Business and Professions Code section 124.
 - 5. Government Code section 11506(c) states, in pertinent part:
 - (c) The respondent shall be entitled to a hearing on the merits if the respondent files a notice of defense . . . and the notice shall be deemed a specific denial of all parts of the accusation . . . not expressly admitted. Failure to file a notice of defense . . . shall constitute a waiver of respondent's right to a hearing, but the agency in its discretion may nevertheless grant a hearing.
- 6. The Board takes official notice of its records and the fact that Respondent failed to file a Notice of Defense within 15 days after service upon them of the Accusation, and therefore waived their right to a hearing on the merits of Accusation No. 6945.
 - 7. California Government Code section 11520(a) states, in pertinent part:
 - (a) If the respondent either fails to file a notice of defense . . . or to appear at the hearing, the agency may take action based upon the respondent's express admissions or upon other evidence and affidavits may be used as evidence without

any notice to respondent

1	<u>ORDER</u>				
2	IT IS SO ORDERED that Pharmacy Technician Registration Number TCH 1061, issued to				
3	Respondent Bischoff, is revoked.				
4	Pursuant to Government Code section 11520, subdivision (c), Respondent Bischoff may				
5	serve a written motion requesting that the Decision be vacated and stating the grounds relied on				
6	within seven (7) days after service of the Decision on Respondent Bischoff. The agency in its				
7	discretion may vacate the Decision and grant a hearing on a showing of good cause, as defined in				
8	the statute.				
9	This Decision shall become effective on March 5, 2021 at 5;00 p.m.				
10	It is so ORDERED February 3, 2021				
11	FOR THE BOARD OF PHARMACY				
12	DEPARTMENT OF CONSUMER AFFAIRS				
13	Ay 20 Ligge				
14	By				
15	Greg Lippe DOJ Matter ID:LA2020600741 Greg Lippe Board President				
16	Attachment:				
17	Exhibit A: Accusation				
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19					
20					
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Exhibit A

Accusation

1	XAVIER BECERRA				
2	Attorney General of California SHAWN P. COOK				
3	Supervising Deputy Attorney General ANDREW AMARA				
4	Deputy Attorney General State Bar No. 271311				
5	300 So. Spring Street, Suite 1702 Los Angeles, CA 90013				
6	Telephone: (213) 269-6531 Facsimile: (916) 731-2126				
7	Attorneys for Complainant				
8	BEFOR	E THE			
9	BOARD OF P DEPARTMENT OF CO				
10	STATE OF CA				
11					
12	In the Matter of the Accusation Against:	Case No. 6945			
13	HOFFMANN HOME CARE, INC., DBA HOFFMANN HOMECARE; THOMAS A.				
14	TO THE CANAL PROPERTY PROPERTY A COLICA MY CAL				
15	2225 E. Street, Suite 200 Bakersfield, CA 93301				
16	Pharmacy Permit No. PHY 37014,				
17					
18 19	THOMAS ALAN HOFFMANN 306 Penzance Dr., Bakersfield, CA 93312				
20	Registered Pharmacist License No. RPH				
21	38673				
22	and DENIES SHE DISCHOES				
23	RENEE SUE BISCHOFF 4816 Planz Rd., #5 Bakersfield, CA 93309				
24	Pharmacy Technician Registration No. TCH				
25	1061,				
26	Respondents.				
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28	///				
	(HOFFMANN HOME CARE, INC., DBA HOFFMANN F	OMECADE: THOMAS A HOEEMANN DENIES SHE			
		F, and THOMAS ALAN HOFFMANN, RENEE SUE			

PARTIES

- 1. Anne Sodergren (Complainant) brings this Accusation solely in her official capacity as the Executive Officer of the Board of Pharmacy, Department of Consumer Affairs.
- 2. On or about March 26, 1991, the Board of Pharmacy issued Pharmacy Permit

 Number PHY 37014 to Hoffmann Home Care, Inc., dba Hoffmann Homecare; Thomas Hoffman,

 President; Beth Hoffman, Vice-President (Respondent Hoffman Homecare); Thomas A.

 Hoffmann (Respondent Hoffman). The Pharmacy Permit expired on October 1, 2019, and has
 not been renewed.
- 3. On or about August 14, 1984, the Board of Pharmacy issued Registered Pharmacist License Number RPH 38673 to Respondent Hoffman. The Registered Pharmacist License was in full force and effect at all times relevant to the charges brought herein and will expire on December 31, 2021, unless renewed.
- 4. On or about October 28, 1992, the Board of Pharmacy issued Pharmacy Technician Registration Number TCH 1061 to Renee Sue Bischoff (Respondent Bischoff). The Pharmacy Technician Registration expired on September 30, 2018, and has not been renewed.

JURISDICTION

- 5. This Accusation is brought before the Board of Pharmacy (Board), Department of Consumer Affairs, under the authority of the following laws. All section references are to the Business and Professions Code (Code) unless otherwise indicated.
- 6. Section 118, subdivision (b), of the Code provides that the suspension, expiration surrender, or cancellation of a license shall not deprive the Board of jurisdiction to proceed with a disciplinary action during the period within which the license may be renewed, restored, reissued or reinstated.
- 7. Section 4300, subdivision (a), of the Code provides that every license issued by the Board may be suspended or revoked.
 - 8. 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.

STATUTORY AND REGULATORY PROVISIONS

9. Section 4022 of the Code states:

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

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

10. Section 4307 of the Code states:

- "(a) Any person who has been denied a license or whose license has been revoked or is under suspension, or who has failed to renew his or her license while it was under suspension, or who has been a manager, administrator, owner, member, officer, director, associate, partner, or any other person with management or control of any partnership, corporation, trust, firm, or association whose application for a license has been denied or revoked, is under suspension or has been placed on probation, and while acting as the manager, administrator, owner, member, officer, director, associate, partner, or any other person with management or control had knowledge of or knowingly participated in any conduct for which the license was denied, revoked, suspended, or placed on probation, shall be prohibited from serving as a manager, administrator, owner, member, officer, director, associate, partner, or in any other position with management or control of a licensee as follows:
- (1) Where a probationary license is issued or where an existing license is placed on probation, this prohibition shall remain in effect for a period not to exceed five years.
- (2) Where the license is denied or revoked, the prohibition shall continue until the license is issued or reinstated.
- (b) "Manager, administrator, owner, member, officer, director, associate, partner, or any other person with management or control of a license" as used in this section and Section 4308, may refer to a pharmacist or to any other person who serves in such capacity in or for a licensee.
- (c) The provisions of subdivision (a) may be alleged in any pleading filed pursuant to Chapter 5 (commencing with Section 11500) of Part 1 of Division 3 of the Government Code. However, no order may be issued in that case except as to a person who is named in the caption, as to whom the pleading alleges the applicability of this section, and where the person has been given notice of the proceeding as required by Chapter 5 (commencing with Section 11500) of Part 1 of Division 3 of the Government Code. The authority to proceed as provided by this subdivision shall be in addition to the board's authority to proceed under Section 4339 or any other provision of law."
- 11. Section 4060 of the Code states:

No person shall possess any controlled substance, except that furnished to a person upon the prescription of a physician, dentist, podiatrist, optometrist, veterinarian, or naturopathic doctor pursuant to Section 3640.7, or furnished pursuant to a drug order issued by a certified nurse-midwife pursuant to Section 2746.51, a nurse practitioner pursuant to Section 2836.1, or a physician assistant pursuant to Section 3502.1, or naturopathic doctor pursuant to Section 3640.5, or a pharmacist pursuant to either subparagraph (D) of paragraph (4) of, or clause (iv) of subparagraph (A) of paragraph (5) of, subdivision (a) of Section 4052. This section shall not apply to the possession of any controlled substance by a manufacturer, wholesaler, pharmacy, pharmacist, physician, podiatrist, dentist, optometrist, veterinarian, naturopathic doctor, certified nurse-midwife, nurse practitioner, or physician assistant, when in stock in containers correctly labeled with the name and address of the supplier or producer.

Nothing in this section authorizes a certified nurse-midwife, a nurse practitioner, a physician assistant, or a naturopathic doctor, to order his or her own stock of dangerous drugs and devices.

12. Section 4301 of the Code 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 issued by mistake. Unprofessional conduct shall include, but is not limited to, any of the following:

. . . .

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

. . .

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

. . . .

(1) The conviction of a crime substantially related to the qualifications, functions, and duties of a licensee under this chapter. The record of conviction of a violation of Chapter 13 (commencing with Section 801) of Title 21 of the United States Code regulating controlled substances or of a violation of the statutes of this state regulating controlled substances or dangerous drugs shall be conclusive evidence of unprofessional conduct. In all other cases, the record of conviction shall be conclusive evidence only of the fact that the conviction occurred. The board may inquire into the circumstances surrounding the commission of the crime, in order to fix the degree of discipline or, in the case of a conviction not involving controlled substances or dangerous drugs, to determine if the conviction is of an offense substantially related to the qualifications, functions, and duties of a licensee under this chapter. A plea or verdict of guilty or a conviction following a plea of nolo contendere is deemed to be a conviction within the meaning of this provision. The board may take action when the time for appeal has elapsed, or the judgment of conviction has been affirmed on appeal or when an order granting probation is made suspending the imposition of sentence, irrespective of a subsequent order under Section 1203.4 of the Penal Code allowing the person to withdraw his or her plea of guilty and to enter a plea of not guilty, or setting aside the verdict of guilty, or

1	dismissing the accusation, information, or indictment.
2	
3	(o) Violating or attempting to violate, directly or indirectly, or assisting in or
4	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
5	regulatory agency.
6	13. Section 4116, subdivision (a), of the Code states:
7	(a) No person other than a pharmacist, an intern pharmacist, an authorized
8 9	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 controlled substances or dangerous drugs or dangerous devices are stored, possessed, prepared,
10	manufactured, derived, compounded, dispensed, or repackaged. However, a pharmacist shall be responsible for any individual who enters the pharmacy for the
11	purposes of receiving consultation from the pharmacist or performing clerical, inventory control, housekeeping, delivery, maintenance, or similar functions relating
12	to the pharmacy if the pharmacist remains present in the pharmacy during all times as the authorized individual is present.
13	14. Section 4059, subdivision (a), of the Code states, in pertinent part:
14	(a) A parson may not furnish any dengarous drug, execut upon the prescription
15 16	(a) A person may not furnish any dangerous drug, except upon the prescription of a physician, dentist, podiatrist, optometrist, veterinarian, or naturopathic doctor pursuant to Section 3640.7. A person may not furnish any dangerous device, except upon the prescription of a physician, dentist, podiatrist, optometrist, veterinarian, or
17	naturopathic doctor pursuant to Section 3640.7.
18	15. Section 4081, subdivision (a), of the Code states:
19	(a) All records of manufacture and of sale, acquisition, receipt, shipment, or disposition of dangerous drugs or dangerous devices shall be at all times during
20	business hours open to inspection by authorized officers of the law, and shall be preserved for at least three years from the date of making. A current inventory shall
21	be kept by every manufacturer, wholesaler, third-party logistics provider, pharmacy, veterinary food-animal drug retailer, outsourcing facility, physician, dentist, podiatrist, veterinarian, laboratory, licensed correctional clinic, as defined in Section
22	clinic, hospital, institution, or establishment holding a currently valid and
23	unrevoked certificate, license, permit, registration, or exemption under Division 2 (commencing with Section 1200) of the Health and Safety Code or under Part 4 (commencing with Section 16000) of Division 2 of the Welford and Institutions Code
24	(commencing with Section 16000) of Division 9 of the Welfare and Institutions Code who maintains a stock of dangerous drugs or dangerous devices.
25	16. California Code of Regulations, Title 16, section 1714, subdivision (b) and (d) states:
26	
27	(b) Each pharmacy licensed by the board shall maintain its facilities, space, fixtures, and equipment so that drugs are safely and properly prepared, maintained,
28	secured and distributed. The pharmacy shall be of sufficient size and unobstructed

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1	area to accommodate the safe practice of pharmacy.					
2						
3	(d) Each pharmacist while on duty shall be responsible for the security of the					
4	prescription department, including provisions for effective control against theft or diversion of dangerous drugs and devices, and records for such drugs and devices. Possession of a key to the pharmacy where dangerous drugs and controlled					
5	substances are stored shall be restricted to a pharmacist.					
6	17. California Code of Regulations, Title 16, section 1718 states: "Current Inventory" as used					
7	in Sections 4081 and 4332 of the Business and Professions Code shall be considered to include					
8	complete accountability for all dangerous drugs handled by every licensee enumerated in Sectio					
9	4081 and 4332.					
10	The controlled substances inventories required by Title 21, CFR, Section 1304 shall be available					
11	for inspection upon request for at least 3 years after the date of the inventory.					
12	18. Health and Safety Code section 11173, subdivision (a) states:					
13	(a) No person shall obtain or attempt to obtain controlled substances, or procure					
14	or attempt to procure the administration of or prescription for controlled substances, (1) by fraud, deceit, misrepresentation, or subterfuge; or (2) by the concealment of a material fact.					
15						
16	COST RECOVERY					
17	19. Section 125.3 of the Code provides, in pertinent part, that the Board may request the					
18	administrative law judge to direct a licentiate found to have committed a violation or violations of					
19	the licensing act to pay a sum not to exceed the reasonable costs of the investigation and					
20	enforcement of the case, with failure of the licentiate to comply subjecting the license to not being					
21	renewed or reinstated. If a case settles, recovery of investigation and enforcement costs may be					
22	included in a stipulated settlement.					
23	<u>DRUGS</u>					
24	20. Prior to August 18, 2014, Tramadol was classified as a dangerous drug. Effective					
25	August 18, 2014, federal law scheduled tramadol (brand name: Ultram) as a Schedule IV					
26						
27	controlled substance pursuant to 21 C.F.R. 1308.4(b)(3) and a dangerous drug pursuant to section					
28	4022. Tramadol is used as an analgesic.					
-						

FACTUAL ALLEGATIONS

- 21. On or about November 27, 2017, the Board received a written notification from owner and pharmacist-in-charge Respondent Hoffman of Respondent Hoffman Homecare, stating technician Respondent Bischoff was terminated for shipping drugs using the pharmacy's UPS (United Parcel Service) shipping service. Respondent Hoffman stated the following in his letter:
 - Food and Drug Administration (FDA) Special Agent Larry Henderhan (SA
 Henderhan) notified [Respondent Hoffman] of Respondent Bischoff's endeavors.
 Respondent Bischoff used UPS to ship drugs back east for many months. The
 drugs were obtained from another source.
 - On November 3, 2017, [Respondent Hoffman] terminated Respondent Bischoff's employment.
- 22. On or about August 13, 2018, a Board Investigator (Investigator) spoke with Respondent Hoffman who stated he had previously been contacted by SA Henderhan informing him Respondent Bischoff shipped drugs to Ohio using the pharmacy's UPS service. Respondent Hoffman stated he reviewed the shipping records and discovered shipments were made to Ohio and Kentucky. Respondent Hoffman stated he did not know that Respondent Bischoff was using the pharmacy's UPS service and did not witness it.
 - 23. Respondent Hoffman additionally confirmed the following to the Investigator:
 - Respondent Bischoff was responsible for shipping items using UPS for the pharmacy business, and Hoffman Homecare staff used the UPS service for personal use;
 - Sometimes Hoffman Homecare staff used the UPS service and paid the bookkeeper for the service;
 - Respondent Hoffman never personally witnessed Respondent Bischoff ship items
 for personal use, but while reviewing the shipping records he discovered
 Respondent Bischoff used the UPS service and reimbursed some but not all of her
 personal shipments.

- 24. On or about August 21, 2018, Respondent Hoffman e-mailed the Investigator another written statement stating the following:
 - On November 1, 2017, SA Henderhan informed Respondent Hoffman that Respondent Bischoff shipped illegal drugs to friends and family. Hoffman Homecare was not the drug provider but provided the shipping;
 - Respondent Hoffman investigated and reviewed the UPS shipping manifest for items shipped east. Respondent Bischoff accrued \$453.94 in shipping charges in 2016. Respondent Bischoff paid for five invoices in 2017 but did not reimburse Hoffman Homecare for any personal shipping charges accrued in 2016;
 - On November 1, 2017, Respondent Hoffman sent Respondent Bischoff home after conducting his own review of the shipping records, and Respondent Bischoff having stated she was shipping to her friends and family;
 - On November 3, 2017, Respondent Hoffman terminated Respondent Bischoff's employment.
- 25. The Investigator spoke with Respondent Hoffman to clarify documentation he provided, and Respondent Hoffman stated the following:
 - After SA Henderhan informed Respondent Hoffman about the investigation, he
 reviewed the UPS shipping records for zip codes outside of California because the
 pharmacy only conducted business in California. Respondent Hoffman discovered
 numerous shipments were out of state;
 - Respondent Hoffman asked Respondent Bischoff about the 2016 shipments, and she stated she shipped items but did not pay for the service;
 - Respondent Bischoff did not inform Respondent Hoffman about using the pharmacy's UPS service, and he did not know what the shipments contained.
- 26. On or about August 24, 2018, the Investigator spoke with SA Henderhan of the FDA, who was investigating controlled substances shipments, along with drug distribution with intent to sell, from California to Canton, Ohio. SA Henderhan stated it was a years long operation and primarily involved the drug tramadol.

- 27. SA Henderhan informed the Investigator that Respondent Bischoff shipped the drugs to her mother in Ohio, and her brother, Randall Borntrager in Ohio, who sold the drugs or used them for himself. SA Henderhan stated search warrants were executed on Respondent Bischoff's mother and Randall Borntrager, and admissions were obtained from Respondent Bischoff and Randall Borntrager. SA Henderhan further stated Respondent Bischoff and her brother had been arraigned, pled guilty, and were awaiting sentencing.
- 28. SA Henderhan stated he believed Respondent Bischoff obtained the drugs from the pharmacy waste [at Respondent Hoffman Homecare] because it was a closed door pharmacy with returned waste from facilities. Further supporting that view, SA Henderhan interviewed Respondent Hoffman, who informed him that Respondent Hoffman Homecare pharmacy did not have a strict protocol for handling waste.
- 29. On or about August 25, 2018, SA Henderhan e-mailed the Investigator a copy of Respondent Bischoff's indictment, which contained the following:
 - United States of America vs. Randall S. Borntrager and Renee Bischoff; United
 States District Court for the Northern District of Ohio, Eastern Division; Case No.
 5:18 CR 388;
 - Count 1: Conspiracy to possess with intent to distribute and distribute a Controlled Substances Act Level IV (CIV controlled substance), 21 USC 841(a)(l) and (b)(l)(E) in violation of 21 USC 846;
 - From in or around 2013 to on or about June 30, 2017, Mr. Borntrager (Respondent Bischoff's brother) and Respondent Bischoff knowingly and intentionally combined, conspired, confederated, and agreed together and with each other, to possess with intent to distribute and distribute a CIV controlled substance. While employed as a technician at a pharmacy, Respondent Bischoff shipped tramadol to Ohio. On or about March 7, 2017; March 30, 2017; May 2, 2017; and June 29, 2017, Respondent Bischoff shipped a parcel via UPS from Hoffman Homecare to Canton, Ohio. On July 1, 2017, Randall Borntrager distributed approximately 100 tablets of tramadol 50 mg to another person for \$120;

- Count 2: Conspiracy to ship misbranded drugs in interstate commerce, 21 USC 33
 1 (a) in violation of 21 USC 846;
- From in or around 2013 to on or about June 30, 2017, Randall Borntrager and Respondent Bischoff knowingly and intentionally conspired to cause the introduction and delivery of tramadol, that was adulterated and misbranded, into interstate commerce to Ohio through UPS, and Respondent Bischoff fraudulently used Hoffman Homecare's UPS shipping account to send tramadol to Randall Borntrager, and knowingly dispensed tramadol without a valid prescription. While employed as a technician at a pharmacy, Respondent Bischoff shipped misbranded tramadol to Ohio without a valid prescription.
- 30. A CURES (Controlled Substance Utilization Review and Evaluation System) patient activity report was generated for Respondent Bischoff, which showed that from January 1, 2013, to August 27, 2018, there were only two controlled substances dispensed to Respondent Bischoff: On or about June 22, 2018, for 20 tablets of hydrocodone/acetaminophen; and 5 tablets of 5 mg's of diazepam.
- 31. On or about September 5, 2018, the Investigator informed Respondent Bischoff of the complaint investigation. Respondent Bischoff admitted the following to the Investigator:
 - She was terminated from Hoffman Homecare on November 5, 2017;
 - She pled guilty to two counts of conspiracy and was awaiting sentencing in Ohio;
 - She mailed drugs to her brother, Randall Borntrager, in Ohio using Hoffman Homecare's UPS shipping service;
 - She had access to the UPS shipping system and shipped the drugs without the pharmacy's authorization or knowledge;
 - She shipped the drug tramadol, which she also admitted to shipping in her plea agreement.
- 32. On or about September 6, 2018, the U.S. Attorney in Ohio handling the matter emailed the Investigator a copy of Respondent Bischoff's indictment and plea agreement.

 Respondent Bischoff's plea agreement contained the following:

- Respondent Bischoff stipulated and admitted that the number of drugs conspired
 possessed with the intent to distribute and distributed in Count 1 was 80,000 units
 or more of tramadol 50 mg;
- As to Count 1, from 2013 to June 30, 2017, Respondent Bischoff and Randall
 Borntrager unlawfully, knowingly, and intentionally conspired with each other to
 possess with intent to distribute a controlled substance in violation of 21 USC
 841(a)(l) and (b)(l)(E). Part of the conspiracy included Respondent Bischoff
 shipping tramadol to Ohio for distribution by Randall Borntrager;
- As to Count 2, from 2013 to June 30, 2017, Respondent Bischoff and Randall
 Borntrager with the intent to defraud and mislead, knowingly and intentionally
 conspired to deliver into interstate commerce, a drug that was adulterated and
 misbranded, and Respondent Bischoff fraudulently used her employer's shipping
 account to send tramadol to Randall Borntrager without a valid prescription in
 violation of 21 USC 33 l(a);
- The amount of drugs possessed and distributed by Respondent Bischoff during the conspiracy and/or attributable to Respondent Bischoff's actions was at least 80,000 units of tramadol, which Respondent Bischoff knew was a CIV drug;
- 33. Subsequently, the Investigator spoke with Respondent Bischoff's attorney, David Torres, who informed the Investigator he believed tramadol was the only drug used in Respondent Bischoff's operation.

Hoffman Homecare Pharmacy Inspection

- 34. On or about September 11, 2018, the Investigator attempted to conduct an inspection and complaint investigation at Respondent Hoffman Homecare's facility. In the course of that inspection, the Investigator encountered D.S., the pharmacy biller, who was the only person on the premises.
- 35. D.S. informed the Investigator the pharmacy was not open, Respondent Hoffman was out of town, and there were no other pharmacists employed there. D.S. further stated she was there to do billing and entered by using her own front door key. D.S. explained that she and other

staff members possessed keys to the main entrance, but not to the pharmacy drug area. D.S. stated she was nearing her final day of work with Hoffman Homecare and came in to help with the billing.

- 36. D.S. stated the pharmacy compounding and drug areas were locked and Respondent Hoffman alone had access to that area, which the Investigator confirmed. The Investigator next walked through the pharmacy and found dangerous devices in the area just outside the pharmacy drug area and prescription records in the office area. The dangerous devices were stored on a small portable storage unit and included the following items:
 - PICC Dressing Change Kit, One-Link Needle Tree IV Connector, IV Start Kit,
 Primary Solution Set with Flow Regulator, Smallbore Extension Set, Shielded IV Catheter;
 - Quick-Set, Port Access Infusion Set, Safety Huber Needle Set, Dressing Change
 Tray with Chloraprep, and Liftloc Safety Infusion Set
- 37. The Investigator instructed D.S. to request that Respondent Hoffman coordinate a meeting with him to transfer the pharmacy key to Respondent Hoffman, which D.S. placed in a sealed envelope and turned over to the Investigator. The Investigator reviewed the inspection report with D.S. and issued the following written notices of non-compliance.
 - Business and Professions Code section 4116 (a): D.S., a non-pharmacist, was
 inside the pharmacy where dangerous devices and pharmacy records were stored
 without a pharmacist present;
 - C.C.R., Title 16, section 1714 (b), in conjunction with C.C.R., Title 16, Section 1714 (d) and (e): D.S. a non-pharmacist, was inside the pharmacy where dangerous devices and pharmacy records were stored without a pharmacist present and was in possession of the pharmacy key.
- 38. The investigator placed a copy of the report under the pharmacy door with instructions for Respondent Hoffman to contact him immediately. The Investigator noted that D.S. refused to sign the report despite her request that she so sign.

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Discovery of Additional Dangerous Drugs

- 39. Upon exiting the building, the Investigator noticed eleven boxes of acetic acid 0.25% irrigation solution. The label indicated the products were delivered to Hoffman Homecare from Amerisourcebergen.
- 40. After confirming the acetic acid irrigation solution was a dangerous drug, the Investigator moved all the acetic acid boxes into the pharmacy with D.S.'s permission.
- 41. D.S. locked the pharmacy and placed the pharmacy key into a new signed and sealed envelope of which the Investigator took possession. D.S. and the Investigator then exited the building.

Interview with Respondent Hoffman and Further Hoffman Homecare Inspection

- 42. On or about September 13, 2018, the Investigator spoke with Respondent Hoffman who stated the pharmacy was a closed door pharmacy (a pharmacy that provides pharmaceutical care to a defined and exclusive group). Respondent Hoffman stated he sold most of his pharmacy business to Rina's Pharmacy on September 9, 2018. Respondent Hoffman stated his pharmacy was still open and licensed and was filling some intravenous prescriptions for hospice patients.
- 43. Respondent Hoffman stated he was unaware that the dangerous devices and pharmacy records were required to be in a locked area.
- 44. On or about September 17, 2018, the Investigator conducted a routine inspection and complaint investigation at Respondent Hoffman Homecare's facility. Respondent Hoffman was present and assisted with the inspection.
- 45. Respondent Hoffman stated he believed all the required items were moved into the pharmacy drug area when he sold the pharmacy to Hina's Pharmacy but must have missed a few items. Regarding the pharmacy records, Respondent Hoffman stated he was unsure and unaware of the requirement to have the records locked.
- 46. The Investigator stated to Respondent Hoffman that D.S. and other pharmacy staff had keys to the front pharmacy entrance door, which Respondent Hoffman admitted. Respondent Hoffman claimed the staff was not scheduled to work until the pharmacist was on premise.

- 47. Respondent Hoffman stated he had a stroke in October 2014 and was away from the pharmacy until 2016. Respondent Hoffman stated he was still the pharmacist in charge because he was unable to find someone to fill that role, but he was unable to oversee the pharmacy. Respondent Hoffman stated staff pharmacists B.C., S.K., and A.M. ran the pharmacy while he was away. The Investigator asked if one person was designated as head pharmacist, and Respondent Hoffman stated B.C. was the supervisor and oversaw the staff. Respondent Hoffman stated his health improved and he returned to the pharmacy in 2016.
- 48. Respondent Hoffman stated he was not aware of any drug loss or drug diversion and did not have any suspicions of drug loss or diversion. Respondent Hoffman admitted the pharmacy did not closely account for tramadol because there were other controlled substances with a higher potential for abuse. Respondent Hoffman stated he maintained a schedule II controlled substance perpetual inventory but did not maintain one for schedule III through V controlled substances.
- 49. When asked if he reviewed the pharmacy's controlled substance purchase summaries provided by wholesalers, Respondent Hoffman stated he reviewed them for schedule II and III drugs but not for schedule IV and V drugs.
- 50. Respondent Hoffman stated SA Henderhan came to the pharmacy and reviewed the shipping records and discovered that Respondent Bischoff had shipped packages out of state. After SA Henderhan left, Respondent Hoffman stated that he spoke with Respondent Bischoff, who denied shipping pharmacy drugs but admitted shipping from the pharmacy. Respondent Hoffman stated he sent Respondent Bischoff home that day upon learning this and later terminated her employment.
- 51. Respondent Hoffman stated he audited all of Hoffman Homecare's schedule II drugs and benzodiazepines and there was no discrepancy. Respondent Hoffman stated he did not consider tramadol as a drug that one would attempt to divert, so he did not audit it. Respondent Hoffman stated SA Henderhan did not inform him which drugs were involved in Respondent Bischoff's conspiracy, or that the drugs originated from Hoffman Homecare

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52. Respondent Hoffman stated that Respondent Bischoff denied diverting drugs from the pharmacy. Respondent Hoffman stated because his schedule II drug and benzodiazepines audit found no discrepancies, he did not investigate any further.

Review of Biennial Controlled Substance Inventory

- 53. The Investigator also reviewed Hoffman Homecare's DEA (Drug Enforcement Administration) biennial controlled substance inventory, which was conducted at the start of business on January 24, 2016, by B.C. and another individual, C.V. The tramadol 50 mg inventory on January 24, 2016, was 244 tablets. From January 1, 2014, to January 23, 2016, a total of 8,497 tablets of tramadol 50 mg were dispensed, and from January 24, 2016, to September 8, 2018, a total of 11,340 tablets were dispensed. From January 1, 2014, to September 8, 2018, a total of 19,837 tablets of tramadol 50 mg were dispensed by Respondent Hoffman Homecare.
- 54. The tramadol 50 mg inventory on January 24, 2016 was 244 tablets, and 180 tablets on September 8, 2018.
- Hoffman Homecare purchased a total of 34,400 tablets of tramadol from 55. Amerisourcebergen, Anda, and McKesson from January 1, 2014, to September 8, 2018. From January 1, 2014, to September 8, 2018, the pharmacy purchased 19,100 tablets of tramadol.

(1) AMERISOURCEBERGEN

Drug Audit

On or about September 19, 2018, the Investigator sent a record request for acquisition and disposition records concerning Hoffman Homecare's acquisition of tramadol 50 mg from Amerisourcebergen between January 1, 2014, and September 8, 2018. On or about September 24, 2018, an Amerisourcebergen Legal Specialist, S.M., provided the tramadol sales history to the Investigator, which showed Hoffman Homecare purchased 2,800 tablets of tramadol 50 mg from January 1, 2014, to September 8, 2018. The purchases were in the following increments:

- From January 1, 2014, to January 23, 2016, the pharmacy purchased 300 tablets; and
- From January 24, 2016, to September 8, 2018, the pharmacy purchased 2,500 tablets.

(2) ANDA

On or about September 19, 2018, the Investigator sent a record request for acquisition and disposition records concerning Hoffman Homecare's acquisition of tramadol 50 mg from Anda between January 1, 2014, and September 8, 2018. On or about September 27, 2018, an Anda Regulatory Compliance Associate Director indicated there were no sales of tramadol to Hoffman Homecare.

(3) MCKESSON:

On or about September 19, 2018, the Investigator sent a record request for acquisition and disposition records concerning Hoffman Homecare's acquisition of tramadol 50 mg from McKesson between January 1, 2014, and September 8, 2018. On or about September 20, 2018, a McKesson Senior Legal Analyst, E.M., provided the tramadol sales history to the Investigator, which indicated Hoffman Homecare purchased 31,600 tablets of tramadol 50 mg from January 1, 2014 to September 8, 2018. Those purchases were in the following increments:

- From January 1, 2014, to January 23, 2016, the pharmacy purchased 14,900 tablets; and
- From January 24, 2016, to September 8, 2018, the pharmacy purchased 16,600 tablets.

Audit of Tramadol

The Investigator's audit determined that from January 1, 2014, to January 23, 2016, Respondent Hoffman Homecare dispensed 8,497 tablets of tramadol 50 mg, and from January 24, 2016, to September 8, 2018, 11,340 tablets. In total, from January 1, 2014, to September 8, 2018, Respondent Hoffman Homecare dispensed 19,837 tablets of tramadol 50 mg.

Respondent Hoffman Homecare's tramadol 50 mg inventory on January 24, 2016, was 244 tablets, and on September 8, 2018, 180 tablets. Respondent Hoffman Homecare purchased a total of 34,400 tablets of tramadol from Amerisourcebergen, Anda, and McKesson from January 1, 2014, to September 8, 2018. And, from January 24, 2016, to September 8, 2018, the pharmacy purchased 19,100 tablets of tramadol. The following charts provide a breakdown of the inventory:

Table 1: Audit from January 1, 2014 to September 8, 2018

Drug	Total Acquisition (a)	Total Disposition (b)	Inventory on 9/8/18 (c)	Variance d=b+c-a	% Variance of Total Acquisition
Tramadol 50mg	34,400	19,837	180	-14,383	41.8%

Table 2: Audit from January 24, 2016 to September 8, 2018

Drug	Inventory on 1/24/16 (a)	Total Acquisition (b)	Total Disposition (c)	Inventory on 9/8/18 (cl)		% Variance of Total Acquisition
Tramadol 50mg	244	19,100	11,340	180	-7,824	41%

- 56. On or about October 9, 2018, the Investigator issued letters and written notices of non-compliance to Respondent Hoffman Homecare, Respondent Hoffman, and Respondent Bischoff. The written notices of non-compliance to Respondent Hoffman Homecare and Respondent Hoffman included the following:
 - C.C.R., Title 16, section 1714 (b): An audit from January 24, 2016, to September 8, 2018, at Respondent Hoffman Homecare's facility revealed a shortage of 7,824 tablets of tramadol 50 mg.
 - Section 4116(a) and C.C.R., Title 16, section 1714, subdivisions (b) and (d): On September 11, 2018, an inspection at Respondent Hoffman Homecare's facility revealed non-pharmacist, D.S., possessed the pharmacy key, and dangerous devices and pharmacy records were stored inside the pharmacy without a pharmacist present. In addition, eleven cases of acetic acid 0.25% irrigation solution were stored outside the pharmacy secured area.
 - Section 4081(a) and C.C.R., Title 16, section 1718: An audit from January 24, 2016, to September 8, 2018, at Respondent Hoffman Homecare revealed the pharmacy was unable to account for 7,824 tablets of tramadol 50 mg. Therefore, the pharmacy failed to maintain an accurate inventory or complete accountability for all dangerous drugs.
- 57. The Investigator also issued notices of non-compliance to Respondent Bischoff which contained the following:

- Section 4301(f), (j), (1), & (o): On July 26, 2018, Respondent Bischoff pled guilty to two felony counts of conspiracy for shipping with intent to distribute at least 80,000 tablets of tramadol 50 mg, a schedule IV controlled substance without a prescription in violation of 21 United States Code 841(a)(l) and (b)(l)(E) and 21 United States Code 33 l(a).
- Section 4059 (a): From on or about 2013 to on or about June 29, 2017,
 Respondent Bischoff furnished at least 80,000 tablets of tramadol, a schedule IV controlled substance, to her brother Randall Borntrager without a prescription.
- Section 4060 and Health and Safety Code section 1 1173 (a):From on or about 2013 to on or about June 29, 2017, Respondent Bischoff was in possession of at least 80,000 tablets of tramadol, a schedule IV controlled substance, without a prescription.
- 58. On or about October 9, 2018, the Investigator informed Respondent Hoffman that the audit showed a drug loss of over 7,800 tramadol tablets from 2016 to 2018, and a loss of over 14,000 tablets from 2014 to 2018. The Investigator further informed Respondent Hoffman that written notice provided to him of the drug loss at that time was exclusively based on the DEA inventory conducted on January 24, 2016 and September 8, 2018 resulting in the loss of 7,824 tablets of tramadol 50 mg.

Respondent Hoffman Homecare, Inc.

FIRST CAUSE FOR DISCIPLINE

(Failure to Maintain Operational Standards and Security)

- 59. Respondent Hoffman Homecare is subject to disciplinary action under C.C.R. Title 16, Section 1714, subdivision (b), in that Respondent Hoffman Homecare failed to maintain its facilities, space, fixtures, and equipment so that drugs are safely and properly prepared, maintained, secured, and distributed.
- 60. As set forth in paragraphs 20 through 57, above, which are incorporated herein by reference, an audit of Respondent Hoffman Homecare's facility revealed a shortage of 7,824 tablets of trainadol 50 mg.

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SECOND CAUSE FOR DISCIPLINE

(Failure to Maintain Records and Current Inventory)

- 61. Respondent Hoffman Homecare is subject to disciplinary action under, Section 4081, subdivision (a), of the Code in that Respondent Hoffman Homecare failed to maintain records of manufacture and of sale, acquisition, receipt, shipment, or disposition of dangerous drugs and dangerous devices at all times during business hours for inspection by authorized officers of the law. Respondent Hoffman Homecare further failed to preserve for at least three years from the making, and a current inventory of its stock of dangerous drugs or dangerous devices.
- 62. As set forth in paragraphs 20 through 57, above, which are incorporated herein by reference, an audit of Respondent Hoffman Homecare's facility revealed the pharmacy was unable to account for the loss of 7,824 tablets of tramadol 50 mg.
- Respondent is subject to disciplinary action under C.C.R. Title 16, Section 1718, in 63. that Respondent failed to maintain a current inventory of dangerous drugs.
- 64. As set forth in paragraphs 20 through 57, above, which are incorporated herein by reference, an audit of Respondent Hoffman Homecare's facility revealed the pharmacy was unable to account for the loss of 7,824 tablets of tramadol 50 mg.

THIRD CAUSE FOR DISCIPLINE

(Failure to Maintain Pharmacy Security)

- 65. Respondent Hoffman Homecare is subject to disciplinary action under, Section 4116, subdivision (a), of the Code in that Respondent Hoffman Homecare allowed non-pharmacists into areas where controlled substances, or dangerous drugs, or dangerous devices were stored, possessed, prepared, manufactured, derived, compounded, dispensed, or repackaged.
- As set forth in paragraphs 20 through 57, above, which are incorporated herein by reference, an inspection of Respondent Hoffman Homecare's pharmacy revealed non-pharmacist, D.S., was in possession of the pharmacy key and present at the pharmacy where dangerous devices and pharmacy records were stored without a pharmacist present. In addition, eleven cases of acetic acid 0.25% irrigation solution were stored outside the pharmacy secured area.

- 67. Respondent Hoffman Homecare is further subject to disciplinary action under C.C.R. Title 16, section 1714, subdivisions (b) and (d) in that Respondent Hoffman Homecare failed to maintain its facilities, space, fixtures, and equipment so that drugs are safely and properly prepared, maintained, secured, and distributed; and failed to maintain responsibility for the security of the prescription department, including provisions for effective control against theft or diversion of dangerous drugs and devices, and records for such drugs and devices, and possession of a key to the pharmacy where dangerous drugs are stored shall be restricted to a pharmacist.
- 68. As set forth in paragraphs 20 through 57, above, which are incorporated herein by reference, an inspection of Respondent Hoffman Homecare's pharmacy revealed D.S., who was not a pharmacist, was in possession of the pharmacy key and inside the pharmacy where dangerous devices and pharmacy records were stored without a pharmacist present. In addition, eleven cases of acetic acid 0.25% irrigation solution were stored outside the pharmacy secured area.

Respondent Hoffman

FOURTH CAUSE FOR DISCIPLINE

(Failure to Maintain Operational Standards and Security)

- 69. Respondent Hoffman is subject to disciplinary action under C.C.R. Title 16, Section 1714, subdivision (b), in that Respondent Hoffman failed to maintain Respondent Hoffman Homecare's facilities, space, fixtures, and equipment so that drugs were safely and properly prepared, maintained, secured, and distributed.
- 70. As set forth in paragraphs 20 through 57, above, which are incorporated herein by reference, an audit of Respondent Hoffman Homecare's facility, in which Respondent Hoffman was pharmacist-in-charge, revealed a shortage of 7,824 tablets of tramadol 50 mg.

FIFTH CAUSE FOR DISCIPLINE

(Failure to Maintain Records and Current Inventory)

71. Respondent Hoffman is subject to disciplinary action under, Section 4081, subdivision (a), of the Code in that Respondent Hoffman failed to maintain Respondent Hoffman Homecare's records of manufacture and of sale, acquisition, receipt, shipment, or disposition of

dangerous drugs and dangerous devices at all times during business hours for inspection by authorized officers of the law. Respondent Hoffman further failed to preserve the foregoing records for at least three years from the making, and failed to maintain an accurate and true current inventory of Respondent Hoffman Homecare's stock of dangerous drugs or dangerous devices.

- 72. As set forth in paragraphs 20 through 57, above, which are incorporated herein by reference, an audit of Respondent Hoffman Homecare's facility revealed that while Respondent Hoffman was the pharmacist in charge, Respondent Hoffman Homecare was unable to account for the loss of 7,824 tablets of transdol 50 mg.
- 73. Respondent Hoffman is further subject to disciplinary action under C.C.R. Title 16, section 1718 in that Respondent Hoffman failed to maintain complete accountability for all dangerous drugs handled by every licensee.
- 74. As set forth in paragraphs 20 through 57, above, which are incorporated herein by reference, an audit of Respondent Hoffman Homecare's facility revealed that while Respondent Hoffman was the pharmacist in charge, Respondent Hoffman Homecare was unable to account for the loss of 7,824 tablets of tramadol 50 mg.

SIXTH CAUSE FOR DISCIPLINE

(Failure to Maintain Security)

- 75. Respondent Hoffman is subject to disciplinary action under, Section 4116, subdivision (a), of the Code in that Respondent Hoffman allowed a non-pharmacist into an area, place, or premises described in the license issued by the board wherein controlled substances or dangerous drugs or dangerous devices were stored, possessed, prepared, manufactured, derived, compounded, dispensed, or repackaged.
- 76. As set forth in paragraphs 20 through 57, above, which are incorporated herein by reference, an inspection of Respondent Hoffman Homecare's pharmacy revealed that D.S., who was not a pharmacist, was in possession of the pharmacy key and present inside the pharmacy where dangerous devices and pharmacy records were stored without a pharmacist being present.

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In addition, eleven cases of acetic acid 0.25% irrigation solution were stored outside the pharmacy secured area.

- 77. Respondent is further subject to disciplinary action under C.C.R. Title 16, section 1714, subdivisions (b) and (d) in that Respondent failed to maintain Respondent Hoffman Homecare's facilities, space, fixtures, and equipment so that drugs were safely and properly prepared, maintained, secured, and distributed; and failed to maintain responsibility for the security of the prescription department, including provisions for effective control against theft or diversion of dangerous drugs and devices, and records for such drugs and devices, and possession of a key to the pharmacy where dangerous drugs are stored that are required to be restricted to a pharmacist.
- 78. As set forth in paragraphs 20 through 57, above, which are incorporated herein by reference, an inspection of Respondent Hoffman Homecare's pharmacy revealed non-pharmacist, D.S., was in possession of the pharmacy key and present at the pharmacy where dangerous devices and pharmacy records were stored without a pharmacist being present. In addition, eleven cases of acetic acid 0.25% irrigation solution were stored outside the pharmacy secured area.

Respondent Bischoff

SEVENTH CAUSE FOR DISCIPLINE

(Unprofessional Conduct)

- 79. Respondent is subject to disciplinary action under Section 4301, subdivisions (f), (j), (l), and (o) of the Code in that Respondent committed acts of unprofessional conduct.
- 80. As set forth in paragraphs 20 through 57, above, which are incorporated herein by reference, on or about July 26, 2018, Respondent Bischoff pled guilty to two felony counts of conspiracy for shipping with intent to distribute at least 80,000 tablets of tramadol 50 mg without a prescription in violation of 21 United States Code 841(a)(l) and (b)(l)(E), 21 United States Code 846 and 21 United States Code 331 (a), in *The United States vs. Randall S. Borntrager and Renee Bischoff,* United States District Court for the Northern District of Ohio, Eastern Division; Case No. 5:18 CR 388.

EIGHTH CAUSE FOR DISCIPLINE

(Furnishing Dangerous Devices Prohibited Without Prescription)

- 81. Respondent Bischoff is subject to disciplinary action under Section 4059, subdivision (a), of the Code in that Respondent Bischoff furnished a dangerous drug without a prescription.
- 82. As set forth in paragraphs 20 through 57, above, which are incorporated herein by reference, Respondent Bischoff shipped with the intent to distribute at least 80,000 tablets of tramadol 50 mg, a schedule IV controlled substance, without a valid prescription.

NINTH CAUSE FOR DISCIPLINE

(Controlled Substance Prescription Required)

- 83. Respondent Bischoff is subject to disciplinary action under Section 4060 of the Code and California Health and Safety Code section 11173, subdivision (a) in that Respondent Bischoff furnished a dangerous drug without a prescription.
- 84. As set forth in paragraphs 20 through 57, above, which are incorporated herein by reference, Respondent Bischoff shipped with the intent to distribute at least 80,000 tablets of tramadol 50 mg, a schedule IV controlled substance, without a valid prescription.

OWNERSHIP PROHIBITION

- 85. As set forth above, section 4307, subdivision (a), provides, in pertinent part, that any person whose license has been revoked or is under suspension shall be prohibited from serving as a manager, administrator, owner, member, officer, director, associate or partner of a licensee.
- 86. Pursuant to section 4307, if Respondent Hoffman had knowledge of, or knowingly participated in, any conduct for which Pharmacy Permit PHY 37014 was revoked, suspended or placed on probation, while acting as administrator, owner, officer, director, or any other person with management or control of Hoffman Homecare, Inc. dba Hoffman Homecare, he shall be prohibited from serving as administrator, owner, member, officer, director, associate, or partner of a licensee for five years if Pharmacy Permit Number PHY 37014 is placed on probation, or until Pharmacy Permit Number PHY 37014 is reinstated if Pharmacy Permit Number PHY 37014 is revoked.

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1	6. Taking such other and f	urther action as deemed necessary and proper.
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5	DATED: <u>9/19/2020</u>	Anne Sodergren ANNE SODERGREN
6		Executive Officer
7		Board of Pharmacy Department of Consumer Affairs State of California
8		Complainant
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