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

In the Matter of the Accusation Against:

PROFESSIONAL PARTNERS INC,
DBA WESTCLIFF COMPOUNDING PHARMACY,

Pharmacy Permit No. PHY 50599,

Sterile Compounding Permit No. LSC 100822;

and

MICHAEL ANTHONY PAVLOVICH,

Pharmacist License No. RPH 42798,

Respondents.

Agency Case No. 7438

OAH No. 2023090129

DECISION AND ORDER

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

This Decision shall become effective at 5:00 p.m. on June 19, 2024.

It is so ORDERED on May 20, 2024.

BOARD OF PHARMACY
DEPARTMENT OF CONSUMER AFFAIRS
STATE OF CALIFORNIA

By 

Seung W. Oh, Pharm.D.
Board President

ROB BONTA
Attorney General of California
ERIN M. SUNSERI
Supervising Deputy Attorney General
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San Diego, CA 92101
P.O. Box 85266
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Attorneys for Complainant

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

In the Matter of the Accusation Against**:** **PROFESSIONAL PARTNERS INC, DBA WESTCLIFF COMPOUNDING PHARMACY** **1901 Westcliff Dr., #3A** **Newport Beach, CA 92660** **Pharmacy Permit No. PHY 50599** **Sterile Compounding Permit No. LSC 100822,** **and** **MICHAEL ANTHONY PAVLOVICH** **1901 Westcliff Dr., #3A** **Newport Beach, CA 92660** **Pharmacist License No. RPH 42798** Respondents.	Case No. 7438 OAH No. 2023090129 **STIPULATED SETTLEMENT AND DISCIPLINARY ORDER FOR PUBLIC REPROVAL AS TO RESPONDENT PAVLOVICH ONLY** **[Bus. & Prof. Code § 495]**

IT IS HEREBY STIPULATED AND AGREED by and between the parties to the above-entitled proceedings that the following matters are true:

PARTIES

1. Anne Sodergren (Complainant) is the Executive Officer of the Board of Pharmacy (Board). She brought this action solely in her official capacity and is represented in this matter by Rob Bonta, Attorney General of the State of California, by Amie J. Flynn, Deputy Attorney General.

2. Respondent Michael Anthony Pavlovich (Respondent Pavlovich) is represented in this proceeding by attorney Tony J. Park whose address is: 9090 Irvine Center Drive, 2nd Floor Irvine, California 92618.

JURISDICTION

3. On August 10, 1989, the Board issued Pharmacist License Number RPH 42798 to Respondent Pavlovich. The Pharmacist License was in full force and effect at all times relevant to the charges brought in Accusation No. 7438 and will expire on December 31, 2025, unless renewed.

4. Accusation No. 7438 was filed before the Board and is currently pending against Respondent Pavlovich. The Accusation and all other statutorily required documents were properly served on Respondent Pavlovich on June 7, 2023. Respondent Pavlovich timely filed his Notice of Defense contesting the Accusation. A copy of Accusation No. 7438 is attached as Exhibit A and incorporated herein by reference.

ADVISEMENT AND WAIVERS

5. Respondent Pavlovich has carefully read, fully discussed with counsel, and understands the charges and allegations in Accusation No. 7438. Respondent Pavlovich has also carefully read, fully discussed with counsel, and understands the effects of this Stipulated Settlement and Disciplinary Order for Public Reproval.

6. Respondent Pavlovich is fully aware of his legal rights in this matter, including the right to a hearing on the charges and allegations in the Accusation; the right to confront and cross-examine the witnesses against him; the right to present evidence and to testify on his own behalf; the right to the issuance of subpoenas to compel the attendance of witnesses and the production of

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documents; the right to reconsideration and court review of an adverse decision; and all other rights accorded by the California Administrative Procedure Act and other applicable laws.

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

CULPABILITY

8. Respondent Pavlovich admits the truth of each and every charge and allegation in Accusation No. 7438.

9. Respondent Pavlovich agrees that his Pharmacist License is subject to discipline and he agrees to be bound by the Disciplinary Order below.

CONTINGENCY

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

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

12. This Stipulated Settlement and Disciplinary Order for Public Reproval is intended by the parties to be an integrated writing representing the complete, final, and exclusive embodiment of their agreement. It supersedes any and all prior or contemporaneous agreements, understandings, discussions, negotiations, and commitments (written or oral). This Stipulated Settlement and Disciplinary Order for Public Reproval may not be altered, amended, modified,

supplemented, or otherwise changed except by a writing executed by an authorized representative of each of the parties.

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

DISCIPLINARY ORDER

IT IS HEREBY ORDERED that Pharmacist License Number RPH 42798 issued to Respondent Pavlovich shall be publicly reproved by the Board of Pharmacy under Business and Professions Code section 495 in resolution of Accusation No. 7438, attached as Exhibit A.

Cost Recovery. Respondent Pavlovich shall pay the amount of $5,000.00 to the Board for its costs of investigation and prosecution. Respondent Pavlovich shall be jointly and severally liable with Respondent Professional Partners Inc, dba Westcliff Compounding Pharmacy for costs. Full payment shall be made within one year of the effective date of the Disciplinary Order for Public Reproval.

If Respondent Pavlovich fails to pay the Board costs as ordered, Respondent Pavlovich shall not be allowed to renew his Pharmacist License until Respondent Pavlovich pays costs in full. In addition, the Board may enforce this order for payment of its 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. 7438, this stipulated settlement is contingent upon Respondent Pavlovich's full compliance with all conditions of this Order. If Respondent Pavlovich fails to satisfy any of these conditions, such failure to comply constitutes cause for discipline, including outright revocation, of Respondent Pavlovich's Pharmacist License Number RPH 42798.

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ACCEPTANCE

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

DATED: _____

MICHAEL ANTHONY PAVLOVICH
Respondent

I have read and fully discussed with Respondent Michael Anthony Pavlovich 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: _____

TONY J. PARK
Attorney for Respondent

ACCEPTANCE

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

DATED: 3/21/2024

DocuSigned by:
Michael Pavlovich
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MICHAEL ANTHONY PAVLOVICH
Respondent

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

DATED: 3/21/2024

DocuSigned by:
Tony J. Park
BBF9CC7A091B410...

TONY J. PARK
Attorney for Respondent

ENDORSEMENT

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

DATED: _____

Respectfully submitted,

ROB BONTA
Attorney General of California
ERIN M. SUNSERI
Supervising Deputy Attorney General

AMIE J. FLYNN
Deputy Attorney General
Attorneys for Complainant

SD2023800057
Stipulated Settlement for Public Reproval PIC in ADA Compliant Format.docx

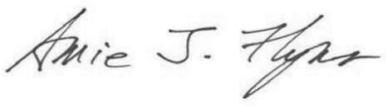
ENDORSEMENT

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

DATED: March 22, 2024

Respectfully submitted,

ROB BONTA
Attorney General of California
ERIN M. SUNSERI
Supervising Deputy Attorney General



AMIE J. FLYNN
Deputy Attorney General
Attorneys for Complainant

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Exhibit A

Accusation No. 7438

ROB BONTA
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Supervising Deputy Attorney General
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Attorneys for Complainant

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

In the Matter of the Accusation Against**:** **PROFESSIONAL PARTNERS INC., DBA WESTCLIFF COMPOUNDING PHARMACY** **MICHAEL ANTHONY PAVLOVICH, CEO/Pres./Shareholder/PIC** **1901 Westcliff Dr. #3A** **Newport Beach, CA 92660** **Pharmacy Permit No. PHY 50599** **Sterile Compounding Permit No. LSC 100822,** **and** **MICHAEL ANTHONY PAVLOVICH** **1901 Westcliff Dr. #3A** **Newport Beach, CA 92660** **Pharmacist License No. RPH 42798** Respondents.	Case No. 7438 **ACCUSATION**

PARTIES

1. Anne Sodergren (Complainant) brings this Accusation solely in her official capacity as the Executive Officer of the Board of Pharmacy (Board), Department of Consumer Affairs.

2. On March 28, 2011, the Board issued Pharmacy Permit Number PHY 50599 to Professional Partners Inc., dba Westcliff Compounding Pharmacy (Respondent Pharmacy). Michael Anthony Pavlovich has served or been listed in Board records as the Chief Executive Officer, 60% Shareholder, President of Respondent Professional Partners Inc. since March 28, 2011. The Pharmacy Permit was in full force and effect at all times relevant to the charges brought herein and will expire on March 1, 2024, unless renewed.

3. On January 6, 2016, the Board issued Sterile Compounding Permit Number LSC 100822 to Respondent Pharmacy. The Sterile Compounding Permit was in full force and effect at all times relevant to the charges brought herein and will expire on March 1, 2024, unless renewed.

4. On or about August 10, 1989, the Board issued Pharmacist License Number RPH 42798 to Michael Anthony Pavlovich (Respondent Pavlovich). Respondent Pavlovich has served and been listed in Board records as Pharmacist-in-Charge of Respondent Pharmacy since March 28, 2011. The Pharmacist License was in full force and effect at all times relevant to the charges brought herein and will expire on August 31, 2023, unless renewed.

JURISDICTION

5. 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.

6. Code section 4011 provides that the Board shall administer and enforce both the Pharmacy Law (Bus. & Prof. Code, § 4000 *et seq*.) and the Uniform Controlled Substances Act (Health & Safety Code, § 11000 *et seq*.).

7. Code section 4300, subdivision (a) provides that every license issued by the Board may be suspended or revoked.

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8. Code section 4300.1 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.

9. Code section 4307, subdivision (a) states:

> 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, or partner of any partnership, corporation, 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 manger, administrator, owner, member, officer, director, associate, or partner had knowledge 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 manger, administrator, owner, member, officer, director, associate, or partner 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.

10. Code section 4342, subdivision (a) states:

> The board may institute any action or actions as may be provided by law and that, in its discretion, are necessary, to prevent the sale of pharmaceutical preparations and drugs that do not conform to the standard and tests as to quality and strength, provided in the latest edition of the United States Pharmacopoeia or the National Formulary, or that violate any provision of the Sherman Food, Drug, and Cosmetic Law (Part 5 (commencing with section 109875) of Division 104 of the Health & Safety Code).

INTRODUCTION

11. This case involves the compounding of prescription drugs, including those designated for sterile administration, in a pharmacy. Pharmacy compounding is when a licensed pharmacist combines, mixes, or alters drug ingredients to create a medication tailored to the needs of an individual patient. (e.g., Cal. Code Regs., tit. 16, § 1735.) Compounding is a form of drug manufacturing subject to the drug manufacturing requirements of the Federal Food, Drug, and

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Cosmetic Act (FDCA) [21 U.S.C. § 301 et seq.]. Compounding in a pharmacy as a form of drug manufacturing is permitted under federal law by section 503A of the FDCA [21 U.S.C. § 353a].

12. The Food and Drug Administration (FDA) oversees drug manufacturing, but does not license pharmacies or pharmacists, nor control when or how their licenses permit compounding. The states issue these licenses, and have primary jurisdiction. The states also set compounding standards that complement FDA standards for compounding as a form of drug manufacturing.

13. California law authorizes the Board to treat violations of federal statutes regulating controlled substances and dangerous drugs, as well as federal laws and regulations governing pharmacy practice, as grounds for discipline. (Bus. & Prof. Code, § 4301, subds. (j), (o).)

14. Compounds may be either "non-sterile" or "sterile," depending on the intended route of drug administration. Sterile drugs are those intended for parenteral administration (i.e., other than through the digestive system), including injectables and ophthalmic or inhalation drugs in aqueous format. It is important that these drugs be sterile and uncontaminated, because they bypass some of the body's natural defenses against pathogens and impurities.

15. California law allows all licensed pharmacists to compound *non-sterile* drug products in licensed pharmacies. (e.g., Bus. & Prof. Code, §§ 4037, 4051, 4110.) All compounding must be consistent with standards in the pharmacy compounding chapters of the current version of the United States Pharmacopeia-National Formulary (USP-NF), including relevant testing and quality assurance standards. (Bus. & Prof. Code, § 4126.8.) The Pharmacy Law also contains additional standards that supplement the USP-NF standards. (*Id.*; see, e.g., Bus. & Prof. Code, §§ 4126.10, 4127 *et seq*., 4128 *et seq*., 4129 *et seq*., Cal. Code Regs., tit. 16, §§ 1735 *et seq*., 1751 *et seq*.)

16. An additional specialty license is required before any licensed pharmacy is allowed to compound *sterile* drug products, (Bus. & Prof. Code, § 4127 *et seq*.) and particular regulatory requirements apply to preparation, maintenance, and distribution of sterile drug products. (Cal. Code Regs., tit. 16, § 1751 *et seq.*; see also Cal. Code Regs., tit. 16, § 1735 *et seq*.) Each sterile compounding pharmacy must be inspected prior to each annual renewal of a

sterile compounding license to ensure compliance with all compounding and sterile compounding requirements. (Bus. & Prof. Code, § 4127.1, subd. (c).) All of this demonstrates the attention and resources devoted to sterile drug compounding. This is because of the unique risks posed by sterile drug products. In 2012, for instance, a contaminated sterile drug compound was widely distributed, and caused a nationwide fungal meningitis outbreak, killing 64 people and causing infections in almost 800 others who received the drug.

17. In this case, Respondents have engaged in significant compounding of drug products intended for sterile administration. In designating a prescription XR, (extended release), Respondents did so without any accompanying supporting studies of the compounded sterile product formulation to validate their claim and thus provided a misbranded compounded sterile product to 36 patients from January 1, 2021 through December 30, 2021. Respondents also assigned a misleading extended beyond use date to this product without an appropriate stability study and thus provided a misbranded compounded sterile product to 36 patients from January 1, 2021 through December 30, 2021.

STATUTORY PROVISIONS

18. 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.
>
> ….
>
> (c) Any other drug or device that by federal or state law can be lawfully dispensed only on prescription or furnished pursuant to Section 4006.

19. Code section 4023.5 states:

> For the purposes of this chapter, "direct supervision and control" means that a pharmacist is on the premises at all times and is fully aware of all activities performed by either a pharmacy technician or intern pharmacist.

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20. Code section 4113 states in pertinent part:

(a) Every pharmacy shall designate a pharmacist-in-charge and, within 30 days thereof, shall notify the board in writing of the identity and license number of that pharmacist and the date he or she was designated.

(b) The proposed pharmacist-in-charge shall be subject to approval by the board. The board shall not issue or renew a pharmacy license without identification of an approved pharmacist-in-charge for the pharmacy.

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

…

21. Code section 4301 states in pertinent part:

The board shall take action against any holder of a license who is guilty of unprofessional conduct or whose license has been procured by fraud or misrepresentation or issued by mistake. Unprofessional conduct shall include, but is not limited to, any of the following:

…

…

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

…

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

22. Code section 4306.5, subdivision (a), states, in pertinent part:

Unprofessional conduct for a pharmacist may include any of the following:

Acts or omissions that involve, in whole or in part, the inappropriate exercise of his or her education, training, or experience as a pharmacist, whether or not the act or omission arises in the course of the practice of pharmacy or the ownership, management, administration, or operation of a pharmacy or other entity licensed by the board.

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23. Health and Safety Code section 111330 states:

Any drug or device is misbranded if its labeling is false or misleading in any particular.

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24. Health and Safety Code section 111440 states:

It is unlawful for any person to manufacture, sell, deliver, hold, or offer for sale any drug or device that is misbranded.

25. Health and Safety Code section 111445 states:

It is unlawful for any person to misbrand any drug or device.

REGULATORY PROVISIONS

26. California Code of Regulations, Title 16, section 1735.2, states, in pertinent part:

…

(i) Every compounded drug preparation shall be given beyond use date representing 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 judgment of the pharmacist performing or supervising the compounding.

…

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

(A) Method Suitability Test,

(B) Container Closure Integrity Test, and

(C) Stability Studies

(4) In addition to the requirements of paragraph three (3), the drugs or compounded 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 drug preparation.

…

COST RECOVERY

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

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DEFINITIONS

28. Naltrexone is a medication primarily used to manage alcohol use or opioid use disorder by reducing cravings and feelings of euphoria associated with substance use disorder. Naltrexone is a dangerous drug pursuant to Business and Professions Code section 4022.

29. The designation Naltrexone XR means extended release.

FACTUAL ALLEGATIONS

30. Respondent Pharmacy is a pharmacy located in Newport Beach, California. It compounds non-sterile to sterile preparations for administration to patients.

31. At all times mentioned herein, Respondent Pavlovich has been the Pharmacist-in-Charge (PIC) at Respondent Pharmacy and has served or been listed in Board records as the Chief Executive Officer, 60% Shareholder, President of Respondent Professional Partners Inc. since March 28, 2011

32. On February 3, 2022, a Board of Pharmacy inspector conducted a remote sterile compounding license inspection of Respondent Pharmacy. Prior to the inspection, the inspector requested and received documents from PIC, Respondent Pavlovich, relating to the upcoming inspection. In preparation for the inspection, Respondent Pavlovich stated that Respondent Pharmacy compounded and dispensed the following sterile preparations (including risk level) from January 1, 2021 through December 30, 2021:

- Naltrexone XR 200mg units (high risk): 51 Prescriptions, 409 units
- Naltrexone 200mg units (high risk): 49 Prescriptions, 198 units
- Sotrovimab 500mg in D5W infusion (low risk): 17 Prescriptions

33. Respondent Pavlovich also provided compounding logs for Naltrexone Base, Monohydrate 200mg pellet (lot #04272021@2), and Naltrexone XR 200mg pellet (lot #09062021@1) which provided the following information:

- Naltrexone Base, Monohydrate 200mg pellet
  - Complete list of ingredients included naltrexone monohydrate, stearic acid, povidone k30, ascorbic acid.
  - Beyond use date (BUD) for this formulation stated as 180 days after the date of

compounding, based on extended BUD testing.

- BUD for lot #04272021@2 was August 14, 2021 (109 days from the date of compounding), as one of the ingredients (povidone k30) expired on August 14, 2021
- Batch yielded 200 units
- 22 units were sent to ARL Bio Pharma for batch sterility and endotoxin testing

• Naltrexone XR 200mg pellet

- Complete list of ingredients included naltrexone monohydrate, stearic acid, glyceryl monostearate, and ascorbic acid
- Beyond use date (BUD) for this formulation stated as 180 days after the date of compounding, noting a "stability test on file"
- BUD for lot #09062021@1 was January 31, 2022 (147 days from the date of compounding), as one of the ingredients (glyceryl monostearate) expired on January 31, 2022
- Batch yielded 235 units
- 22 units were sent to ARL Bio Pharma for batch sterility and endotoxin testing

34. On January 26, 2022, the Board Inspector requested documentation in support of the extended BUD for Naltrexone XR 200mg implant.

35. On January 27, 2022, Respondent Pavlovich e-mailed the following response to the Board's inquiry regarding the Naltrexone XR 200mg implant: "[t]he formulation is rendered "XR" (our designation) by the inclusion of glyceryl monostearate (GMS), which is cited in the Handbook of Pharmaceutical Excipients as being used to form sustained-release matrices for solid dosage forms. It has also been used as a matrix ingredient for a biodegradable, implantable, controlled-release dosage form. GMS is considered GRAS by FDA, and is essentially just stearic acid with a fatty acid attached, which is already part of the formulation. All ingredients are biodegradable." Respondent Pharmacy cited the inclusion of inactive ingredient glyceryl monostearate as its singular rationale for the "XR" designation in its Naltrexone XR 200mg

implant formulation. Respondent Pharmacy did not perform any studies of the actual compounded product to validate its claim.

36. On January 27, 2022, the Board Inspector requested information for the XR formulation. On January 27, 2022, Respondent Pavlovich e-mailed the following response to the Board's inquiry regarding supportive documentation for the extended BUD of Naltrexone XR 200mg implant: "Naltrexone formulations are made using the same equipment, are the same size, weight and composition, except for the removal of povidone in the XR formula. This study gives reasonable expectation of similar stability, and in my professional judgment is appropriately applied. The opinions of two different USP committee members and an FDA official with 30+ years experience in approving these types of dosage forms concur." The response also included a validation study, initiated by Advanced Diagnostic Labs on October 14, 2019 and completed on April 21, 2020, for the stability of Naltrexone 200mg pellets compounded by Respondent Pharmacy. The validation protocol measured the overall product stability of the naltrexone pellet over the course of 180 days (time points at 0, 45, 90, and 180 days), stored at ambient temperature. The study demonstrated the ability of the compounded product to maintain stability for up to 180 days.

37. On January 28, 2022, the Board Inspector sent an email to PIC Pavlovich to request justification of the extended BUD for Naltrexone XR 200mg implant because the provided validation study did not match the exact ingredients of the Naltrexone XR 200mg formulation. Respondents did not provide information or documentation confirming that they relied on studies which used identical ingredients.

FIRST CAUSE FOR DISCIPLINE

(Failure to Support Beyond Use Date)

38. Respondents are subject to disciplinary action under Code section 4301 (j) and (o) in conjunction with CCR section 1735.2(i)(3) in that from January 1, 2021 through December 30, 2021, Respondents assigned a 180-day beyond use date without a stability study specific to Naltrexone XR 200mg pellets, a compounded sterile preparation.

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SECOND CAUSE FOR DISCIPLINE

(Misbranding of Prescriptions)

39. Respondents are subject to disciplinary action under Code section 4301 (j) and (o) in conjunction with Health and Safety Code section 111330 in that from January 1, 2021 through December 30, 2021, Respondents compounded, labeled, and dispensed Nal-Plant® XR 200mg pellets. Respondent's claim of XR, (extended release), was stated without any accompanying supporting studies of the compounded sterile product formulation to validate its claim and thus provided a misbranded compounded sterile product to 36 patients. In addition, Respondents also assigned a misleading extended beyond use date to the Nal-Plant® XR 200mg without an appropriate stability study and thus provided a misbranded compounded sterile product to 36 patients from January 1, 2021 through December 30, 2021.

THIRD CAUSE FOR DISCIPLINE

(Unlawful Sale of Misbranded Prescriptions)

40. Respondents are subject to disciplinary action under Code section 4301 (j) and (o) in conjunction with Health and Safety Code section 111440 in that from January 1, 2021 through December 30, 2021, Respondents provided misbranded Nal-Plant® XR 200mg pellets for sale with misleading claims regarding the product's modified release and extended beyond use date.

DISCIPLINE CONSIDERATIONS

41. To determine the degree of discipline, if any, to be imposed on Respondent Professional Partners Inc, dba Westcliff Compounding Pharmacy and Respondent Pavlovich, Complainant alleges that on August 6, 2021, in case number CI 2020 91359, the Board issued a Letter of Admonishment to Respondent Pharmacy and Respondent Pavlovich, pursuant to Code section 4005 and 4315, et seq., for failure to comply with the laws and regulations that govern the practice of pharmacy in California. Specifically, Respondent Pharmacy and Respondent Pavlovich violated 1735.2(i)(3)(A(B)(C) for extension of a beyond use date. That decision is now final.

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OTHER MATTERS

42. Pursuant to Code section 4307, if discipline is imposed on Pharmacy Permit No. PHY 50599 and/or Sterile Compounding License No. LSC 100822 issued to Professional Partners, Inc., dba Westcliff Compounding Pharmacy, it shall be prohibited from serving as a manager, administrator, owner, member, officer, director, associate, or partner of a licensee for five years if the Pharmacy Permit and/or Sterile Compounding License are placed on probation or until the Pharmacy Permit and/or Sterile Compounding License are reinstated if they are revoked.

43. Pursuant to Code section 4307, if discipline is imposed on Pharmacy Permit No. PHY 50599 and/or Sterile Compounding License No. LSC 100822 issued to Professional Partners, Inc., dba Westcliff Compounding Pharmacy, while Michael Anthony Pavlovich has been a manager or owner and had knowledge of or knowingly participated in any conduct for which the licensees were disciplined, he shall be prohibited from serving as a manager, administrator, owner, member, officer, director, associate, or partner of a licensee for five years if the Pharmacy Permit and/or Sterile Compounding License are placed on probation or until the Pharmacy Permit and/or Sterile Compounding Licenses are reinstated, if they are revoked.

44. Pursuant to Code section 4307, if discipline is imposed on Pharmacist License No. RPH 42798 issued to Michael Anthony Pavlovich, he shall be prohibited from serving as a manager, administrator, owner, member, officer, director, associate, or partner of a licensee for five years if the Pharmacist License is placed on probation or until the Pharmacist License is reinstated, if it is revoked.

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 Pharmacy Permit Number PHY 50599, issued to Professional Partners Inc, dba Westcliff Compounding Pharmacy;

2. Revoking or suspending Sterile Compounding Permit Number LSC 100822, issued to Professional Partners Inc, dba Westcliff Compounding Pharmacy;

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3. Revoking or suspending Pharmacist License Number RPH 42798, issued to Michael Anthony Pavlovich;

4. Prohibiting Professional Partners Inc, dba Westcliff Compounding Pharmacy from serving as a manager, administrator, owner, member, officer, director, associate, or partner of a licensee for five years if Pharmacy Permit Number PHY 50599 and/or Sterile Compounding License Number 100822 are placed on probation or until the Pharmacy Permit and/or Sterile Compounding License are reinstated, if they are revoked;

5. Prohibiting Michael Anthony Pavlovich from serving as a manager, administrator, owner, member, officer, director, associate, or partner of a licensee for five years if Pharmacy Permit Number PHY 50599 and/or Sterile Compounding License Number LSC 100822 are placed on probation or until the Pharmacy Permit and/or Sterile Compounding License are reinstated, if they are revoked;

6. Prohibiting Michael Anthony Pavlovich from serving as a manager, administrator, owner, member, officer, director, associate, or partner of a licensee for five years if Pharmacist License Number RPH 42798 is placed on probation or until the Pharmacist License is reinstated, if it is revoked;

7. Ordering Professional Partners Inc, dba Westcliff Compounding Pharmacy and Michael Anthony Pavlovich to pay the Board of Pharmacy the reasonable costs of the investigation and enforcement of this case, pursuant to Business and Professions Code section 125.3; and,

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

DATED: 5/30/2023

Sodergren, Anne@DCA

Digitally signed by Sodergren, Anne@DCA
Date: 2023.05.30 20:09:26 -07'00'

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

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