

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

In the Matter of the Accusation Against:

**WEDGEWOOD VILLAGE PHARMACY LLC; dba
WEDGEWOOD VILLAGE PHARMACY;
INTERMEDIATE HOLDINGS LLC 59% SHAREHOLDER;
TW DIAMONDBACK HOLDINGS CORPORATION, 41%
SHAREHOLDER;
MARCY ANN BLISS, CEO; JOSEPH COSTA, COO; ALISON LYNCH, PIC,
Nonresident Pharmacy Permit No. NRP 2526,
Nonresident Sterile Compounding Permit No. NSC 101673; and**

**WEDGEWOOD VILLAGE PHARMACY LLC;
WEDGEWOOD VILLAGE PHARMACY
INTERMEDIATE HOLDINGS LLC 59% SHAREHOLDER;
TW DIAMONDBACK HOLDINGS CORPORATION, 41%
SHAREHOLDER;
MARCY ANN BLISS, CEO; ALISON LYNCH, PIC,
Nonresident Pharmacy Permit No. NRP 1826,
Nonresident Sterile Compounding Permit No. NSC 100970**

Respondents

Agency Case No. 7286

DECISION AND ORDER

The attached Stipulated Settlement and Disciplinary Order for Public Repeval 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 March 22, 2024.

It is so ORDERED on February 21, 2024.

BOARD OF PHARMACY
DEPARTMENT OF CONSUMER AFFAIRS
STATE OF CALIFORNIA

By

A handwritten signature in black ink, appearing to read "Seung W. Oh". The signature is fluid and cursive, with the first name "Seung" and last name "Oh" being clearly legible.

Seung W. Oh, Pharm.D.
Board President

1 ROB BONTA
Attorney General of California
2 ANDREW M. STEINHEIMER
Supervising Deputy Attorney General
3 KRISTINA T. JARVIS
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7 *Attorneys for Complainant*

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INTERMEDIATE HOLDINGS LLC, 59%
15 **shareholder;**
TW DIAMONDBACK HOLDINGS
16 **CORPORATION, 41% shareholder;**
MARCY ANN BLISS, CEO;
17 **JOSEPH COSTA, COO;**
ALISON LYNCH, PIC;
18 **405 Heron Drive**
Swedesboro, NJ 08085

19 **Nonresident Pharmacy Permit No. NRP 2526,**
20 **Nonresident Sterile Compounding Permit No.**
NSC 101673

21 **and**

22 **WEDGEWOOD VILLAGE PHARMACY LLC;**
23 **WEDGEWOOD VILLAGE PHARMACY**
INTERMEDIATE HOLDINGS LLC, 59%
24 **Shareholder;**
TW DIAMONDBACK HOLDINGS
25 **CORPORATION, 41% shareholder;**
MARCY ANN BLISS, CEO;
26 **ALISON LYNCH, PIC;**
405 Heron Drive, Suite 200
27 **Swedesboro, NJ 08085**

Case No. 7286

STIPULATED SETTLEMENT AND
DISCIPLINARY ORDER FOR
PUBLIC REPROVAL

[Bus. & Prof. Code § 495]

Respondents.

PARTIES

3. On or about June 6, 2016, the Board issued Nonresident Sterile Compounding Pharmacy Permit Number NSC 100970 to Respondent Original Licensee. The Nonresident Sterile Compounding Pharmacy Permit was in full force and effect at all times relevant to the charges brought herein until April 1, 2021, at which point the license was cancelled due to a change of ownership as set forth in paragraph 5, below.

///

4. On or about April 1, 2021, due to a change of ownership application, the Board issued Nonresident Pharmacy Permit Number NRP 2526 to Wedgewood Village Pharmacy Intermediate Holdings LLC, 59% shareholder, and TW Diamondback Holdings Corporation, 41% shareholder dba Wedgewood Village Pharmacy LLC; Marcy Ann Bliss, CEO; Joseph Costa, COO; and Alison Lynch, Pharmacist-in-Charge; (Respondent Successor Licensee, collectively “Respondents”). The Nonresident Pharmacy Permit was in full force and effect at all times relevant to the charges brought herein from April 1, 2021, and will expire on April 1, 2024, unless renewed.

5. On or about April 1, 2021, the Board issued Nonresident Sterile Compounding Permit Number NSC 101673 to Respondent Successor Licensee. The Nonresident Sterile Compounding Permit was in full force and effect at all times relevant to the charges brought herein from April 1, 2021, and will expire on April 1, 2024, unless renewed.

6. Respondent is represented in this proceeding by attorney Derek Shaffer whose address is: 1300 I Street NW, Suite 900, Washington D.C. 20005.

JURISDICTION

7. Accusation No. 7286 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 April 27, 2023. Respondent timely filed its Notice of Defense contesting the Accusation. On July 26, 2023, Complainant filed a First Amended Accusation. A copy of First Amended Accusation No. 7286 is attached as exhibit A and incorporated herein by reference.

ADVISEMENT AND WAIVERS

8. Respondent has carefully read, fully discussed with counsel, and understands the charges and allegations in First Amended Accusation No. 7286. Respondent has also carefully read, fully discussed with counsel, and understands the effects of this Stipulated Settlement and Disciplinary Order for Public Reprimand.

9. Respondent is fully aware of its legal rights in this matter, including the right to a hearing on the charges and allegations in the First Amended Accusation; the right to be

1 represented by counsel at its own expense; the right to confront and cross-examine the witnesses
2 against them; the right to present evidence and to testify on its own behalf; the right to the
3 issuance of subpoenas to compel the attendance of witnesses and the production of documents;
4 the right to reconsideration and court review of an adverse decision; and all other rights accorded
5 by the California Administrative Procedure Act and other applicable laws.

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

8 11. NRP 1826 and NSC 101673 have been cancelled, and the Board confirms that there
9 are no pending allegations or investigations against these licenses, and therefore no future
10 administrative or disciplinary action is contemplated.

11 **CULPABILITY**

12 12. Respondent understands and agrees that the charges and allegations in Accusation
13 No. 7286, if proven at a hearing, constitute cause for imposing discipline upon its Nonresident
14 Pharmacy Permits and Nonresident Sterile Compounding Permits.

15 13. For the purpose of resolving the Accusation without the expense and uncertainty of
16 further proceedings, Respondent hereby gives up its right to contest those charges.

17 14. Respondent agrees that its Nonresident Pharmacy Permit and Nonresident Sterile
18 Compounding Permit are subject to discipline and they agree to be bound by the Disciplinary
19 Order below.

20 **CONTINGENCY**

21 15. This stipulation shall be subject to approval by the Board of Pharmacy. Respondent
22 understands and agrees that counsel for Complainant and the staff of the Board of Pharmacy may
23 communicate directly with the Board regarding this stipulation and settlement, without notice to
24 or participation by Respondent or its counsel. By signing the stipulation, Respondent understands
25 and agrees that they may not withdraw its agreement or seek to rescind the stipulation prior to the
26 time the Board considers and acts upon it. If the Board fails to adopt this stipulation as its
27 Decision and Order, the Stipulated Settlement and Disciplinary Order for Public Repeval shall
28 be of no force or effect, except for this paragraph, it shall be inadmissible in any legal action

1 between the parties, and the Board shall not be disqualified from further action by having
2 considered this matter.

3 16. The parties understand and agree that Portable Document Format (PDF) and facsimile
4 copies of this Stipulated Settlement and Disciplinary Order for Public Reproval, including PDF
5 and facsimile signatures thereto, shall have the same force and effect as the originals.

6 17. This Stipulated Settlement and Disciplinary Order for Public Reproval is intended by
7 the parties to be an integrated writing representing the complete, final, and exclusive embodiment
8 of their agreement. It supersedes any and all prior or contemporaneous agreements,
9 understandings, discussions, negotiations, and commitments (written or oral). This Stipulated
10 Settlement and Disciplinary Order for Public Reproval may not be altered, amended, modified,
11 supplemented, or otherwise changed except by a writing executed by an authorized representative
12 of each of the parties.

13 18. In consideration of the foregoing admissions and stipulations, the parties agree that
14 the Board may, without further notice or formal proceeding, issue and enter the following
15 Disciplinary Order:

16 **DISCIPLINARY ORDER**

17 IT IS HEREBY ORDERED that Nonresident Pharmacy Permit No. NRP 1826,
18 Nonresident Sterile Compounding Permit No. NSC 100970, Nonresident Pharmacy Permit No.
19 NRP 2526 and Nonresident Sterile Compounding Permit No. NSC 101673 issued to Respondents
20 shall be publicly reproved by the Board of Pharmacy under Business and Professions Code
21 section 495 in resolution of Accusation No. 7286, attached as exhibit A.

22 **Cost Recovery.** No later than 1 YEAR from the effective date of the Decision, Respondent
23 shall pay \$11,054.75 to the Board for its costs associated with the investigation and enforcement
24 of this matter pursuant to Business and Professions Code Section 125.3. If Respondent fails to
25 pay the Board costs as ordered, Respondent shall not be allowed to renew their Nonresident
26 Pharmacy Permit NRP 2526, or Nonresident Sterile Compounding Permit No. NSC 101673 until
27 Respondent pays costs in full. In addition, the Board may enforce this order for payment of its
28 costs in any appropriate court, in addition to any other rights the Board may have.

Full Compliance. As a resolution of the charges in Accusation No. 7286, this stipulated settlement is contingent upon Respondent's full compliance with all conditions of this Order. If Respondent fails to satisfy any of these conditions, such failure to comply constitutes cause for discipline, including outright revocation, of Respondent's Nonresident Pharmacy Permit No. NRP 2526 and Nonresident Sterile Compounding Permit No. NSC 101673.

ACCEPTANCE

I have carefully read the above Stipulated Settlement and Disciplinary Order for Public Reprimand and have fully discussed it with my attorney, Derek Shaffer. I understand the stipulation and the effect it will have on my Nonresident Pharmacy Permits and Nonresident Sterile Compounding Permits. I enter into this Stipulated Settlement and Disciplinary Order for Public Reprimand voluntarily, knowingly, and intelligently, and agree to be bound by the Decision and Order of the Board of Pharmacy.

DATED: 1/2/2024 1:23 PM PST

WEDGEWOOD VILLAGE PHARMACY
INTERMEDIATE HOLDINGS LLC, and TW
DIAMONDBACK HOLDINGS CORPORATION,
dba WEDGEWOOD VILLAGE PHARMACY
LLC;

By: MARCY ANN BLISS

Title: CEO
Respondent

I have read and fully discussed with Respondent Wedgewood Village Pharmacy Intermediate Holdings LLC, and TW Diamondback Holdings Corporation, dba Wedgewood Village Pharmacy LLC, 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: 1/4/2024 7:34 AM PST

DocuSigned by:
Derek Shaffer

DEREK SHAFFER
Attorney for Respondent

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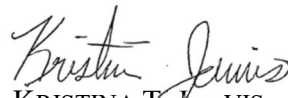
ENDORSEMENT

The foregoing Stipulated Settlement and Disciplinary Order for Public Reapproval is hereby respectfully submitted for consideration by the Board of Pharmacy of the Department of Consumer Affairs.

DATED: January 11, 2024_____

Respectfully submitted,

ROB BONTA
Attorney General of California
ANDREW M. STEINHEIMER
Supervising Deputy Attorney General


KRISTINA T. JAVIS
Deputy Attorney General
Attorneys for Complainant

SA2022301557

Exhibit A

Accusation No. 7286

1 ROB BONTA
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2 ANDREW M. STEINHEIMER
Supervising Deputy Attorney General
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LLC;
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15 **shareholder;**
TW DIAMONDBACK HOLDINGS
16 **CORPORATION, 41% shareholder;**
MARCY ANN BLISS, CEO;
17 **JOSEPH COSTA, COO;**
ALISON LYNCH, PIC;
18 **405 Heron Drive**
Swedesboro, NJ 08085

ACCUSATION

19 **Nonresident Pharmacy Permit No. NRP**
20 **2526,**
21 **Nonresident Sterile Compounding Permit**
No. NSC 101673

22 **and**

23 **WEDGEWOOD VILLAGE PHARMACY**
LLC;
24 **WEDGEWOOD VILLAGE PHARMACY**
INTERMEDIATE HOLDINGS LLC, 59%
25 **Shareholder;**
TW DIAMONDBACK HOLDINGS
26 **CORPORATION, 41% shareholder;**
LUDMILLA MALMBERG, Chairman;
27 **MARCH ANN BLISS, CEO;**
JOCELYN ROSE STANLEY, Secretary;
28 **THOMAS J. FORMOLO, Secretary;**

**EDWARD MICHAEL LHEE, Secretary;
ALISON LYNCH, PIC;
405 Heron Drive, Suite 200
Swedesboro, NJ 08085**

**Nonresident Pharmacy Permit No. NRP
1826,
Nonresident Sterile Compounding Permit
No. NSC 100970**

Respondent.

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 (Board).

2. On or about June 6, 2016, the Board issued Nonresident Pharmacy Permit Number NRP 1826 to Wedgewood Village Pharmacy Intermediate Holdings LLC, 100% shareholder, doing business as (dba) Wedgewood Village Pharmacy LLC, Ludmilla Malmberg, Chairman, Marcy Ann Bliss, CEO; Joseph Costa, COO; and Alison Lynch, Pharmacist-in-Charge. On or about July 17, 2018, the Board was notified and updated its records to reflect a change in ownership such that Wedgewood Village Pharmacy Intermediate Holdings LLC became a 59% shareholder and TW Diamondback Holdings Corporation became a 41% shareholder, still dba Wedgewood Village Pharmacy LLC; Ludmilla Malmberg, Chairman, Marcy Ann Bliss, CEO; Joseph Costa, COO; and Alison Lynch, Pharmacist-in-Charge, (Respondent Original Licensee, collectively "Respondents"). The Nonresident Pharmacy Permit was in full force and effect at all times relevant to the charges brought herein until April 1, 2021, at which point the license was cancelled due to a change of ownership as set forth in paragraph 4, below.

3. On or about June 6, 2016, the Board issued Nonresident Sterile Compounding Pharmacy Permit Number NSC 100970 to Respondent Original Licensee. The Nonresident Sterile Compounding Pharmacy Permit was in full force and effect at all times relevant to the charges brought herein until April 1, 2021, at which point the license was cancelled due to a change of ownership as set forth in paragraph 5, below.

///

4. On or about April 1, 2021, due to a change of ownership application, the Board issued Nonresident Pharmacy Permit Number NRP 2526 to Wedgewood Village Pharmacy Intermediate Holdings LLC, 59% shareholder, and TW Diamondback Holdings Corporation, 41% shareholder dba Wedgewood Village Pharmacy LLC; Marcy Ann Bliss, CEO; Joseph Costa, COO; and Alison Lynch, Pharmacist-in-Charge; (Respondent Successor Licensee, collectively “Respondents”). The Nonresident Pharmacy Permit was in full force and effect at all times relevant to the charges brought herein from April 1, 2021, and will expire on April 1, 2024, unless renewed.

5. On or about April 1, 2021, the Board issued Nonresident Sterile Compounding Permit Number NSC 101673 to Respondent Successor Licensee. The Nonresident Sterile Compounding Permit was in full force and effect at all times relevant to the charges brought herein from April 1, 2021, and will expire on April 1, 2024, unless renewed.

JURISDICTION

6. This Accusation is brought before the Board under the authority of the following laws. All section references are to the Business and Professions Code (Code) unless otherwise indicated.

7. Section 4011 of the Code states:

The board shall administer and enforce this chapter and the Uniform Controlled Substances Act (Division 10 (commencing with Section 11000) of the Health and Safety Code).

8. Section 4300 of the Code states in pertinent part:

(a) Every license issued may be suspended or revoked.

...

(e) The proceedings under this article shall be conducted in accordance with Chapter 5 (commencing with Section 11500) of Part 1 of Division 3 of the Government Code, and the board shall have all the powers granted therein. The action shall be final, except that the propriety of the action is subject to review by the superior court pursuant to Section 1094.5 of the Code of Civil Procedure.

9. 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.

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.

STATUTORY PROVISIONS

11. 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:

...

(c) Gross negligence.

...

1 (f) The commission of any act involving moral turpitude, dishonesty, fraud,
2 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.

3 (g) Knowingly making or signing any certificate or other document that falsely
4 represents the existence or nonexistence of a state of facts.

5 ...

6 (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.

7 ...

8 (o) Violating or attempting to violate, directly or indirectly, or assisting in or
9 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,
10 including regulations established by the board or by any other state or federal
regulatory agency....

11 **REGULATORY PROVISIONS**

12 12. California Code of Regulations, title 16, (Regulations) section 1735.2 states in
13 pertinent part:

14 ...

15 (i) Every compounded drug preparation shall be given a beyond use date representing
16 the date or date and time beyond which the compounded drug preparation should not be
used, stored, transported or administered, and determined based on the professional
17 judgment of the pharmacist performing or supervising the compounding.

18 ...

19 (3) For sterile compounded drug preparations, extension of a beyond use date is only
allowable when supported by the following:

20 (A) Method Suitability Test,

21 (B) Container Closure Integrity Test, and

22 (C) Stability Studies

23 (4) In addition to the requirements of paragraph three (3), the drugs or compounded
24 drug preparations tested and studied shall be identical in ingredients, specific and essential
compounding steps, quality reviews, and packaging as the finished drug or compounded
25 drug preparation.

26 ...

27 (I) Packages of ingredients, both active and inactive, that lack a supplier's expiration
28 date are subject to the following limitations:

1 (1) such ingredients cannot be used for any non-sterile compounded drug preparation
2 more than three (3) years after the date of receipt by the pharmacy.

3 (2) such ingredients cannot be used for any sterile compounded drug preparation
4 more than one (1) year after the date of receipt by the pharmacy.

5 13. Regulations section 1735.3 states in pertinent part:

6 (a) For each compounded drug preparation, pharmacy records shall include:

7 ...

8 (2) A compounding log consisting of a single document containing all of the following:

9 ...

10 (F) The manufacturer, expiration date and lot number of each component. If the
11 manufacturer name is demonstrably unavailable, the name of the supplier may be
12 substituted. If the manufacturer does not supply an expiration date for any component, the
13 records shall include the date of receipt of the component in the pharmacy, and the
14 limitations of section 1735.2, subdivision (l) shall apply....

15 **COST RECOVERY**

16 14. Section 125.3 of the Code states, in pertinent part, that the Board may request the
17 administrative law judge to direct a licensee found to have committed a violation or violations of
18 the licensing act to pay a sum not to exceed the reasonable costs of the investigation and
19 enforcement of the case.

20 **DRUG PREPARATIONS**

21 15. Tacrolimus Ophthalmic Suspension is an eye drop generally prescribed to dogs to
22 treat dry eyes, particularly when caused by low tear production or tears of poor quality. It is a
23 dangerous drug pursuant to Code section 4022.

24 16. Protirelin is an injectable drug product generally prescribed for horses as a
25 thyrotropin-releasing hormone in order to test for certain metabolic disorders or illnesses. It is a
26 dangerous drug pursuant to Code section 4022.

27 17. Cyclosporine in MCT oil solution is an eye drop generally prescribed to dogs. It is
28 used to decrease inflammation in the eye and tear glands and increase tear production. It is a
dangerous drug pursuant to Code section 4022.

18 18. Edetate Disodium (EDTA) is a chelating agent generally prescribed to treat corneal
19 ulcers in dogs, cats, and horses. It is a dangerous drug pursuant to Code section 4022.

FACTUAL ALLEGATIONS

19. Respondents own and operate a nonresident pharmacy which also possesses a nonresident sterile compounding pharmacy permit, and is located in the State of New Jersey.

20. On or about April 1, 2021, due to a change in the ownership structure of certain parent corporations that own the corporations that own Respondent Original Licensee, successor licensees, both a nonresident pharmacy permit and a nonresident sterile compounding pharmacy permit, were issued to the same immediate ownership structure. Nearly all of the immediate owners and officers of Respondent Original Licensee remained with Respondent Successor Licensee. The conduct set forth in this accusation came to the attention of the Board due to the change of ownership inspection that is required by pharmacy law. Therefore, all of the actions were taken on dates on which Respondent Original Licensee was the owner and operator of the pharmacy. However, since the immediate ownership structure did not change, the owners and operators of Respondent Successor Licensee are responsible for the actions of Respondent Original Licensee.

21. Respondents specialize in veterinary compounding.

22. On January 1, 2017, the Board's sterile compounding regulations became effective.

23. In 2017, Board inspector S.P. issued a written warning to Respondents due to Respondents issuing many of its drug preparations extended beyond use dates (BUDs) without the appropriate data to support those BUDs.

24. In 2018, and again in 2020, during inspections of Respondents facility, Board inspector S.P. discussed with Respondents the documentation Respondents needed to provide, obtain, or test for, in order determine and assign extended BUDs and noted that Respondents had not obtained, tested for, or provided this documentation such that the extended BUDs were still inappropriate.

25. After the 2020 inspection, the Board issued a citation to Respondents for providing 120-day extended BUDs without having the tests and studies required to support the extended BUDs.

///

26. On and between approximately March 17, 2021, and May 28, 2021, Board Inspector M.V. conducted a change of ownership inspection regarding Respondents as discussed in additional depth, above. Due to the COVID-19 pandemic, the inspection was conducted remotely via records review. The investigation report is dated March 1, 2022 (March 1, 2022 Inspection Report).

27. On or about March 19, 2021, Board Inspector M.V. requested five specific compounding logs for review, including certificates of analyses, end-product release testing, documentation supporting any extended BUDs assigned to preparations, sample labels, and training records for Respondents' compounding pharmacist and compounding pharmacy technician. M.V.'s review of just these five compounding logs lead to the causes for discipline set forth below.

FIRST CAUSE FOR DISCIPLINE

(Assignment of Unsupported Extended Beyond Use Dates)

28. Respondents are subject to disciplinary action for unprofessional conduct pursuant to Code section 4301, subdivisions (j) and (o), for failing to follow laws and regulations governing pharmacy and regulating dangerous drugs in that Respondents violated Regulations 1735.2, subdivision (i). The circumstances are as follows:

A. On or about July 1, 2020, Respondents compounded 623 bottles of Tacrolimus 0.03% ophthalmic aqueous suspensions and gave an extended BUD of 160 days. Respondents only had data to support a 45-day BUD for this drug product.

B. On or about November 27, 2020, Respondents compounded 581 bottles of Cyclosporine 2% in MCT oil ophthalmic solutions and gave an extended BUD of 180 days. Respondents only had data to support a 45-day BUD for this drug product.

C. On or about February 8, 2021, Respondents compounded 353 vials of Protirelin Acetate 1mg/ml injectable solution and gave an extended BUD of 240 days. Respondents had no data to support an extended BUD for this product.

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1 D. On or about March 10, 2020, Respondents compounded 53 bottles
2 (15mL) of Edetate Disodium and gave an extended BUD of 240 days. Respondents had no data
3 to support an extended BUD for the product.

4 **SECOND CAUSE FOR DISCIPLINE**

5 **(Incomplete Compounding Records)**

6 29. Respondents are subject to disciplinary action for unprofessional conduct pursuant to
7 Code section 4301, subdivisions (j) and (o), for failing to follow laws and regulations governing
8 pharmacy and regulating dangerous drugs in that Respondents violated Regulations section
9 1735.3, subdivision (a)(2). The circumstances are that Respondents' compounding logs reviewed
10 by Board Inspector M.V. failed to list the manufacturers of the drug components Respondents
11 used for compounding.

12 **THIRD CAUSE FOR DISCIPLINE**

13 **(Gross Negligence)**

14 30. Respondents are subject to disciplinary action for unprofessional conduct pursuant to
15 Code section 4301, subdivision (c), in that Respondents committed acts constituting gross
16 negligence when Respondents assigned extended BUDs without having the required data to
17 support those BUDs.

18 **FOURTH CAUSE FOR DISCIPLINE**

19 **(Knowingly Making or Signing a False Document)**

20 31. Respondents are subject to disciplinary action for unprofessional conduct pursuant to
21 Code section 4301, subdivision (g), in that Respondents knowingly made or signed false
22 documents when Respondents assigned extended BUDs without having the required data to
23 support those BUDs.

24 **FIFTH CAUSE FOR DISCIPLINE**

25 **(Acts Involving Moral Turpitude, Dishonesty, Fraud, Deceit, or Corruption)**

26 32. Respondents are subject to disciplinary action for unprofessional conduct pursuant to
27 Code section 4301, subdivision (g), in that Respondents committed acts involving moral
28 turpitude, dishonesty, fraud, deceit, or corruption when Respondents continued to assign extended

1 BUDs and ship the compounded drugs to patients without having the required data to support
2 those BUDs.

3 **DISCIPLINARY CONSIDERATIONS**

4 33. On or about June 17, 2021, Citation number CI 2020 90874 was issued to Respondent
5 Original Licensee's Nonresident Pharmacy permit for violation of Regulations section 1735.2,
6 subdivision (i)(3), for assigning an extended BUD without the required data. The citation did not
7 order a fine, it was not appealed, and it is final.

8 34. On or about June 17, 2021, Citation number CI 2020 89042 was issued to Respondent
9 Original Licensee's Nonresident Sterile Compounding Pharmacy permit for violation of
10 Regulations section 1735.2, subdivision (i)(3), for assigning an extended BUD without the
11 required data. The citation ordered a \$2,500 fine, and required proof of abatement regarding
12 justification for assigning extended BUDs for antibacterial eye ointment. The citation was not
13 appealed and is final.

14 35. On or about December 5, 2018, Citation number CI 2018 82132 was issued to
15 Respondent Original Licensee's Nonresident Pharmacy permit for violation of Regulations
16 section 1735.2, subdivisions (c)(1), and (c)(4) for furnishing over 2,200 unites of compounded
17 ophthalmic drops to a prescriber for office use. This amount exceeds the reasonable quantity that
18 may be furnished and Respondent Original Licensee failed to have a credible basis for
19 determining a reasonable quantity for office use. The citation was not appealed and is final.

20 36. On or about December 5, 2018, Citation number CI 2016 73882 was issued to
21 Respondent Original Licensee's Nonresident Sterile Compounding Pharmacy permit for violation
22 of Regulations section 1735.2, subdivisions (c)(1), and (c)(4) for furnishing over 2,200 unites of
23 compounded ophthalmic drops to a prescriber for office use. This amount exceeds the reasonable
24 quantity that may be furnished and Respondent Original Licensee failed to have a credible basis
25 for determining a reasonable quantity for office use. The citation was not appealed and is final.

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37. On or about October 13, 2017, Citation number CI 2017 77042 was issued to Respondent Original Licensee's Nonresident Pharmacy permit for violation of Code section 4059.5, subdivision (b), for selling prescription items to individual. S.G. who was not authorized to purchase these items. S.G. represented himself as a physician and Respondent Original Licensee failed to note the discrepancy between S.G.'s address and the address of the physician he was impersonating. The citation ordered a \$1,000 fine, it was not appealed, and it is final.

OTHER MATTERS

38. Pursuant to Code section 4307, if discipline is imposed on Nonresident Pharmacy Permit Number NRP 2526 or on Nonresident Sterile Compounding Pharmacy Permit Number NSC 101673 issued to Wedgewood Village Pharmacy Intermediate Holdings LLC, and TW Diamondback Holdings Corporation dba Wedgewood Village Pharmacy LLC then Wedgewood Village Pharmacy Intermediate Holdings LLC, and TW Diamondback Holdings Corporation dba Wedgewood Village Pharmacy LLC, and if Ludmilla Malmberg, Marcy Ann Bliss, Joseph Costa, and Alison Lynch are proven to have knowledge of or have participated in the conduct, then each shall be prohibited from serving as a manager, administrator, owner, member, officer, director, associate, or partner of a licensee for 1) a period not to exceed five (5) years if either or both of the pharmacy permits are placed on probation; or, 2) if either or both of the pharmacy permits are revoked, the prohibition shall continue until either of the permits are reinstated.

PRAYER

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

1. Revoking or suspending Nonresident Pharmacy Permit number NRP 1826, issued to Wedgewood Village Pharmacy Intermediate Holdings LLC, and TW Diamondback Holdings Corporation dba Wedgewood Village Pharmacy LLC;

2. Revoking or suspending Nonresident Sterile Compounding Permit number NSC 100970, issued to Wedgewood Village Pharmacy Intermediate Holdings LLC, and TW Diamondback Holdings Corporation dba Wedgewood Village Pharmacy LLC;

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1 3. Revoking or suspending Nonresident Pharmacy Permit number NRP 2526, issued to
2 Wedgewood Village Pharmacy Intermediate Holdings LLC, and TW Diamondback Holdings
3 Corporation dba Wedgewood Village Pharmacy LLC;

4 4. Revoking or suspending Nonresident Sterile Compounding Permit number NSC
5 101673, issued to Wedgewood Village Pharmacy Intermediate Holdings LLC, and TW
6 Diamondback Holdings Corporation dba Wedgewood Village Pharmacy LLC;

7 5. Prohibiting Wedgewood Village Pharmacy Intermediate Holdings LLC, and TW
8 Diamondback Holdings Corporation dba Wedgewood Village Pharmacy LLC from serving as a
9 manager, administrator, owner, member, officer, director, associate, partner, or in any other
10 position with management or control of any pharmacy licensee;

11 6. Ludmilla Malmberg from serving as a manager, administrator, owner, member,
12 officer, director, associate, partner, or in any other position with management or control of any
13 pharmacy licensee;

14 7. Prohibiting Marcy Ann Bliss from serving as a manager, administrator, owner,
15 member, officer, director, associate, partner, or in any other position with management or control
16 of any pharmacy licensee;

17 8. Prohibiting Joseph Costa from serving as a manager, administrator, owner, member,
18 officer, director, associate, partner, or in any other position with management or control of any
19 pharmacy licensee;

20 9. Prohibiting Alison Lynch from serving as a manager, administrator, owner, member,
21 officer, director, associate, partner, or in any other position with management or control of any
22 pharmacy licensee;

23 10. Ordering Wedgewood Village Pharmacy Intermediate Holdings LLC, and TW
24 Diamondback Holdings Corporation dba Wedgewood Village Pharmacy LLC, Ludmilla
25 Malmberg, Marcy Ann Bliss, and Joseph Costa to pay the Board of Pharmacy the reasonable
26 costs of the investigation and enforcement of this case, pursuant to Business and Professions
27 Code section 125.3; and,

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11. Taking such other and further action as deemed necessary and proper.

DATED: 4/5/2023

Sodergren,
Anne@DCA

Digitally signed by Sodergren,
Anne@DCA
Date: 2023.04.15 07:02:07
-07'00'

ANNE SODERGREN
Executive Officer
Board of Pharmacy
Department of Consumer Affairs
State of California
Complainant

SA2022301557
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