

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

In the Matter of the Accusation Against:

WEST MARIN PHARMACY INC., ZSUZSANNA BIRAN and

JASON YOON, Owners,

Original Pharmacy Permit No. PHY 48531; and

ZSUZSANNA BIRAN,

Original Pharmacist License No. RPH 35444,

Respondents.

Agency Case No. 7080

OAH No. 2021020332

DECISION AND ORDER

The attached Proposed Decision of the Administrative Law Judge is hereby adopted by the Board of Pharmacy (Board), Department of Consumer Affairs, as its Decision in the above-entitled matter, except that, pursuant to the provisions of Government Code section 11517, subdivision (c)(2)(C), the Board is making a technical, non-substantive change to the Decision's Order that does not impact the decision as follows:

On page 3 in the section entitled Standard of Proof, at the end of paragraph 4 add the following sentence: "Complainant is required to prove cause for discipline of a non-professional license, such as for a facility, by a preponderance of the evidence."

The technical change made above does not affect the factual or legal basis of the Proposed Decision, which shall become effective at 5:00 p.m. on October 30, 2021.

It is so ORDERED on September 30, 2021.

BOARD OF PHARMACY
DEPARTMENT OF CONSUMER AFFAIRS
STATE OF CALIFORNIA

By

A handwritten signature in black ink, appearing to read "Seung W. Oh".

Seung W. Oh, Pharm.D.
Board President

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PROPOSED DECISION

Administrative Law Judge Michael C. Starkey, State of California, Office of Administrative Hearings, heard this matter on May 24, 2021, via telephone and videoconference.

Deputy Attorney General Carla L. Cheung represented complainant Anne Sodergren, Executive Officer of the Board of Pharmacy, Department of Consumer Affairs.

Attorney Natalia Mazina represented respondent West Marin Pharmacy Inc., and respondent Zsuzsanna Biran, who was present.

The record closed and the matter was submitted on May 24, 2021.

FACTUAL FINDINGS

Jurisdictional Matters

1. On or about June 11, 2007, the Board of Pharmacy (Board) issued Original Pharmacy Permit Number PHY 48531 to respondent West Marin Pharmacy Inc. (West Marin Pharmacy). Since that date, Jason Yoon has been the Chairman, 50-percent shareholder, and Secretary; and respondent Zsuzsanna Biran (Biran) has been the President, 50-percent shareholder, Treasurer/Chief Financial Officer, and Pharmacist-in-Charge (PIC) of West Marin Pharmacy. The pharmacy permit was in full force and effect at all relevant times and will expire on June 1, 2022, unless renewed.

2. On August 14, 1980, the Board issued Original Pharmacist License Number RPH 35444 to Biran. The license was in full force and effect at all relevant times and will expire on March 31, 2022, unless renewed.

3. On January 23, 2021, complainant Anne Sodergren issued the accusation solely in her capacity as Executive Officer of the Board. Complainant alleges that cause exists to discipline respondents' licenses because they: 1) compounded copies of commercially available drugs not found on the Federal Drug Administration (FDA) or

ASHP (American Society of Health-System Pharmacists) drug shortage lists; 2) failed to maintain adequate master formulas for compounded drugs; 3) failed to maintain adequate recordkeeping for compounded drug preparations; 4) failed to timely review, and failed to document a timely review, of written policies and procedures for compounding; 5) failed to keep a compounding hood clean and free of clutter; and 6) failed to demonstrate that all pharmacy personnel engaged in compounding are knowledgeable of West Marin Pharmacy's processes and procedures prior to compounding. Respondents timely submitted a notice of defense and this proceeding followed.

Standard of Proof

4. Complainant is required to prove cause for discipline of a professional license or registration by "clear and convincing proof to a reasonable certainty." (Cf. *Ettinger v. Board of Medical Quality Assurance* (1982) 135 Cal.App.3d 853, 856; see Bus. & Prof. Code, § 23.7 [all statutory references are to the Business and Professions Code, unless otherwise stated].) If respondents contend mitigation or rehabilitation, it is their burden to prove those contentions by a preponderance of the evidence. (Evid. Code, §§ 115, 500.)

Background/Current Probation

5. The Board investigated West Marin Pharmacy in 2019, resulting in accusation No. 6801 (OAH No. 2020020972), alleging that respondents: 1) failed to maintain a current inventory of controlled substances and dangerous drugs; 2) accepted unused medications from patients without an authorized take-back receptacle; 3) incorrectly labeled prescription bottles intended for dispensing to customers; 4) failed to properly label a compounded drug preparation prior to

dispensing; 5) incorrectly labeled a non-sterile compounded drug preparation with a beyond-use date that exceeded the date allowed by regulation; 6) failed to properly maintain a complete compounding log; 7) deviated from the requirements of a prescription by dispensing extended release, instead of immediate release, tablets of morphine sulphate; and 8) failed to provide a recent, completed compounding self-assessment upon request.

6. On November 9, 2020, the Board issued a stipulated disciplinary order effective December 9, 2020, revoking the licenses held by West Marin Pharmacy and Biran, staying the revocation, and placing the licenses on probation for a period of three years, under numerous terms and conditions, including that respondents retain at their expense an independent consultant responsible for conducting monthly inspections of the pharmacy to ensure compliance with applicable state and federal laws and regulations. In the stipulated disciplinary order, respondents admitted that complainant could prove the allegations in accusation No. 6801.

7. Biran does not deny the allegations in the instant accusation.

8. West Marin Pharmacy is located in Point Reyes Station, a rural area. The nearest other pharmacy is approximately 16 miles away, accessible only by winding roads.

The October 8, 2020 Inspection

9. On September 23, 2020, the Board received a complaint from a consumer that an opiate painkiller medication (hydrocodone/acetaminophen, 5/325 mg capsules) dispensed to him by West Marin Pharmacy was ineffective and he was up all night with pain; West Marin Pharmacy refused take the medication back; and that

West Marin Pharmacy told him the drug was compounded capsules instead of in tablet form because the wholesaler would not ship the drug to West Marin Pharmacy.

10. In connection with that complaint, on October 8, 2020, Board investigator Sara Mullin, Pharm.D., conducted an inspection of West Marin Pharmacy. Mullin spoke with Biran, who informed her that she had the compounded capsules tested for potency by a laboratory and learned that there “was nothing wrong with them.” This claim was corroborated by a laboratory report respondents submitted to the Board on October 21, 2020. Mullin agrees that the capsules were correctly compounded and that West Marin Pharmacy was not allowed to take them back from the customer.

11. Biran told Mullin that West Marin Pharmacy compounded the hydrocodone/acetaminophen capsules because all wholesalers had “cut her off.” She believed that the reason for this was that a local doctor was overprescribing controlled substances. Biran stated that she believed that she was allowed to compound such drugs because they were not available to West Marin Pharmacy and that it was a good service to local patients who were on hospice and unable to drive to another pharmacy.

12. At hearing Mullin explained that, in response to the current opioid drug epidemic, drug wholesalers sometimes refuse to sell controlled substances to certain pharmacies, often based on unexpected fluctuations in purchase histories. Such decisions are typically permanent, but sometimes a pharmacy can provide an explanation and the wholesaler resumes selling such drugs to the pharmacy.

13. Mullin reviewed West Marin Pharmacy’s compounding logs and observed that between February 20, 2019, and October 8, 2020, respondents West Marin Pharmacy and Biran compounded the following drug preparations, which were copies

of commercially available drugs not found on the FDA or ASHP drug shortage lists
(listed by number of capsules compounded, name of drug, dosage):

- 300 Diazepam, 2 mg
- 320 Diazepam, 8 mg
- 30 Diazepam, 9 mg
- 1,870 Diazepam, 10 mg
- 24 Codeine, 15 mg
- 500 Hydrocodone 3 mg
- 1,100 Hydrocodone 5 mg
- 100 Hydrocodone 10 mg
- 1,000 Hydrocodone/acetaminophen 5-325 mg
- 3,000 Hydrocodone/acetaminophen 10-325 mg
- 100 Hydrocodone/acetaminophen 2.5-325 mg
- 210 Hydrocodone/acetaminophen 5-162.5 mg
- 200 Hydrocodone/acetaminophen 7.5-325 mg
- 100 Hydrocodone/acetaminophen 3.75-162.5 (dosage unit not reported)
- 500 Morphine sulfate IR 15 mg
- 600 Morphine sulfate ER 15 mg

- 30 Morphine sulfate 20 mg/ml syrup (ml)

14. During the October 8, 2020 inspection Mullin reviewed West Marin Pharmacy's master formulas for diazepam 2mg capsules, hydrocodone/acetaminophen 5-325mg capsules, and morphine sulfate extended release 15mg capsules compounded by respondents. The master formulas did not include the equipment to be used for compounding, the maximum allowable beyond-use date and supporting reference, specific and essential compounding steps, quality reviews required at each step in preparation, post-compounding procedures, and instructions for storage and handling of drug preparations.

15. During the October 8, 2020 inspection Mullin reviewed respondents' compounding log. The compounding log did not include the date of compounding, documentation of quality reviews, or documentation of post-compounding processes and procedures. However, the log did include a reference or lot number that was a combination of initials and a date, which Mullin assumed was the date of compounding. Biran later provided proof of correction of this violation to Mullin.

16. During the October 8, 2020 inspection Mullin reviewed West Marin Pharmacy's written policies and procedures for compounding. The written policies and procedures for compounding did not include documentation of the annual review required by Biran. As shown by the documentation, Biran had not reviewed the written policies and procedures since March 5, 2019. Also, the pharmacy staff had not completed an annual competency evaluation and training, as outlined in West Marin Pharmacy's policies and procedures, since March 2019.

17. During the October 8, 2020 inspection Mullin observed a water bottle, a coffee beverage, and a pen inside the direct compounding area of West Marin

Pharmacy's compounding hood. No evidence was received regarding whether this was in accordance with the specifications of manufacturers of the compounding equipment.

Subsequent Information

18. On February 19, 2021, another Board investigator, Hilda Nip, conducted an inspection of West Marin Pharmacy. Nip observed violations of pharmacy law, including CBD products on shelves in the retail area of store, no written notice of consultation for delivery, employees without name badges, an undersized notice to consumer, a log indicating refrigerator temperatures averaging one degree Celsius higher than allowed, and a failure to document review of compounding policies and procedures since March 2019 (the same issue Mullin observed on October 8, 2020).

Further Disciplinary Considerations

19. In addition to the 2020 disciplinary order and ongoing probation described in Factual Findings 5 and 6, on September 6, 2018, the Board issued Citation Number CI 2016 75710 and ordered West Marin Pharmacy to pay a fine of \$3,000. Also, on September 6, 2018, the Board issued Citation Number CI 2018 80820 and ordered Biran to pay a fine of \$3,000. Both citations are final, and Board records indicate that they were paid. The September 6, 2018 citations included violations related to compounding, recordkeeping, and training that were also found in the subsequent inspections that underlie the 2020 disciplinary order and this proceeding.

Respondents' Evidence

20. Biran has been licensed as a pharmacist in California for more than 40 years. Her license was not disciplined prior to 2020. She was also licensed as a

pharmacist in New Hampshire for three years prior to becoming licensed in California. She came out of a brief retirement to co-own and operate West Marin Pharmacy in 2007, after the previous owner passed away. Before that Biran had worked as the manager and PIC for multiple chain pharmacies, and as a staff pharmacist for Stanford, Kaiser, and San Francisco General hospitals.

21. Biran is involved in West Marin Pharmacy's local community, helping to build a playground, sponsoring a local radio station, speaking at local events and clubs, and giving interviews to the local radio station and writing articles for the local newspaper. Biran makes pharmacy deliveries to West Marin Pharmacy customers after hours, if urgent.

22. Biran reports that West Marin Pharmacy does not perform sterile compounding and that non-sterile compounding represents only one to two percent of its output. She reports that she interpreted the prohibition against compounding commercially available drugs to mean drugs available to her, and was attempting to comply with the spirit of the regulation and serve the needs of her elderly or infirm customers.

23. After the October 8, 2020 inspection, Biran requested a waiver from the Board to compound commercially available drugs to prevent West Marin Pharmacy customers from having to make long, dangerous drives to obtain controlled substances medications. That request was denied. She also tried to negotiate with wholesalers, but to no avail. She now understands the regulation and has a link to the relevant shortage lists to facilitate compliance. She understands that West Marin Pharmacy must comply with the letter of each law applicable to its practice of pharmacy, despite any perceived hardship to its customers.

24. Biran admits that West Marin Pharmacy's own written compounding procedures require compounding equipment to be free of dust, debris, and clutter. She explained that she placed the coffee cup in the compounding area, which was not being used at the time, to make space for Mullin to use her laptop during the October 8, 2020 inspection.

25. Pursuant to the terms of probation in the November 9, 2020 disciplinary order, West Marin Pharmacy hired Terry Cater as an independent consultant responsible for conducting monthly inspections of the pharmacy to ensure compliance with applicable state and federal laws and regulations. Biran reports that she feels capable of running West Marin Pharmacy in a fully compliant manner, but reports that Cater has been very helpful in that regard.

26. Cater testified at hearing and authored reports of his monthly inspections of West Marin Pharmacy, dated March 22 and April 27, 2021. He holds a master of business administration degree and bachelor of science degree in pharmacy. He has been licensed as a pharmacist since 1973, without discipline. Since 2016, Cater has been the vice president of a pharmacy technology company. In his individual capacity, he has also provided consulting services to the healthcare and pharmaceutical industries since 2006. Before then, Cater was vice president of two large retail pharmacy companies. He has also worked as an executive in consulting and managed care companies. From 1984 through 1995, Cater was director of pharmacy for chain supermarket pharmacies.

27. Cater reports that during his initial monthly inspection on March 22, 2021, he observed no violations of pharmacy law and compliance with the probation terms of the 2020 disciplinary order. Cater also reviewed the causes for discipline and probation terms of the 2020 disciplinary action with Biran and reports

that she appeared “intent on complying with probation requirements and” all applicable laws and regulations.

28. Cater reports that during his second monthly inspection on April 27, 2021, he confirmed that West Marin Pharmacy had rectified the violations underlying the 2020 disciplinary order and some of the violations observed during the October 8, 2020 inspection. He found Biran to have a positive, good attitude, and she appeared open to his recommendations. Again, Cater observed no violations of pharmacy law.

29. Cater also reports that he reviewed the February 19, 2021 inspection report with Biran and observed that West Marin Pharmacy had corrected all the reported violations. Cater opines that Biran is naïve but caring, and now on the right course towards keeping West Marin Pharmacy in compliance with all pharmacy laws and regulations. Cater reports that he addressed these issues in his third report for May 2021, which was not received in evidence in this proceeding.

30. Respondents submitted written statements of 18 West Marin Pharmacy customers or health practitioners in the local community. The authors emphasized that West Marin Pharmacy provides critical services to local residents and many expressed their gratitude and high regard for West Marin Pharmacy, Biran and her efforts to serve the local residents.

Costs

31. In connection with the investigation and enforcement of this accusation, complainant requests an award of costs in the total amount of \$12,545.75, for investigation costs in the amount of \$3,115.75, and attorney and paralegal services provided by the Department of Justice and billed to the Board in the amount of

\$9,430. That request is supported by declarations. In the absence of any argument or evidence to the contrary, these costs are found to be reasonable.

LEGAL CONCLUSIONS

First Cause for Discipline (Compounding Commercial Drugs Not Found on the FDA or ASHP Drug Shortage List)

1. The Board may discipline the license of a licensee who commits unprofessional conduct, which includes any violations of California's Pharmacy Law (§§ 4000, et seq.) or the applicable state and federal laws and regulations governing the practice of pharmacy (§ 4301, subd. (o)). Additionally, the PIC is responsible for a pharmacy's compliance with all state and federal laws and regulations pertaining to the practice of pharmacy. (§ 4113, subd. (c).)

2. No pharmacy or pharmacist shall compound a drug preparation that:

[i]s a copy or essentially a copy of one or more commercially available drug products, unless that drug product appears on an [ASHP] or FDA list of drugs that are in short supply at the time of compounding and at the time of dispense, and the compounding of that drug preparation is justified by a specific, documented medical need made known to the pharmacist prior to compounding.

(Cal. Code Regs., tit. 16, § 1735.2, subd. (d)(3).)

3. Between February 20, 2019, and October 8, 2020, West Marin Pharmacy and Biran compounded numerous drug preparations which were copies of

commercially available drugs not found on the FDA or ASHP drug shortage lists. (Factual Finding 13.) Concern for the convenience of customers is not an excuse for these violations. Cause was established to discipline West Marin Pharmacy's pharmacy permit and Biran's pharmacist license under section 4301, subdivision (o), and California Code of Regulations, title 16, section 1735.2, subdivision (d)(3).

Second Cause for Discipline (Compounding Limitations and Requirements)

4. A drug preparation shall not be compounded until the pharmacy has first prepared a written master formula document that includes the following elements: equipment to be used; the maximum allowable beyond use date for the preparation, and the rationale or reference source justifying its determination; quality reviews required at each step in preparation of the drug; post-compounding process or procedures required, if any; and instructions for storage and handling of the compounded drug preparation. (Cal. Code Regs., tit. 16, § 1735.2, subds. (e)(2), (3), (6), (7) & (8).)

5. During the October 8, 2020 inspection, Mullin observed that West Marin Pharmacy's master formulas for multiple drugs compounded by respondents did not contain these elements. (Factual Finding 14.) Cause was established to discipline West Marin Pharmacy's pharmacy permit and Biran's pharmacist license under section 4301, subdivision (o), and California Code of Regulations, title 16, section 1735.2, subdivisions (e)(2), (3), (6), (7) & (8.)

Third Cause for Discipline (Recordkeeping of Compounded Drug Preparations)

6. Barring exceptions inapplicable here, for each compounded drug preparation, pharmacy records must include: the date the drug preparation was compounded, and documentation of quality reviews and required post-compounding process and procedures. (Cal. Code Regs., tit. 16, § 1735.3, subds. (a)(2)(B) & (J).)

7. During the October 8, 2020 inspection, Mullin observed that respondents' compounding log did not include this required information, although the log did include a reference or lot number that was a combination of initials and a date, which Mullin assumed was the date of compounding. (Factual Finding 15.) Cause was established to discipline West Marin Pharmacy's pharmacy permit and Biran's pharmacist license under section 4301, subdivision (o), and California Code of Regulations, title 16, section 1735.3, subdivisions (a)(2)(B) & (J).

Fourth Cause for Discipline (Compounding Policies and Procedures)

8. Any pharmacy engaged in compounding shall:

maintain written policies and procedures for compounding that establishes procurement procedures, methodologies for the formulation and compounding of drugs, facilities and equipment cleaning, maintenance, operation, and other standard operating procedures related to compounding.

Any material failure to follow the pharmacy's written policies and procedures shall constitute a basis for disciplinary action.

(b) The policies and procedures shall be reviewed and such review shall be documented on an annual basis by the pharmacist-in-charge. The policies and procedures shall be updated whenever changes in policies and procedures are implemented.

(c) The policies and procedures shall include at least the following:

... ¶ ...

(7) Dates and signatures reflecting all annual reviews of the policies and procedures by the pharmacist-in-charge.

(Cal. Code Regs., tit. 16, § 1735.5, subds. (a), (b), and (c)(7).)

9. During the October 8, 2020 inspection, Mullin observed that the written policies and procedures for compounding did not include documentation of the annual review required by Biran. (Factual Finding 16.) Biran had not reviewed the written policies and procedures since March 5, 2019. Cause was established to discipline West Marin Pharmacy's pharmacy permit and Biran's pharmacist license under section 4301, subdivision (o), and California Code of Regulations, title 16, section 1735.5, subdivisions (a), (b), and (c)(7).)

Fifth Alleged Cause for Discipline (Compounding Facilities and Equipment)

10. "Any equipment used to compound drug preparations shall be stored, used, maintained, and cleaned in accordance with manufacturers' specifications." (Cal. Code Regs., tit. 16, § 1735.6, subd. (b).)

11. During the October 8, 2020 inspection Mullin observed a water bottle, a coffee beverage, and a pen inside the direct compounding area of West Marin Pharmacy's compounding hood, but no evidence was received regarding whether this was in accordance with manufacturer's specifications. (Factual Finding 17.) Respondents did not specifically dispute this alleged cause for discipline, but they did not concede it. Cause was not established to discipline West Marin Pharmacy's pharmacy permit and Biran's pharmacist license under section 4301, subdivision (o), and California Code of Regulations, title 16, section 1735.6, subdivision (b).

Sixth Cause for Discipline (Training of Compounding Staff)

12. The regulations provide:

(b) The pharmacy shall develop and maintain an on-going competency evaluation process for pharmacy personnel involved in compounding, and shall maintain documentation of any and all training related to compounding undertaken by pharmacy personnel.

(c) Pharmacy personnel assigned to compounding duties shall demonstrate knowledge about processes and procedures used in compounding prior to compounding any drug preparation.

(Cal. Code Regs., tit. 16, § 1735.7, subds. (b) & (c).)

13. During the October 8, 2020 inspection, Mullin observed that the pharmacy staff had not completed an annual competency evaluation and training, as outlined in West Marin Pharmacy's policies and procedures, since March 2019. (Factual

Finding 16.) Cause was established to discipline West Marin Pharmacy's pharmacy permit and Biran's pharmacist license under section 4301, subdivision (o), and California Code of Regulations, title 16, section 1735.7, subdivision (c).

Determination of Discipline

14. Cause for discipline having been established, the remaining issue is what level of discipline is required to protect the public. Protection of the public "shall be paramount." (§ 4001.1.) Where a licensee has repeat or serious violation(s) involving the improper compounding of drug products or repeat or serious violation(s) resulting from the misuse of education or licensing privileges, the Board's disciplinary guidelines recommend a minimum discipline of revocation, stayed; a 90-day term of actual suspension; a three- to five-year term of probation, with standard and optional conditions of probation as appropriate; and a maximum discipline of revocation. (Disciplinary Guidelines, A Manual of Disciplinary Guidelines and Model Disciplinary Orders (Feb. 2017 Rev.) (Disciplinary Guidelines), at pp. 11–12; Cal. Code Regs., tit. 16, § 1760.) In determining whether the minimum, maximum, or an intermediate penalty is to be imposed in a given case, the relevant factors include: nature and severity of the acts; actual or potential harm to the public; actual or potential harm to any consumer; time passed since the act(s); aggravating and mitigating evidence; and rehabilitation evidence. (Disciplinary Guidelines at p. 4.)

15. Respondents' violations of the pharmacy law are numerous and serious. Respondents were recently cited and placed on probation for similar misconduct. These repeated violations raise serious questions as to whether respondents have the willingness or ability to operate lawfully. However, prior to 2020, neither West Marin Pharmacy, nor Biran had any record of license discipline. Biran practiced as a pharmacist for almost 40 years without formal discipline; West Marin Pharmacy

operated for more than 13 years without license discipline. Respondents submitted the reports and testimony of their probation consultant Cater and numerous other letters of support. Biran accepts responsibility for the misconduct and demonstrated insight and a resolve to operate lawfully. No actual harm to the public was shown. Critically, the instant violations and those observed in the February 2021 inspection predated Cater's involvement as a consultant. Cater reports observing no new violations and a willingness to change. The public will be adequately protected by extending the probation of each respondent by one year, subject to the same terms and conditions.

Other Matters

16. Pursuant to section 4307, if discipline is imposed on Original Pharmacy Permit Number PHY 48531, issued to respondent West Marin 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 Original Pharmacy Permit Number PHY 48531 is placed on probation or until reinstated if it is revoked.

17. Pursuant to section 4307, if discipline is imposed on Original Pharmacy Permit Number PHY 48531, issued to respondent West Marin Pharmacy while Biran and/or Jason Yoon have been an officer or owner and had knowledge of or knowingly participated in any conduct for which the license was disciplined, Biran and/or Jason Yoon shall be prohibited from serving as a manager, administrator, owner, member, officer, director, associate, or partner of a licensee for five years if Original Pharmacy Permit Number PHY 48531 is placed on probation or until reinstated if it is revoked.

18. Pursuant to section 4307 of the Code, if discipline is imposed on Original Pharmacist License Number RPH 35444 issued to Biran, she shall be prohibited from serving as a manager, administrator, owner, member, officer, director, associate, or

partner of a licensee for five years if Original Pharmacist License Number RPH 35444 is placed on probation or until reinstated if it is revoked.

Costs

19. A licensee who is found to have committed a violation of the licensing act may be ordered to pay a sum not to exceed the reasonable costs of investigation and enforcement. (§ 125.3.) Cause exists to order respondents to pay the Board's costs in the amount of \$12,545.75. (Factual Finding 31 and Legal Conclusions 3, 5, 7, 9, & 13.)

20. Cost awards must not deter licensees with potentially meritorious claims from exercising their right to an administrative hearing. (*Zuckerman v. State Board of Chiropractic Examiners* (2002) 29 Cal.4th 32, 45.) Cost awards must be reduced where a licensee has been successful at hearing in getting the charges dismissed or reduced; a licensee is unable to pay; or where the scope of the investigation was disproportionate to the alleged misconduct. (*Ibid.*) The agency must also consider whether the licensee has raised a colorable challenge to the proposed discipline, and a licensee's good faith belief in the merits of his or her position. (*Ibid.*) Here, complainant proved five of six alleged causes for discipline, so the cost award will be reduced by one-sixth, to \$10,454.79.

ORDER

1. Original Pharmacy Permit Number PHY 48531, issued to respondent West Marin Pharmacy Inc., Zsuzsanna Biran and Jason Yoon, Owners (West Marin Pharmacy), shall remain on probation. Probation is extended by one year, on the same

terms and conditions imposed pursuant to the November 9, 2020 stipulated disciplinary order in Case No. 6801.

2. Original Pharmacist License Number RPH 35444, issued to Zsuzsanna Biran, shall remain on probation. Probation is extended by one year, on the same terms and conditions imposed pursuant to the November 9, 2020 stipulated disciplinary order in Case No. 6801.

3. West Marin Pharmacy is prohibited from serving as a manager, administrator, owner, member, officer, director, associate, or partner of a licensee for five years.

4. Zsuzsanna Biran is prohibited from serving as a manager, administrator, owner, member, officer, director, associate, or partner of a licensee other than West Marin Pharmacy for five years.

5. Jason Yoon is prohibited from serving as a manager, administrator, owner, member, officer, director, associate, or partner of a licensee other than West Marin Pharmacy for five years.

6. West Marin Pharmacy and Zsuzsanna Biran, jointly and severally, are ordered to pay the Board of Pharmacy \$10,454.79 for the reasonable costs of the investigation and enforcement of this case, pursuant to Business and Professions Code section 125.3.

DATE: 06/22/2021



MICHAEL C. STARKEY

Administrative Law Judge

Office of Administrative Hearings

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

12 In the Matter of the Accusation Against:

Case No. 7080

13 **WEST MARIN PHARMACY INC.,**
14 **ZSUZSANNA BIRAN and JASON YOON,**
Owners
11 4th Street
Point Reyes Station, CA 94956

ACCUSATION

16 Original Pharmacy Permit No. PHY 48531

17 and

18 **ZSUZSANNA BIRAN,**
PO Box 1287
19 Point Reyes Station, CA 94956

20 Registered Pharmacist License No. RPH 35444

21 Respondents.

22
23 **PARTIES**

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

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2. On or about June 11, 2007, the Board issued Original Pharmacy Permit Number PHY 48531 to West Marin Pharmacy Inc., Zsuzsanna Biran and Jason Yoon, Owners (Respondent Pharmacy). The Original Pharmacy Permit was in full force and effect at all times relevant to the charges brought herein and will expire on June 1, 2021, unless renewed.

3. On or about August 14, 1980, the Board issued Registered Pharmacist License Number RPH 35444 to Zsuzsanna Biran (Respondent Biran). The Registered Pharmacist License was in full force and effect at all times relevant to the charges brought herein and will expire on March 31, 2022, unless renewed.

4. From on or about June 11, 2007 to the present, Respondent Biran served as, and/or was listed in Board records as, Pharmacist-in-Charge for Respondent Pharmacy.

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. 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.

7. Section 4113, subdivision (c), of the Code, states, in pertinent part:

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.

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

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 118, subdivision (b), of the Code provides that the suspension/expiration/surrender/cancellation of a license shall not deprive the Board of jurisdiction to proceed with a disciplinary action during the period within which the license may be renewed, restored, reissued or reinstated.

STATUTORY PROVISIONS

11. Section 4301 of the Code states:

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:

...

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

...

REGULATORY PROVISIONS

12. California Code of Regulations, title 16, section 1735, states:

(a) "Compounding" means any of the following activities occurring in a licensed pharmacy, by or under the supervision of a licensed pharmacist, pursuant to a prescription:

(1) Altering the dosage form or delivery system of a drug

(2) Altering the strength of a drug

(3) Combining components or active ingredients

(4) Preparing a compounded drug preparation from chemicals or bulk drug substances

...

13. California Code of Regulations, title 16, section 1735.2, states:

...

(d) No pharmacy or pharmacist shall compound a drug preparation that:

...

(3) Is a copy or essentially a copy of one or more commercially available drug products, unless that drug product appears on an ASHP (American Society of Health-System Pharmacists) or FDA list of drugs that are in short supply at the time of compounding and at the time of dispense, and the compounding of that drug preparation is justified by a specific, documented medical need made known to the pharmacist prior to compounding. The pharmacy shall retain a copy of the documentation of the shortage and the specific medical need in the pharmacy records for three years from the date of receipt of the documentation.

(e) A drug preparation shall not be compounded until the pharmacy has first prepared a written master formula document that includes at least the following elements:

(1) Active ingredients to be used.

(2) Equipment to be used.

(3) The maximum allowable beyond use date for the preparation, and the rationale or reference source justifying its determination.

(4) Inactive ingredients to be used.

(5) Specific and essential compounding steps used to prepare the drug.

(6) Quality reviews required at each step in preparation of the drug.

(7) Post-compounding process or procedures required, if any.

1 (8) Instructions for storage and handling of the compounded drug preparation.
2 ...

3 14. California Code of Regulations, title 16, section 1735.3, states:

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

5 (1) The master formula document.

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

7 (A) Name and Strength of the compounded drug preparation.

8 (B) The date the drug preparation was compounded.

9 (C) The identity of any pharmacy personnel engaged in compounding the drug preparation.

10 (D) The identity of the pharmacist reviewing the final drug preparation.

11 (E) The quantity of each ingredient used in compounding the drug preparation.

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

17 (i) Exempt from the requirements in this paragraph (1735.3(a)(2)(F)) are sterile
18 preparations compounded in a single lot for administration within seventy-two (72)
19 hours to a patient in a health care facility licensed under section 1250 of the Health
20 and Safety Code and stored in accordance with standards for "Redispensed CSPs"
21 found in Chapter 797 of the United States Pharmacopeia - National Formulary
22 (USP37-NF32) Through 2nd Supplement (37th Revision, Effective December 1,
23 2014), hereby incorporated by reference.

24 (G) A pharmacy-assigned unique reference or lot number for the compounded
25 drug preparation.

26 (H) The beyond use date or beyond use date and time of the final compounded
27 drug preparation, expressed in the compounding document in a standard date and
28 time format.

 (I) The final quantity or amount of drug preparation compounded for
dispensing.

 (J) Documentation of quality reviews and required post-compounding process
and procedures.

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1 15. California Code of Regulations, title 16, section 1735.5, states:

2 (a) Any pharmacy engaged in compounding shall maintain written policies and
3 procedures for compounding that establishes procurement procedures, methodologies
4 for the formulation and compounding of drugs, facilities and equipment cleaning,
5 maintenance, operation, and other standard operating procedures related to
6 compounding. Any material failure to follow the pharmacy's written policies and
7 procedures shall constitute a basis for disciplinary action.

8 (b) The policies and procedures shall be reviewed and such review shall be
9 documented on an annual basis by the pharmacist-in-charge. The policies and
10 procedures shall be updated whenever changes in policies and procedures are
11 implemented.

12 (c) The policies and procedures shall include at least the following:
13 ...

14 (7) Dates and signatures reflecting all annual reviews of the policies and
15 procedures by the pharmacist-in-charge.

16 ...

17 16. California Code of Regulations, title 16, section 1735.6, states:

18 ...

19 (b) Any equipment used to compound drug preparations shall be stored, used,
20 ...

21 17. California Code of Regulations, title 16, section 1735.7, states:

22 ...

23 (c) Pharmacy personnel assigned to compounding duties shall demonstrate
24 knowledge about processes and procedures used in compounding prior to
25 compounding any drug preparation.

26 ...

27 **COST RECOVERY**

28 18. Section 125.3 of the Code states, in pertinent part, that the Board may request the
administrative law judge to direct a licensee 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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FIRST CAUSE FOR DISCIPLINE

(Compounding Limitations and Requirements)

19. Respondent Pharmacy's Original Pharmacy Permit and Respondent Biran's Registered Pharmacist License are subject to disciplinary action under Code section 4301(o) and California Code of Regulations, title 16, section 1735.2(d)(3), in that between on or about February 20, 2019, and October 8, 2020, Respondents compounded the following drug preparations which were copies of commercially available drugs not found on the FDA or ASHP drug shortage list:

Drug (in dosage unit capsules)	Total Quantity Compounded
Diazepam 2mg	300
Diazepam 8mg	320
Diazepam 9mg	30
Diazepam 10mg	1,870
Codeine 15mg	24
Hydrocodone 3mg	500
Hydrocodone 5mg	1,100
Hydrocodone 10mg	100
Hydrocodone/acetaminophen 5-325mg	1,000
Hydrocodone/acetaminophen 10-325mg	3,000
Hydrocodone/acetaminophen 2.5-325mg	100
Hydrocodone/acetaminophen 5-162.5mg	210
Hydrocodone/acetaminophen 7.5-325mg	200
Hydrocodone/acetaminophen 3.75-162.5	100
Morphine sulfate IR 15mg	500
Morphine sulfate ER 15mg	600
Morphine sulfate 20mg/ml syrup (ml)	30

1 **SECOND CAUSE FOR DISCIPLINE**

2 (Compounding Limitations and Requirements)

3 20. Respondent Pharmacy's Original Pharmacy Permit and Respondent Biran's
4 Registered Pharmacist License are subject to disciplinary action under Code section 4301(o) and
5 California Code of Regulations, title 16, section 1735.2(e), in that Respondents failed to maintain
6 adequate master formulas for compounded drugs. The circumstances are as follows:

7 21. On or about October 8, 2020, during an inspection at Respondent Pharmacy with
8 Respondent Biran present, a Board inspector reviewed master formulas for diazepam 2mg
9 capsules, hydrocodone/acetaminophen 5-325mg capsules, and morphine sulfate ER 15mg
10 capsules compounded by Respondents. The master formulas did not include the equipment to be
11 used for compounding, the maximum allowable beyond use date and supporting reference,
12 specific and essential compounding steps, quality reviews required at each step in preparation,
13 post compounding procedures, and instructions for storage and handling of drug preparations.

14 **THIRD CAUSE FOR DISCIPLINE**

15 (Recordkeeping of Compounded Drug Preparations)

16 22. Respondent Pharmacy's Original Pharmacy Permit and Respondent Biran's
17 Registered Pharmacist License are subject to disciplinary action under Code section 4301(o) and
18 California Code of Regulations, title 16, section 1735.3(a), in that Respondents failed to maintain
19 adequate recordkeeping for compounded drug preparations. The circumstances are as follows:

20 23. On or about October 8, 2020, during an inspection at Respondent Pharmacy with
21 Respondent Biran present, a Board inspector reviewed Respondents' compounding log. The
22 compounding log did not include the date of compounding, documentation of quality reviews, or
23 documentation of post compounding processes and procedures.

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1 **FOURTH CAUSE FOR DISCIPLINE**

2 (Compounding Policies and Procedures)

3 24. Respondent Pharmacy's Original Pharmacy Permit and Respondent Biran's
4 Registered Pharmacist License are subject to disciplinary action under Code section 4301(o) and
5 California Code of Regulations, title 16, sections 1735.5(b) and 1735.5(c)(7), in that Respondents
6 failed to timely review, and failed to document a timely review, of written policies and
7 procedures for compounding. The circumstances are as follows:

8 25. On or about October 8, 2020, during an inspection at Respondent Pharmacy with
9 Respondent Biran present, a Board inspector reviewed Respondents' written policies and
10 procedures for compounding. The written policies and procedures for compounding did not
11 include documentation of the annual review required by Respondent Biran. Respondent Biran
12 had not reviewed the written policies and procedures since March 5, 2019.

13 **FIFTH CAUSE FOR DISCIPLINE**

14 (Compounding Facilities and Equipment)

15 26. Respondent Pharmacy's Original Pharmacy Permit and Respondent Biran's
16 Registered Pharmacist License are subject to disciplinary action under Code section 4301(o) and
17 California Code of Regulations, title 16, section 1735.6(b), in that Respondents failed to keep
18 their compounding hood clean and free of clutter. The circumstances are as follows:

19 27. On or about October 8, 2020, during an inspection at Respondent Pharmacy with
20 Respondent Biran present, a Board inspector observed a water bottle, a coffee beverage, and a
21 pen inside the direct compounding area of Respondent Pharmacy's compounding hood.

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1 **SIXTH CAUSE FOR DISCIPLINE**

2 (Training of Compounding Staff)

3 28. Respondent Pharmacy's Original Pharmacy Permit and Respondent Biran's
4 Registered Pharmacist License are subject to disciplinary action under Code section 4301(o) and
5 California Code of Regulations, title 16, sections 1735.7(c), in that Respondents failed to
6 demonstrate that all pharmacy personnel engaged in compounding are knowledgeable of
7 Respondent Pharmacy's processes and procedures prior to compounding. The circumstances are
8 as follows:

9 29. On or about October 8, 2020, during an inspection at Respondent Pharmacy with
10 Respondent Biran present, a Board inspector observed that the pharmacy staff had not completed
11 an annual competency evaluation and training, as outlined Respondent Pharmacy's policies and
12 procedures, since March 2019.

13 **OTHER MATTERS**

14 30. Pursuant to Code section 4307, if discipline is imposed on Original Pharmacy Permit
15 Number PHY 48531, issued to West Marin Pharmacy Inc., West Marin Pharmacy Inc. shall be
16 prohibited from serving as a manager, administrator, owner, member, officer, director, associate,
17 or partner of a licensee for five years if Original Pharmacy Permit Number PHY 48531 is placed
18 on probation or until Original Pharmacy Permit Number PHY 48531 is reinstated if it is revoked.

19 31. Pursuant to Code section 4307, if discipline is imposed on Original Pharmacy Permit
20 Number PHY 48531, issued to West Marin Pharmacy Inc., while Respondent Biran and/or Jason
21 Yoon have been an owner and had knowledge of or knowingly participated in any conduct for
22 which the licensee was disciplined, Respondent Biran and Jason Yoon shall be prohibited from
23 serving as a manager, administrator, owner, member, officer, director, associate, or partner of a
24 licensee for five years if Original Pharmacy Permit Number PHY 48531 is placed on probation or
25 until Original Pharmacy Permit Number PHY 48531 is reinstated if it is revoked.

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32. Pursuant to section 4307 of the Code, if discipline is imposed on Registered Pharmacist License Number RPH 35444 issued to Respondent Biran, Respondent Biran shall be prohibited from serving as a manager, administrator, owner, member, officer, director, associate, or partner of a licensee for five years if Registered Pharmacist License Number RPH 35444 is placed on probation or until Registered Pharmacist License Number RPH 35444 is reinstated if it is revoked.

DISCIPLINE CONSIDERATIONS

33. To determine the degree of discipline, if any, to be imposed on Respondent Pharmacy and Respondent Biran, Complainant alleges that on or about December 9, 2020, in a prior disciplinary action titled *In the Matter of the Accusation Against West Marin Pharmacy and Zsuzsanna Biran* before the Board, in Case Number 6801, Respondent Pharmacy's Original Pharmacy Permit and Respondent Biran's Registered Pharmacist License were revoked for failing to maintain current inventory, accepting unused medications from patients without an authorized take-back receptacle, incorrectly labeling prescription bottles, failing to properly label compounded prescriptions, failing to maintain a complete compounding log, failing to dispense a drug as prescribed, and failing to provide recent, completed compounding self-assessment. However, the revocations were stayed, and Respondent Pharmacy's Original Pharmacy Permit and Respondent Biran's Registered Pharmacist License were placed on probation for three years with terms and conditions, effective December 9, 2020. That decision is now final.

34. Complainant further alleges that on or about September 6, 2018, in a prior action, the Board of Pharmacy issued Citation Number CI 2016 75710 and ordered Respondent Pharmacy to pay a fine of \$3,000.00. That Citation is now final, and Board records indicate that the citation fine was paid.

35. Complainant further alleges that on or about September 6, 2018, in a prior action, the Board of Pharmacy issued Citation Number CI 2018 80820 and ordered Respondent Biran to pay a fine of \$3,000.00. That Citation is now final, and Board records indicate that the citation fine was paid.

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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 Original Pharmacy Permit Number PHY 48531, issued to West Marin Pharmacy Inc., Zsuzsanna Biran and Jason Yoon, Owners;

2. Revoking or suspending Registered Pharmacist License Number RPH 35444, issued to Zsuzsanna Biran;

3. Prohibiting West Marin Pharmacy Inc. from serving as a manager, administrator, owner, member, officer, director, associate, or partner of a licensee for five years if Original Permit Number PHY 48531 is placed on probation or until Original Permit Number PHY 48531 is reinstated if Original Permit Number 48531 issued to West Marin Pharmacy Inc. is revoked.

4. Prohibiting Zsuzsanna Biran from serving as a manager, administrator, owner, member, officer, director, associate, or partner of a licensee for five years if Original Permit Number PHY 48531 is placed on probation or until Original Permit Number PHY 48531 is reinstated if Original Permit Number 48531 issued to West Marin Pharmacy Inc. is revoked.

5. Prohibiting Jason Yoon from serving as a manager, administrator, owner, member, officer, director, associate, or partner of a licensee for five years if Original Permit Number PHY 48531 is placed on probation or until Original Permit Number PHY 48531 is reinstated if Original Permit Number 48531 issued to West Marin Pharmacy Inc. is revoked.

6. Prohibiting Zsuzsanna Biran from serving as a manager, administrator, owner, member, officer, director, associate, or partner of a licensee for five years if Registered Pharmacist License Number RPH 35444 is placed on probation or until Registered Pharmacist License Number RPH 35444 is reinstated if Original Permit Number 48531 issued to West Marin Pharmacy Inc. is revoked.

7. Ordering Respondents West Marin Pharmacy and Zsuzsanna Biran, 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,

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

DATED: 1/23/2021

Signature on File

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

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