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

10 In the Matter of the Accusation Against:
11 **SHILOH FAMILY PHARMACY INC.**
12 **DBA SHILOH FAMILY PHARMACY,**
13 **DIANA ARONSON and NATALIA**
14 **VOYTOVA, OWNERS**
15 **PIC ALAN BROWN (2/28/14-5/29/14)**
16 **5551 Hollywood Blvd., Space A**
17 **Los Angeles, CA 90028**
18 **Pharmacy Permit No. PHY 51776**
19 **and**
20 **ALAN BROWN**
21 **202 118th Avenue SE, #C11**
22 **Bellevue, WA 98005**
23 **Pharmacist License No. RPH 22146**
24 **Respondents.**

Case No. 5813

ACCUSATION

23 Complainant alleges:

24 **PARTIES**

- 25 1. Virginia Herold (Complainant) brings this Accusation solely in her official capacity
26 as the Executive Officer of the Board of Pharmacy, Department of Consumer Affairs.
27 2. On or about February 28, 2014, the Board of Pharmacy issued Pharmacy Permit
28 Number PHY 51776 to Shiloh Family Pharmacy Inc. dba Shiloh Family Pharmacy (Respondent)

1 Pharmacy). Diana Aronson and Natalia Voytova have been the owners (each own 50% of the
2 stock in Respondent Pharmacy) of Respondent Pharmacy since February 28, 2014. Diana
3 Aronson has been the President and Chief Executive Officer and Natalia Voytova has been the
4 Secretary since February 28, 2014. The Pharmacy Permit was in full force and effect at all times
5 relevant to the charges brought herein and will expire on February 1, 2018, unless renewed.

6 3. On or about August 10, 1961, the Board of Pharmacy issued Pharmacist License
7 Number RPH 22146 to Respondent Alan Brown (Respondent Brown). Respondent Alan Brown
8 (RPH 22146) was the Pharmacist-in-Charge (PIC) of Respondent Pharmacy from February 28,
9 2014, to May 29, 2014. Respondent Brown worked at Respondent Pharmacy as a staff
10 pharmacist from May 30, 2014, through June 11, 2014. The Pharmacist License was in full force
11 and effect at all times relevant to the charges brought herein and expired on February 8, 2017, and
12 has not been renewed. The Pharmacist License is retired.

13 JURISDICTION

14 4. This Accusation is brought before the Board of Pharmacy (Board), Department of
15 Consumer Affairs, under the authority of the following laws. All section references are to the
16 Business and Professions Code (Code), unless otherwise indicated.

17 STATUTORY PROVISIONS

18 5. Section 4300 of the Code provides in pertinent part, that every license issued by the
19 Board is subject to discipline, including suspension or revocation.

20 6. Section 4300.1 of the Code states:

21 "The expiration, cancellation, forfeiture, or suspension of a board-issued license by
22 operation of law or by order or decision of the board or a court of law, the placement of a license
23 on a retired status, or the voluntary surrender of a license by a licensee shall not deprive the board
24 of jurisdiction to commence or proceed with any investigation of, or action or disciplinary
25 proceeding against, the licensee or to render a decision suspending or revoking the license."
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1 7. Section 4301 of the Code states, in part:

2 "The board shall take action against any holder of a license who is guilty of unprofessional
3 conduct or whose license has been procured by fraud or misrepresentation or issued by mistake.

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

5 ...

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

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

12 8. Section 4302 of the Code states:

13 “The board may deny, suspend, or revoke any license of a corporation where conditions
14 exist in relation to any person holding 10 percent or more of the corporate stock of the
15 corporation, or where conditions exist in relation to any officer or director of the corporation that
16 would constitute grounds for disciplinary action against a licensee.”

17 9. Section 4113 of the Code states, in part:

18 “(b) The pharmacist-in-charge shall be responsible for a pharmacy's compliance with all
19 state and federal laws and regulations pertaining to the practice of pharmacy.”

20 10. Section 4115, subdivision (h), states that “[t]he pharmacist on duty shall be directly
21 responsible for the conduct of a pharmacy technician supervised by that pharmacist.”

22 11. Section 4116 of the Code states, in pertinent part:

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

1 clerical, inventory control, housekeeping, delivery, maintenance, or similar functions relating to
2 the pharmacy if the pharmacist remains present in the pharmacy during all times as the authorized
3 individual is present.”

4 12. Section 4307, subdivision (a), of the Code states, in pertinent part:

5 “Any person who has been denied a license or whose license has been revoked or is under
6 suspension, or who has failed to renew his or her license while it was under suspension, or who
7 has been a manager, administrator, owner, member, officer, director, associate, or partner of any
8 partnership, corporation, firm, or association whose application for a license has been denied or
9 revoked, is under suspension or has been placed on probation, and while acting as the manager,
10 administrator, owner, member, officer, director, associate, or partner had knowledge of or
11 knowingly participated in any conduct for which the license was denied, revoked, suspended, or
12 placed on probation, shall be prohibited from serving as a manager, administrator, owner,
13 member, officer, director, associate, or partner of a licensee as follows:

14 (1) Where a probationary license is issued or where an existing license is placed on
15 probation, this prohibition shall remain in effect for a period not to exceed five years.

16 (2) Where the license is denied or revoked, the prohibition shall continue until the
17 license is issued or reinstated.”

18 13. Section 4081 of the Code states, in pertinent part:

19 “(a) All records of manufacture and of sale, acquisition, receipt, shipment, or disposition of
20 dangerous drugs or dangerous devices shall be at all times during business hours open to
21 inspection by authorized officers of the law, and shall be preserved for at least three years from
22 the date of making. A current inventory shall be kept by every manufacturer, wholesaler, third-
23 party logistics provider, pharmacy, veterinary food-animal drug retailer, outsourcing facility,
24 physician, dentist, podiatrist, veterinarian, laboratory, clinic, hospital, institution, or establishment
25 holding a currently valid and unrevoked certificate, license, permit, registration, or exemption
26 under Division 2 (commencing with Section 1200) of the Health and Safety Code or under Part 4
27 (commencing with Section 16000) of Division 9 of the Welfare and Institutions Code who
28 maintains a stock of dangerous drugs or dangerous devices.

1 “(b) The owner, officer, and partner of a pharmacy, wholesaler, third-party logistics
2 provider, or veterinary food-animal drug retailer shall be jointly responsible, with the pharmacist-
3 in-charge, responsible manager, or designated representative-in-charge, for maintaining the
4 records and inventory described in this section.”

5 13. Health and Safety Code Section 111440 states: “It is unlawful for any person to
6 manufacture, sell, deliver, hold, or offer for sale any drug or device that is misbranded.”

7 REGULATORY PROVISIONS

8 14. California Code of Regulations, title 16, section 1770, states:

9 "For the purpose of denial, suspension, or revocation of a personal or facility license
10 pursuant to Division 1.5 (commencing with Section 475) of the Business and Professions Code, a
11 crime or act shall be considered substantially related to the qualifications, functions or duties of a
12 licensee or registrant if to a substantial degree it evidences present or potential unfitness of a
13 licensee or registrant to perform the functions authorized by his license or registration in a manner
14 consistent with the public health, safety, or welfare."

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

16 “(b) Each pharmacy licensed by the board shall maintain its facilities, space, fixtures, and
17 equipment so that drugs are safely and properly prepared, maintained, secured and distributed.
18 The pharmacy shall be of sufficient size and unobstructed area to accommodate the safe practice
19 of pharmacy.”

20 ...

21 “(d) Each pharmacist while on duty shall be responsible for the security of the prescription
22 department, including provisions for effective control against theft or diversion of dangerous
23 drugs and devices, and records for such drugs and devices. Possession of a key to the pharmacy
24 where dangerous drugs and controlled substances are stored shall be restricted to a pharmacist.”

25 16. California Code of Regulations, title 16, section 1718 states:

26 "Current Inventory' as used in Sections 4081 and 4332 of the Business and Professions
27 Code shall be considered to include complete accountability for all dangerous drugs handled by
28 every licensee enumerated in Sections 4081 and 4332.

1 "The controlled substances inventories required by Title 21, CFR, Section 1304 shall be
2 available for inspection upon request for at least 3 years after the date of the inventory."

3 **COST RECOVERY**

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

10 18. **DRUG CLASSIFICATIONS**

Brand Name(s)	Generic Name	Dangerous Drug Per Bus. & Prof. Code § 4022	Scheduled Drug per Health & Safety Code (HSC)	Indications For Use
Ambien	zolpidem tartrate	Yes	Schedule IV per HSC § 11057(d)(32)	Insomnia
Lortab 7.25/325mg, Norco 10/325mg, Vicodin 5/300mg	hydrocodone/acetaminophen (APAP)	Yes	Schedule III per HSC § 11056(e)(4) and Schedule II per 21 CFR 1308 (as of 10/6/14)	Moderate to Severe Pain
Celebrex 200mg	celecoxib	Yes	Not scheduled	Pain, Arthritis
Crestor 10mg/20mg	rosuvastatin calcium	Yes	Not scheduled	Cholesterol
Seroquel 25mg	quetiapine fumarate	Yes	Not scheduled	Schizophrenia, bipolar disorder, and depression.

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1 **FIRST CAUSE FOR DISCIPLINE**

2 **(Failure to Maintain Operational Standards and Security)**

3 19. Respondents are subject to disciplinary action under section 4301, subdivision (o), of
4 the Code, on the grounds of unprofessional conduct, for violating California Code of Regulations,
5 title 16, section 1714, subdivisions (b) and (d), in that they failed to secure the pharmacy to
6 prevent loss of controlled substances. Specifically, a Board audit of the pharmacy's controlled
7 substances for the period of March 4, 2014, through June 2, 2014, while Respondent Brown was
8 the Pharmacist-in-Charge, revealed that 9,675 tablets of controlled substances were unaccounted
9 for, as follows:

10 **TABLE ONE**

11 DRUG NAME	BEGINNING INVENTORY	TOTAL PURCHASED	TOTAL DISPENSED	ON STOCK	TOTAL DRUG LOSS (TABLET)
12 Vicodin 5/300mg	91	2,400	1320	149	1,022
13 Zolpidem 10mg	0	10,000	4,875	1,015	4,110
14 Hydrocodone/ 15 acetaminophen 16 7.5/325mg	100	1,700	990	99	711
17 Hydrocodone/ 18 acetaminophen 19 5/325mg	100	3,500	2,662	247	691
20 Hydrocodone/ 21 acetaminophen 22 10/325mg	280	4,200	1,230	109	3,141
23 TOTAL LOSS					9,675

24 **SECOND CAUSE FOR DISCIPLINE**

25 **(Failure to Account for Controlled Substances)**

26 20. Respondents are subject to disciplinary action under section 4301, subdivision (o), of
27 the Code, on the grounds of unprofessional conduct, for violating section 4081 of the Code and
28 California Code of Regulations, title 16, section 1718, by failing to maintain a "current
inventory", in that Respondents were unable to account for 9,675 tablets of controlled substances.

1 Complainant refers to, and by this reference incorporates, the allegations set forth above in
2 paragraph 19, as though set forth in full herein.

3 **THIRD CAUSE FOR DISCIPLINE**

4 **(Holding Misbranded Drugs)**

5 21. Respondents are subject to disciplinary action under section 4301, subdivision (j), of
6 the Code, on the grounds of unprofessional conduct, for violating Health and Safety Code section
7 111440, by holding misbranded drugs. Specifically, on or about June 2, 2014, during a Board
8 inspection of Respondent Pharmacy's facility, located at 5551 Hollywood Blvd., Space A, Los
9 Angeles, California, misbranded dangerous drugs (Crestor 10 and 20mg, Celebrex 200mg, and
10 Seroquel 25mg) were found on the pharmacy shelves among the pharmacy's active inventory, as
11 follows:

12 **TABLE TWO**

13 DRUG NAME AND 14 STRENGTH	MANUFACTURER AND PACKAGE SIZE	LOT NO. AND EXPIRATION DATE	TOTAL QUANTITY FOUND	COMMENTS
15 Crestor 10mg	AstraZeneca 1 container (90 tablets)	CF0004 (12/2016)	150 tablets	Overfilled packaging ¹ Chipped tablets ²
17 Crestor 20mg	AstraZeneca 1 container (90 tablets)	CF0002 (11/2016)	90 tablets	Chipped tablets. Variation on appearance of imprints ³ Missing temper evidence seal
20 Celebrex 200mg	Pfizer 1 container (100 capsules)	H67410 (09/2016)	35 capsules	Variation on appearance of imprint on the capsules (lighter vs. darker hue)
23 Seroquel 25mg	AstraZeneca 1 container (100 tablets)	AN0021 (02/19/15)	383 tablets	Overfilled packaging

25 ¹ Overfilled packages may indicate that the drugs in the package were from different lot
26 numbers or manufacturers, or the drugs were from a non-FDA approved source.

26 ² Chipped and damaged tablets may indicate mishandling of drugs due to beyond expiry
27 date, over handling, and/or exposure to extreme weather temperatures (freezing or heat)

27 ³ Variations in the imprints may indicate counterfeit drugs or pills from different lot
28 numbers or manufacturers.

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FOURTH CAUSE FOR DISCIPLINE

(Unauthorized Access to Pharmacy)

22. Respondent Pharmacy is subject to disciplinary action under section 4301, subdivision (o), of the Code, on the grounds of unprofessional conduct, for violating section 4116, subdivision (a), of the Code, by allowing personnel into the pharmacy without a pharmacist present. Specifically, on or about June 2, 2014, U.S. Drug Enforcement Administration (DEA) agents observed Diana Aronson (unlicensed) and a pharmacy technician, S.G., enter the pharmacy area of Respondent Pharmacy's facility, located at 5551 Hollywood Blvd., Space A, Los Angeles, California, without a pharmacist present.

OTHER MATTERS

23. Pursuant to section 4307 of the Code, if discipline is imposed on Pharmacy Permit Number PHY 51776 issued to Shiloh Family Pharmacy Inc. dba Shiloh Family Pharmacy, Shiloh Family Pharmacy Inc. shall be prohibited from serving as a manager, administrator, owner, member, officer, director, associate, or partner of a licensee for five years if Pharmacy Permit Number PHY 51776 is placed on probation or until Pharmacy Permit Number PHY 51776 is reinstated if it is revoked.

24. Pursuant to section 4307 of the Code, if discipline is imposed on Pharmacy Permit Number PHY 51776 issued to Shiloh Family Pharmacy Inc. dba Shiloh Family Pharmacy while Diana Aronson and Natalia Voytova have been an officer and owner and had knowledge of or knowingly participated in any conduct for which the licensee was disciplined, Diana Aronson and Natalia Voytova shall be prohibited from serving as a manager, administrator, owner, member, officer, director, associate, or partner of a licensee for five years if Pharmacy Permit Number PHY 51776 is placed on probation or until Pharmacy Permit Number PHY 51776 is reinstated if it is revoked.

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DISCIPLINE CONSIDERATIONS

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2 25. To determine the degree of discipline, if any, to be imposed on Respondent Brown,
3 Complainant alleges that in or about 2001, in a prior action, the Board of Pharmacy issued
4 Citation Number CI 2001 23242 to Respondent Brown, for violating sections 4301
5 (unprofessional conduct), 4301, subdivision (o) (violation of laws or regulations governing
6 pharmacy), and 4076 (inaccurate label), of the Code, and California Code of Regulations, title 16,
7 section 1716 (prescription deviation). That Citation is now final and is incorporated by reference
8 as if fully set forth.

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1 PRAYER

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

4 1. Revoking or suspending Pharmacy Permit Number PHY 51776, issued to Shiloh
5 Family Pharmacy Inc. dba Shiloh Family Pharmacy,

6 2. Revoking or suspending Pharmacy License Number 22146 issued to Alan Brown,

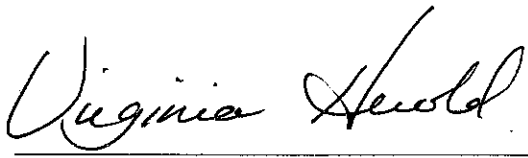
7 3. Prohibiting Diana Aronson from serving as a manager, administrator, owner,
8 member, officer, director, associate, or partner of a licensee for five years if Pharmacy Permit
9 Number PHY 51776 is placed on probation or until Pharmacy Permit Number PHY 51776 is
10 reinstated if Pharmacy Permit Number PHY 51776 issued to Shiloh Family Pharmacy Inc. dba
11 Shiloh Family Pharmacy is revoked;

12 4. Prohibiting Natalia Voytova from serving as a manager, administrator, owner,
13 member, officer, director, associate, or partner of a licensee for five years if Pharmacy Permit
14 Number PHY 51776 is placed on probation or until Pharmacy Permit Number PHY 51776 is
15 reinstated if Pharmacy Permit Number 51776 issued to Shiloh Family Pharmacy Inc. dba Shiloh
16 Family Pharmacy is revoked;

17 5. Ordering Respondent Pharmacy, Respondent Brown, Diana Aronson and Natalia
18 Voytova to pay the Board of Pharmacy the reasonable costs of the investigation and enforcement
19 of this case, pursuant to Business and Professions Code section 125.3;

20 6. Taking such other and further action as deemed necessary and proper.

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24 DATED: 3/18/17


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

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