

**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,
Registered Pharmacist No. RPH 35444,**

Respondents

Agency Case No. 6801

OAH No. 2020020972

DECISION AND ORDER

The attached Stipulated Settlement and Disciplinary Order 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 December 9, 2020.

It is so ORDERED on November 9, 2020.

BOARD OF PHARMACY
DEPARTMENT OF CONSUMER AFFAIRS
STATE OF CALIFORNIA

A handwritten signature in black ink, appearing to read "Greg M. Lippe", written in a cursive style.

By

Greg Lippe
Board President

1 XAVIER BECERRA
Attorney General of California
2 DIANN SOKOLOFF
Supervising Deputy Attorney General
3 TIMOTHY FROEHLE
Deputy Attorney General
4 State Bar No. 279337
1515 Clay Street, 20th Floor
5 P.O. Box 70550
Oakland, CA 94612-0550
6 Telephone: (510) 879-0004
Facsimile: (510) 622-2270
7 E-mail: Tim.Froehle@doj.ca.gov
Attorneys for Complainant
8

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

13 In the Matter of the Accusation Against:

14 **WEST MARIN PHARMACY INC.,**
15 **ZSUZSANNA BIRAN AND JASON YOON,**
16 **OWNERS**
17 **11 4th Street**
18 **Point Reyes Station, CA 94956**

19 **Original Pharmacy Permit No. PHY 48531,**

20 **and**

21 **ZSUZSANNA BIRAN**
22 **PO Box 1287**
23 **Point Reyes Station, CA 94956**

24 **Registered Pharmacist No. RPH 35444**

25 Respondents.

Case No. 6801

OAH No. 2020020972

26 **STIPULATED SETTLEMENT AND**
27 **DISCIPLINARY ORDER**

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

1 **PARTIES**

2 1. Anne Sodergren (Complainant) is the Executive Officer of the Board of Pharmacy
3 (Board). She brought this action solely in her official capacity and is represented in this matter by
4 Xavier Becerra, Attorney General of the State of California, by Timothy Froehle, Deputy
5 Attorney General.

6 2. Respondent West Marin Pharmacy Inc., Zsuzsanna Biran and Jason Yoon, Owners
7 (Respondent West Marin) and Respondent Zsuzsanna Biran (Respondent Biran) are represented
8 in this proceeding by attorney Natalia Mazina.

9 3. On or about June 11, 2007, the Board issued Original Pharmacy Permit No. PHY
10 48531 to Respondent West Marin. The Original Pharmacy Permit was in full force and effect at
11 all times relevant to the charges brought in Accusation No. 6801, and will expire on June 1, 2021,
12 unless renewed.

13 4. On or about August 14, 1980, the Board of Pharmacy issued Registered Pharmacist
14 License Number RPH 35444 to Respondent Biran. The Registered Pharmacist License was in
15 full force and effect at all times relevant to the charges brought here and will expire on March 31,
16 2022, unless renewed.

17 **JURISDICTION**

18 5. Accusation No. 6801 was filed before the Board, and is currently pending against
19 Respondents. The Accusation and all other statutorily required documents were properly served
20 on Respondents on November 22, 2019. Respondent timely filed its Notice of Defense contesting
21 the Accusation.

22 6. A copy of Accusation No. 6801 is attached as exhibit A and incorporated here by
23 reference.

24 **ADVISEMENT AND WAIVERS**

25 7. Respondents have carefully read, fully discussed with counsel, and understand the
26 charges and allegations in Accusation No. 6801. Respondents have also carefully read, fully
27 discussed with counsel, and understands the effects of this Stipulated Settlement and Disciplinary
28 Order.

8. Respondents are fully aware of their 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 them; the right to present evidence and to testify on their own behalf; the right to the issuance of subpoenas to compel the attendance of witnesses and the production of 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.

9. Respondents voluntarily, knowingly, and intelligently waive and give up each and every right set forth above.

CULPABILITY

10. Respondents understand and agree that the charges and allegations in Accusation No. 6801, if proven at a hearing, constitute cause for imposing discipline upon its Original Pharmacy Permit.

11. For the purpose of resolving the Accusation without the expense and uncertainty of further proceedings, Respondents agree that, at a hearing, Complainant could establish a factual basis for the charges in the Accusation, and that Respondents hereby give up their right to contest those charges.

12. Respondents agree that their Original Pharmacy Permit and Registered Pharmacist License, respectively, are subject to discipline and they agree to be bound by the Board's probationary terms as set forth in the Disciplinary Order below.

RESERVATION

13. The admissions made by Respondents here are only for the purposes of this proceeding, or any other proceedings in which the Board of Pharmacy or other professional licensing agency is involved, and shall not be admissible in any other criminal or civil proceeding.

CONTINGENCY

14. This stipulation shall be subject to approval by the Board of Pharmacy. Respondents understand and agree 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

1 or participation by Respondents or their counsel. By signing the stipulation, Respondents
2 understand and agree that they may not withdraw their agreement or seek to rescind the
3 stipulation prior to the time the Board considers and acts upon it. If the Board fails to adopt this
4 stipulation as its Decision and Order, the Stipulated Settlement and Disciplinary Order shall be of
5 no force or effect, except for this paragraph, it shall be inadmissible in any legal action between
6 the parties, and the Board shall not be disqualified from further action by having considered this
7 matter.

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

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

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

20 **DISCIPLINARY ORDER**

21 **WEST MARIN PHARMACY PHY 48531**

22 IT IS HEREBY ORDERED that Original Pharmacy Permit No. PHY 48531 issued to
23 Respondent West Marin Pharmacy Inc., Zsuzsanna Biran and Jason Yoon, Owners is revoked.
24 However, the revocation is stayed and Respondent West Marin is placed on probation for three
25 (3) years on the following terms and conditions:

26 1. **Definition: Respondent**

27 For the purposes of these probation terms and conditions, "Respondent" shall refer to
28 Respondent West Marin. All terms and conditions stated herein shall bind and be applicable to

1 the licensed premises and to all owners, managers, officers, administrators, members, directors,
2 trustees, associates, or partners thereof. For purposes of compliance with any term or condition,
3 any report, submission, filing, payment, or appearance required to be made by Respondent West
4 Marin to or before the Board or its designee shall be made by an owner or executive officer with
5 authority to act on behalf of and legally bind the licensed entity.

6 **2. Obey All Laws**

7 Respondent West Marin shall obey all state and federal laws and regulations.

8 Respondent West Marin shall report any of the following occurrences to the Board, in
9 writing, within seventy- two (72) hours of such occurrence:

- 10 • an arrest or issuance of a criminal complaint for violation of any provision of the
11 Pharmacy Law, state and federal food and drug laws, or state and federal controlled
12 substances laws
- 13 • a plea of guilty, or nolo contendere, no contest, or similar, in any state or federal
14 criminal proceeding to any criminal complaint, information or indictment
- 15 • a conviction of any crime
- 16 • the filing of a disciplinary pleading, issuance of a citation, or initiation of another
17 administrative action filed by any state or federal agency which involves
18 Respondent West Marin's license or which is related to the practice of pharmacy or
19 the manufacturing, obtaining, handling, distributing, billing, or charging for any
20 drug, device or controlled substance.

21 Failure to timely report such occurrence shall be considered a violation of probation.

22 **3. Report to the Board**

23 Respondent West Marin shall report to the Board quarterly, on a schedule as directed by the
24 Board or its designee. The report shall be made either in person or in writing, as directed.
25 Among other requirements, Respondent West Marin shall state in each report under penalty of
26 perjury whether there has been compliance with all the terms and conditions of probation.

27 Failure to submit timely reports in a form as directed shall be considered a violation of
28 probation. Any period(s) of delinquency in submission of reports as directed may be added to the

1 total period of probation. Moreover, if the final probation report is not made as directed,
2 probation shall be automatically extended until such time as the final report is made and accepted
3 by the Board.

4 **4. Interview with the Board**

5 Upon receipt of reasonable prior notice, Respondent West Marin shall appear in person for
6 interviews with the Board or its designee, at such intervals and locations as are determined by the
7 Board or its designee. Failure to appear for any scheduled interview without prior notification to
8 Board staff, or failure to appear for two (2) or more scheduled interviews with the Board or its
9 designee during the period of probation, shall be considered a violation of probation.

10 **5. Cooperate with Board Staff**

11 Respondent West Marin shall timely cooperate with the Board's inspection program and
12 with the Board's monitoring and investigation of Respondent West Marin's compliance with the
13 terms and conditions of its probation, including but not limited to: timely responses to requests
14 for information by Board staff; timely compliance with directives from Board staff regarding
15 requirements of any term or condition of probation; and timely completion of documentation
16 pertaining to a term or condition of probation. Failure to timely cooperate shall be considered a
17 violation of probation.

18 **6. Reimbursement of Board Costs**

19 As a condition precedent to successful completion of probation, Respondents Biran and
20 West Marin shall pay the total of \$10,000.00 to the Board for its costs associated with the
21 investigation and enforcement of this matter. Respondents shall be responsible for payment of
22 these costs both jointly and severally. Respondents shall pay these costs within sixty (60) days of
23 the effective date of this Order.

24 There shall be no deviation from this schedule absent prior written approval by the Board or
25 its designee. Failure to pay costs by the deadline(s) as directed shall be considered a violation of
26 probation.

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1 **7. Probation Monitoring Costs**

2 Respondent West Marin shall pay any costs associated with probation monitoring as
3 determined by the Board each and every year of probation. Such costs shall be payable to the
4 Board on a schedule as directed by the Board or its designee. Failure to pay such costs by the
5 deadline(s) as directed shall be considered a violation of probation.

6 **8. Status of License**

7 Respondent West Marin shall, at all times while on probation, maintain an active, current
8 Original Permit with the Board, including any period during which suspension or probation is
9 tolled. Failure to maintain an active, current Original Permit shall be considered a violation of
10 probation.

11 If Respondent West Marin's Original Permit expires or is cancelled by operation of law or
12 otherwise at any time during the period of probation, including any extensions thereof due to
13 tolling or otherwise, upon renewal or reapplication, Respondent West Marin's license shall be
14 subject to all terms and conditions of this probation not previously satisfied.

15 **9. License Surrender While on Probation**

16 Following the effective date of this decision, should Respondent West Marin wish to
17 discontinue business, Respondent West Marin may tender the premises license to the Board for
18 surrender. The Board or its designee shall have the discretion whether to grant the request for
19 surrender or take any other action it deems appropriate and reasonable. Upon formal acceptance
20 of the surrender of the license, Respondent West Marin will no longer be subject to the terms and
21 conditions of probation.

22 Respondent West Marin may not apply for any new license from the Board for three (3)
23 years from the effective date of the surrender. Respondent West Marin shall meet all
24 requirements applicable to the license sought as of the date the application for that license is
25 submitted to the Board. Respondent West Marin further stipulates that it shall reimburse the
26 Board for its costs of investigation and prosecution prior to the acceptance of the surrender.

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1 **10. Sale or Discontinuance of Business**

2 During the period of probation, should Respondent West Marin sell, trade or transfer all or
3 part of the ownership of the licensed entity, discontinue doing business under the license issued to
4 Respondent West Marin, or should practice at that location be assumed by another full or partial
5 owner, person, firm, business, or entity, under the same or a different premises license number,
6 the Board or its designee shall have the sole discretion to determine whether to exercise
7 continuing jurisdiction over the licensed location, under the current or new premises license
8 number, and/or carry the remaining period of probation forward to be applicable to the current or
9 new premises license number of the new owner.

10 **11. Notice to Employees**

11 Respondent shall upon or before the effective date of this decision, ensure that all
12 employees involved in permit operations are made aware of all the terms and conditions of
13 probation, either by posting a notice of the terms and conditions, circulating such notice, or both.
14 If the notice required by this provision is posted, it shall be posted in a prominent place and shall
15 remain posted throughout the probation period. Respondent shall ensure that any employees
16 hired or used after the effective date of this decision are made aware of the terms and conditions
17 of probation by posting a notice, circulating a notice, or both. Additionally, Respondent shall
18 submit written notification to the Board, within fifteen (15) days of the effective date of this
19 decision, that this term has been satisfied. Failure to timely provide such notification to
20 employees, or to timely submit such notification to the Board shall be considered a violation of
21 probation.

22 "Employees" as used in this provision includes all full-time, part-time, volunteer, temporary
23 and relief employees and independent contractors employed or hired at any time during
24 probation.

25 **12. Owners and Officers: Knowledge of the Law**

26 Respondent West Marin shall provide, within thirty (30) days after the effective date of this
27 decision, signed and dated statements from its owners, including any owner or holder of ten
28 percent (10%) or more of the interest in Respondent West Marin or Respondent West Marin's

1 stock, and all of its officer, stating under penalty of perjury that said individuals have read and are
2 familiar with state and federal laws and regulations governing the practice of pharmacy. The
3 failure to timely provide said statements under penalty of perjury shall be considered a violation
4 of probation.

5 **13. Premises Open for Business**

6 Respondent West Marin shall remain open and engaged in its ordinary business as a
7 pharmacy in California for a minimum of 120 hours per calendar month. Any month during
8 which this minimum is not met shall toll the period of probation, i.e., the period of probation shall
9 be extended by one month for each month during with this minimum is not met. During any such
10 period of tolling of probation, Respondent West Marin must nonetheless comply with all terms
11 and conditions of probation, unless Respondent West Marin is informed otherwise in writing by
12 the Board or its designee. If Respondent West Marin is not open and engaged in its ordinary
13 business as a pharmacy for a minimum of 120 hours in any calendar month, for any reason
14 (including vacation), Respondent West Marin shall notify the Board in writing within ten (10)
15 days of the conclusion of that calendar month. This notification shall include at minimum all of
16 the following: the date(s) and hours Respondent West Marin was open; the reason(s) for the
17 interruption or why business was not conducted; and the anticipated date(s) on which Respondent
18 will resume business as required. Respondent West Marin shall further notify the Board in
19 writing with ten (10) days following the next calendar month during which Respondent West
20 Marin is open and engaged in its ordinary business as a pharmacy in California for a minimum of
21 hours. Any failure to timely provide such notification(s) shall be considered a violation of
22 probation.

23 **14. Posted Notice of Probation**

24 Respondent West Marin shall prominently post a probation notice provided by the Board or
25 its designee in a place conspicuous to and readable by the public within two (2) days of receipt
26 thereof from the Board or its designee. Failure to timely post such notice, or to maintain the
27 posting during the entire period of probation, shall be considered a violation of probation.

28 Respondent West Marin shall not, directly or indirectly, engage in any conduct or make any

statement which is intended to mislead or is likely to have the effect of misleading any patient, customer, member of the public, or other person(s) as to the nature of and reason for the probation of the licensed entity.

15. Violation of Probation

If a Respondent has not complied with any term or condition of probation, the Board shall have continuing jurisdiction over Respondent, and probation shall be automatically extended, until all terms and conditions have been satisfied or the Board has taken other action as deemed appropriate to treat the failure to comply as a violation of probation, to terminate probation, and to impose the penalty that was stayed.

If Respondent West Marin violates probation in any respect, the Board, after giving Respondent West Marin notice and an opportunity to be heard, may revoke probation and carry out the disciplinary order that was stayed. If a petition to revoke probation or an accusation is filed against Respondent West Marin during probation, the Board shall have continuing jurisdiction and the period of probation shall be automatically extended until the petition to revoke probation or accusation is heard and decided, and the charges and allegations in First Amended Accusation No. 6801 shall be deemed true and correct.

16. Completion of Probation

Upon written notice by the Board or its designee indicating a successful completion of probation, Respondent Bascom Pharmacy's license will be fully restored.

17. Consultant Review of Pharmacy Operations

During the period of probation, Respondent West Marin shall retain, at its own expense, an independent consultant who shall be responsible for conducting an on-site physical inspection to review the operations of the pharmacy on a monthly basis for compliance by Respondent West Marin with state and federal laws and regulations governing the practice of the pharmacy, and compliance by Respondent West Marin. During the period of probation, the Board or its designee, retains the discretion to reduce the frequency and/or form of inspection of the pharmacist consultant's review.

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1 The consultant shall be a pharmacist licensed by and not on probation with the Board, who
2 has been approved by the Board or its designee to serve in this position. Respondent shall submit
3 the name of the proposed consultant to the Board or its designee for approval within thirty (30)
4 days of the effective date of the decision. Assumption of any unauthorized supervision
5 responsibilities shall be considered a violation of probation. In addition, failure to timely seek
6 approval for, timely retain, or ensure timely reporting by the consultant shall be considered a
7 violation of probation.

8 **DISCIPLINARY ORDER**

9 **ZSUZSANNA BIRAN RPH 35444**

10 IT IS HEREBY ORDERED that Registered Pharmacist License No. RPH 35444 issued to
11 Respondent Zsuzsanna Biran is revoked. However, the revocation is stayed and Respondent
12 Biran is placed on probation for three (3) years on the following terms and conditions:

13 1. **Obey All Laws**

14 Respondent Biran shall obey all state and federal laws and regulations.

15 Respondent Biran shall report any of the following occurrences to the board, in writing,
16 within seventy- two (72) hours of such occurrence:

- 17 • an arrest or issuance of a criminal complaint for violation of any provision of the
18 Pharmacy Law, state and federal food and drug laws, or state and federal controlled
19 substances laws
- 20 • a plea of guilty, or nolo contendere, no contest, or similar, in any state or federal
21 criminal proceeding to any criminal complaint, information or indictment
- 22 • a conviction of any crime
- 23 • the filing of a disciplinary pleading, issuance of a citation, or initiation of another
24 administrative action filed by any state or federal agency which involves
25 respondent's license or which is related to the practice of pharmacy or the
26 manufacturing, obtaining, handling, distributing, billing, or charging for any drug,
27 device or controlled substance.

28 Failure to timely report such occurrence shall be considered a violation of probation.

1 2. **Report to the Board**

2 Respondent Biran shall report to the board quarterly, on a schedule as directed by the board
3 or its designee. The report shall be made either in person or in writing, as directed. Among other
4 requirements, respondent shall state in each report under penalty of perjury whether there has
5 been compliance with all the terms and conditions of probation.

6 Failure to submit timely reports in a form as directed shall be considered a violation of
7 probation. Any period(s) of delinquency in submission of reports as directed may be added to the
8 total period of probation. Moreover, if the final probation report is not made as directed,
9 probation shall be automatically extended until such time as the final report is made and accepted
10 by the board.

11 3. **Interview with the Board**

12 Upon receipt of reasonable prior notice, Respondent Biran shall appear in person for
13 interviews with the board or its designee, at such intervals and locations as are determined by the
14 board or its designee. Failure to appear for any scheduled interview without prior notification to
15 board staff, or failure to appear for two (2) or more scheduled interviews with the board or its
16 designee during the period of probation, shall be considered a violation of probation.

17 4. **Cooperate with Board Staff**

18 Respondent Biran shall timely cooperate with the board's inspection program and with the
19 board's monitoring and investigation of respondent's compliance with the terms and conditions of
20 Entity probation, including but not limited to: timely responses to requests for information by
21 board staff; timely compliance with directives from board staff regarding requirements of any
22 term or condition of probation; and timely completion of documentation pertaining to a term or
23 condition of probation. Failure to timely cooperate shall be considered a violation of probation.

24 5. **Continuing Education**

25 Respondent Biran shall provide evidence of efforts to maintain skill and knowledge as a
26 pharmacist as directed by the board or its designee.

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1 **6. Reporting of Employment and Notice to Employers**

2 During the period of probation, Respondent Biran shall notify all present and prospective
3 employers of the decision in case number 6801 and the terms, conditions and restrictions imposed
4 on Respondent Biran by the decision, as follows:

5 Within thirty (30) days of the effective date of this decision, and within ten (10) days of
6 undertaking any new employment, respondent shall report to the board in writing the name,
7 physical address, and mailing address of each of Entity employer(s), and the name(s) and
8 telephone number(s) of all of Entity direct supervisor(s), as well as any pharmacist(s)-in- charge,
9 designated representative(s)-in-charge, responsible manager, or other compliance supervisor(s)
10 and the work schedule, if known. Respondent Biran shall also include the reason(s) for leaving
11 the prior employment. Respondent Biran shall sign and return to the board a written consent
12 authorizing the board or its designee to communicate with all of respondent's employer(s) and
13 supervisor(s), and authorizing those employer(s) or supervisor(s) to communicate with the board
14 or its designee, concerning respondent's work status, performance, and monitoring. Failure to
15 comply with the requirements or deadlines of this condition shall be considered a violation of
16 probation.

17 Within thirty (30) days of the effective date of this decision, and within fifteen (15) days of
18 respondent undertaking any new employment, respondent shall cause (a) Entity direct supervisor,
19 (b) Entity pharmacist-in-charge, designated representative-in-charge, responsible manager, or
20 other compliance supervisor, and (c) the owner or owner representative of Entity employer, to
21 report to the board in writing acknowledging that the listed individual(s) has/have read the
22 decision in case number 6801, and terms and conditions imposed thereby. If one person serves in
23 more than one role described in (a), (b), or (c), the acknowledgment shall so state. It shall be the
24 respondent's responsibility to ensure that these acknowledgment(s) are timely submitted to the
25 board. In the event of a change in the person(s) serving the role(s) described in (a), (b), or (c)
26 during the term of probation, respondent shall cause the person(s) taking over the role(s) to report
27 to the board in writing within fifteen (15) days of the change acknowledging that he or she has
28 read the decision in case number 6801, and the terms and conditions imposed thereby.

1 If Respondent Biran works for or is employed by or through an employment service,
2 respondent must notify the person(s) described in (a), (b), and (c) above at every entity licensed
3 by the board of the decision in case number 6801, and the terms and conditions imposed thereby
4 in advance of respondent commencing work at such licensed entity. A record of this notification
5 must be provided to the board upon request.

6 Furthermore, within thirty (30) days of the effective date of this decision, and within fifteen
7 (15) days of Respondent Biran undertaking any new employment by or through an employment
8 service, Respondent Biran shall cause the person(s) described in (a), (b), and (c) above at the
9 employment service to report to the board in writing acknowledging that he or she has read the
10 decision in case number, and the terms and conditions imposed thereby. It shall be Respondent
11 Biran's responsibility to ensure that these acknowledgment(s) are timely submitted to the board.

12 Failure to timely notify present or prospective employer(s) or failure to cause the identified
13 person(s) with that/those employer(s) to submit timely written acknowledgments to the board
14 shall be considered a violation of probation.

15 "Employment" within the meaning of this provision includes any full-time, part-time,
16 temporary, relief, or employment/management service position as a Registered Pharmacist, or any
17 position for which a Registered Pharmacist is a requirement or criterion for employment, whether
18 the respondent is an employee, independent contractor or volunteer.

19 **7. Notification of Change(s) in Name, Address(es), or Phone Number(s)**

20 Respondent Biran shall further notify the board in writing within ten (10) days of any
21 change in name, residence address, mailing address, e-mail address or phone number.

22 Failure to timely notify the board of any change in employer, name, address, or phone
23 number shall be considered a violation of probation.

24 **8. Restrictions on Supervision and Oversight of Licensed Facilities**

25 During the period of probation, Respondent Biran shall not supervise any intern pharmacist,
26 be the pharmacist-in-charge, designated representative-in-charge, responsible manager or other
27 compliance supervisor of any entity licensed by the board, nor serve as a consultant. Respondent
28

1 Biran may remain pharmacist-in-charge at West Marin Pharmacy only. Assumption of any such
2 unauthorized supervision responsibilities shall be considered a violation of probation.

3 **9. Reimbursement of Board Costs**

4 As a condition precedent to successful completion of probation, Respondents Biran and
5 West Marin shall pay the total of \$10,000.00 to the Board for its costs associated with the
6 investigation and enforcement of this matter. Respondents shall be responsible for payment of
7 these costs both jointly and severally. Respondents shall pay these costs within 60 days of the
8 effective date of this Order.

9 There shall be no deviation from this schedule absent prior written approval by the Board or
10 its designee. Failure to pay costs by the deadline(s) as directed shall be considered a violation of
11 probation.

12 **10. Probation Monitoring Costs**

13 Respondent Biran shall pay any costs associated with probation monitoring as determined
14 by the board each and every year of probation. Such costs shall be payable to the board on a
15 schedule as directed by the board or its designee. Failure to pay such costs by the deadline(s) as
16 directed shall be considered a violation of probation.

17 **11. Status of License**

18 Respondent Biran shall, at all times while on probation, maintain an active, current Original
19 Pharmacy Permit with the board, including any period during which suspension or probation is
20 tolled. Failure to maintain an active, current Original Pharmacy Permit shall be considered a
21 violation of probation.

22 If Respondent Biran's Pharmacist License expires or is cancelled by operation of law or
23 otherwise at any time during the period of probation, including any extensions thereof due to
24 tolling or otherwise, upon renewal or reapplication Respondent Biran's license shall be subject to
25 all terms and conditions of this probation not previously satisfied.

26 **12. License Surrender While on Probation/Suspension**

27 Following the effective date of this decision, should Respondent Biran cease practice due to
28 retirement or health, or be otherwise unable to satisfy the terms and conditions of probation,

1 respondent may relinquish Entity license, including any indicia of licensure issued by the board,
2 along with a request to surrender the license. The board or its designee shall have the discretion
3 whether to accept the surrender or take any other action it deems appropriate and reasonable.
4 Upon formal acceptance of the surrender of the license, Respondent Biran will no longer be
5 subject to the terms and conditions of probation. This surrender constitutes a record of discipline
6 and shall become a part of the respondent's license history with the board.

7 Upon acceptance of the surrender, Respondent Biran shall relinquish Entity pocket and/or
8 wall license, including any indicia of licensure not previously provided to the board within ten
9 (10) days of notification by the board that the surrender is accepted if not already provided.
10 Respondent Biran may not reapply for any license from the board for three (3) years from the
11 effective date of the surrender. Respondent Biran shall meet all requirements applicable to the
12 license sought as of the date the application for that license is submitted to the board, including
13 any outstanding costs.

14 13. **Practice Requirement – Extension of Probation**

15 Except during periods of suspension, Respondent Biran shall, at all times while on
16 probation, be employed as a Registered Pharmacist in California for a minimum of 80 hours per
17 calendar month. Any month during which this minimum is not met shall extend the period of
18 probation by one month. During any such period of insufficient employment, Respondent Biran
19 must nonetheless comply with all terms and conditions of probation, unless respondent receives a
20 waiver in writing from the board or its designee.

21 If Respondent Biran does not practice as a Registered Pharmacist in California for the
22 minimum number of hours in any calendar month, for any reason (including vacation),
23 respondent shall notify the board in writing within ten (10) days of the conclusion of that calendar
24 month. This notification shall include at least: the date(s), location(s), and hours of last practice;
25 the reason(s) for the interruption or reduction in practice; and the anticipated date(s) on which
26 respondent will resume practice at the required level. Respondent Biran shall further notify the
27 board in writing within ten (10) days following the next calendar month during which Respondent
28

1 Biran practices as a Registered Pharmacist in California for the minimum of hours. Any failure to
2 timely provide such notification(s) shall be considered a violation of probation.

3 It is a violation of probation for Respondent Biran's probation to be extended pursuant to
4 the provisions of this condition for a total period, counting consecutive and non-consecutive
5 months, exceeding thirty-six (36) months. The board or its designee may post a notice of the
6 extended probation period on its website.

7 **14. Violation of Probation**

8 If Respondent Biran has not complied with any term or condition of probation, the board
9 shall have continuing jurisdiction over respondent, and the board shall provide notice to
10 respondent that probation shall automatically be extended, until all terms and conditions have
11 been satisfied or the board has taken other action as deemed appropriate to treat the failure to
12 comply as a violation of probation, to terminate probation, and to impose the penalty that was
13 stayed. The board or its designee may post a notice of the extended probation period on its
14 website.

15 If Respondent Biran violates probation in any respect, the board, after giving Respondent
16 Biran notice and an opportunity to be heard, may revoke probation and carry out the disciplinary
17 order that was stayed. If a petition to revoke probation or an accusation is filed against
18 Respondent Biran during probation, or the preparation of an accusation or petition to revoke
19 probation is requested from the Office of the Attorney General, the board shall have continuing
20 jurisdiction and the period of probation shall be automatically extended until the petition to
21 revoke probation or accusation is heard and decided, and the charges and allegations in First
22 Amended Accusation No. 6801 shall be deemed true and correct.

23 **15. Completion of Probation**

24 Upon written notice by the board or its designee indicating successful completion of
25 probation, respondent's license will be fully restored.

26 **16. Remedial Education**

27 Within 60 days of the effective date of this decision, Respondent Biran shall submit to the
28 board or its designee, for prior approval, an appropriate program of remedial education related to

1 the grounds for discipline. The program of remedial education shall consist of at least 10 hours,
2 50 percent of which shall be live webinar or in person, and shall be completed each year of
3 probation at Respondent Biran's own expense. All remedial education shall be in addition to, and
4 shall not be credited toward, continuing education (CE) courses used for license renewal purposes
5 for pharmacists.

6 Failure to timely submit for approval or complete the approved remedial education shall be
7 considered a violation of probation. The period of probation will be automatically extended until
8 such remedial education is successfully completed and written proof, in a form acceptable to the
9 board, is provided to the board or its designee.

10 Following the completion of each course, the board or its designee may require the
11 respondent, at the entity's own expense, to take an approved examination to test the respondent's
12 knowledge of the course. If the respondent does not achieve a passing score on the examination
13 that course shall not count towards satisfaction of this term. Respondent Biran shall take another
14 course approved by the board in the same subject area.

15 **17. No New Ownership or Management of Licensed Premises**

16 Respondent Biran shall not acquire any new ownership, legal or beneficial interest nor
17 serve as a manager, administrator, member, officer, director, trustee, associate, or partner of any
18 additional business, firm, partnership, or corporation licensed by the board. If Respondent Biran
19 currently owns or has any legal or beneficial interest in, or serves as a manager, administrator,
20 member, officer, director, trustee, associate, or partner of any business, firm, partnership, or
21 corporation currently or hereinafter licensed by the board, Respondent Biran may continue to
22 serve in such capacity or hold that interest, but only to the extent of that position or interest as of
23 the effective date of this decision. Violation of this restriction shall be considered a violation of
24 probation.

25 **ACCEPTANCE**

26 I have carefully read the above Stipulated Settlement and Disciplinary Order and have fully
27 discussed it with my attorney, Natalia Mazina. I understand the stipulation and the effect it will
28 have on my Original Pharmacy Permit. I enter into this Stipulated Settlement and Disciplinary

1 Order voluntarily, knowingly, and intelligently, and agree to be bound by the Decision and Order
2 of the Board of Pharmacy.

3
4 DATED: _____
5 On behalf of WEST MARIN PHARMACY INC.,
6 ZSUZSANNA BIRAN AND JASON YOON,
OWNERS, *Respondent*

7
8 I have carefully read the above Stipulated Settlement and Disciplinary Order and have fully
9 discussed it with my attorney, Natalia Mazina. I understand the stipulation and the effect it will
10 have on my Pharmacist License. I enter into this Stipulated Settlement and Disciplinary Order
11 voluntarily, knowingly, and intelligently, and agree to be bound by the Decision and Order of the
12 Board of Pharmacy.

13
14 DATED: _____
15 ZSUZSANNA BIRAN
Respondent

16 I have read and fully discussed with Respondents the terms and conditions and other
17 matters contained in the above Stipulated Settlement and Disciplinary Order. I approve its form
18 and content.

19
20 DATED: _____
21 NATALIA MAZINA
Attorney for Respondents

22
23 ///

24 ///

25 ///

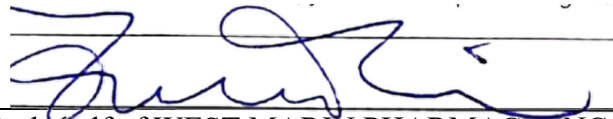
26 ///

27 ///

28 ///

Order voluntarily, knowingly, and intelligently, and agree to be bound by the Decision and Order of the Board of Pharmacy.

DATED: 29 Sept 2020


On behalf of WEST MARIN PHARMACY INC.,
ZSUZSANNA BIRAN AND JASON YOON,
OWNERS, *Respondent*

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

DATED: 29 Sept 2020


ZSUZSANNA BIRAN
Respondent

I have read and fully discussed with Respondents the terms and conditions and other matters contained in the above Stipulated Settlement and Disciplinary Order. I approve its form and content.

DATED: Oct. 2, 2020


NATALIA MAZINA
Attorney for Respondents

///

///

///

///

///

///

ENDORSEMENT

The foregoing Stipulated Settlement and Disciplinary Order is hereby respectfully submitted for consideration by the Board of Pharmacy.

DATED: _____

Respectfully submitted,

XAVIER BECERRA
Attorney General of California
DIANN SOKOLOFF
Supervising Deputy Attorney General

TIMOTHY FROEHLE
Deputy Attorney General
Attorneys for Complainant

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ENDORSEMENT

The foregoing Stipulated Settlement and Disciplinary Order is hereby respectfully submitted for consideration by the Board of Pharmacy.

DATED: Oct. 5, 2020

Respectfully submitted,

XAVIER BECERRA
Attorney General of California
DIANN SOKOLOFF
Supervising Deputy Attorney General



TIMOTHY FROEHLE
Deputy Attorney General
Attorneys for Complainant

OK2019202109/91279543.docx

Exhibit A

Accusation No. 6801

1 XAVIER BECERRA
Attorney General of California
2 DIANN SOKOLOFF
Supervising Deputy Attorney General
3 TIMOTHY FROEHLE
Deputy Attorney General
4 State Bar No. 279337
1515 Clay Street, 20th Floor
5 P.O. Box 70550
Oakland, CA 94612-0550
6 Telephone: (510) 879-0004
Facsimile: (510) 622-2270
7 E-mail: Tim.Froehle@doj.ca.gov
Attorneys for Complainant
8

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

13 In the Matter of the Accusation Against:

Case No. 6801

14 **WEST MARIN PHARMACY INC.,**
15 **ZSUZSANNA BIRAN and JASON YOON,**
Owners
16 11 4th Street
Point Reyes Station, CA 94956

ACCUSATION

17 Original Pharmacy Permit No. PHY 48531

18 and

19 **ZSUZSANNA BIRAN**
P.O. Box 1287
20 Point Reyes Station, CA 94956

21 Registered Pharmacist License
No. RPH 35444

22 Respondents.
23

24
25
26 **PARTIES**

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

1 2. On or about June 11, 2007, the Board of Pharmacy issued Original Pharmacy Permit
2 Number PHY 48531 to West Marin Pharmacy Inc. with Zsuzsanna Biran designated as
3 Pharmacist in Charge, as well as President, Treasurer/Chief Financial Officer, and 50-percent
4 shareholder since June 11, 2007, and with Jason Yoon as the Chairman, Secretary, and 50-percent
5 shareholder since June 11, 2007 (Respondent Pharmacy). The Original Pharmacy Permit was in
6 full force and effect at all times relevant to the charges brought here and will expire on June 1,
7 2020, unless renewed.

8 3. On or about August 14, 1980, the Board of Pharmacy issued Registered Pharmacist
9 License Number RPH 35444 to Zsuzsanna Biran (Respondent Biran). The Registered Pharmacist
10 License was in full force and effect at all times relevant to the charges brought here and will
11 expire on March 31, 2020, unless renewed.

12 **JURISDICTION**

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

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

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

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

21 7. Section 4300.1 of the Code states:

22 “The expiration, cancellation, forfeiture, or suspension of a board-issued license by
23 operation of law or by order or decision of the board or a court of law, the placement of a license
24 on a retired status, or the voluntary surrender of a license by a licensee shall not deprive the board
25 of jurisdiction to commence or proceed with any investigation of, or action or disciplinary
26 proceeding against, the licensee or to render a decision suspending or revoking the license.”

27 8. Section 4307, subdivision (a), of the Code states:
28

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

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

14 “(2) Where the license is denied or revoked, the prohibition shall continue until the license
15 is issued or reinstated.”

16 **STATUTORY PROVISIONS**

17 9. Section 4076 of the Code states, in pertinent part:

18 (a) A pharmacist shall not dispense any prescription except in a container that meets the
19 requirements of state and federal law and is correctly labeled with all of the following:

20 . . .

21 (8) The quantity of the drug or drugs dispensed.

22 (9) The expiration date of the effectiveness of the drug dispensed.

23 . . .

24 (11)(A) Commencing January 1, 2006, the physical description of the dispensed
25 medication, including its color, shape, and any identification code that appears on the tablets or
26 capsules, except as follows:

27 (i) Prescriptions dispensed by a veterinarian.

1 (ii) An exemption from the requirements of this paragraph shall be granted to a
2 new drug for the first 120 days that the drug is on the market and for the 90 days during which the
3 national reference file has no description on file.

4 (iii) Dispensed medications for which no physical description exists in any
5 commercially available database.

6 . . .”

7 10. Section 4081 of the Code states, in pertinent part:

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

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

22 **REGULATORY PROVISIONS**

23 11. California Code of Regulations, title 16, section 1716, states:

24 “Pharmacists shall not deviate from the requirements of a prescription except upon the prior
25 consent of the prescriber or to select the drug product in accordance with Section 4073 of the
26 Business and Professions Code.

27 “Nothing in this regulation is intended to prohibit a pharmacist from exercising commonly-
28 accepted pharmaceutical practice in the compounding or dispensing of a prescription.”

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

“‘Current Inventory’ as used in Sections 4081 and 4332 of the Business and Professions Code shall be considered to include complete accountability for all dangerous drugs handled by every licensee enumerated in Sections 4081 and 4332.

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

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

...

“(i) Every compounded drug preparation shall be given a 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.

“(1) For non-sterile compounded drug preparation(s), the beyond use date shall not exceed any of the following:

...

“(D) for non-aqueous formulations, 180 days or an extended date established by the pharmacist's research, analysis, and documentation,

...

“(k) Prior to allowing any drug product preparation to be compounded in a pharmacy, the pharmacist-in-charge shall complete a self-assessment for compounding pharmacies developed by the board (Incorporated by reference is “Community Pharmacy & Hospital Outpatient Pharmacy Compounding Self-Assessment” Form 17M-39 Rev. 02/12.) as required by Section 1715 of Title 16, Division 17, of the California Code of Regulations. That form contains a first section applicable to all compounding, and a second section applicable to sterile injectable compounding. The first section must be completed by the pharmacist-in-charge before any compounding is performed in the pharmacy. The second section must be completed by the pharmacist-in-charge before any sterile compounding is performed in the pharmacy. The applicable sections of the self-assessment shall subsequently be completed before July 1 of each odd-numbered year, within 30

1 days of the start date of a new pharmacist-in-charge or change of location, and within 30 days of
2 the issuance of a new pharmacy license. The primary purpose of the self-assessment is to promote
3 compliance through self-examination and education.

4 ...”

5 14. California Code of Regulations, title 16, section 1735.3, subdivision (a), states, in
6 pertinent part:

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

8 ...

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

11 ...

12 “(B) The date the drug preparation was compounded.

13 ...

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

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

18 ...”

19 15. California Code of Regulations, title 16, section 1735.4, subdivision (a), states, in
20 pertinent part:

21 “(a) Each compounded drug preparation shall be affixed with a container label prior to
22 dispensing that contains at least:

23 ...

24 “(4) The beyond use date for the drug preparation;

25 ...

26 “(6) The lot number or pharmacy reference number.”

27 ///

28 ///

1 16. California Code of Regulations, title 16, section 1776, states:

2 “Pharmacies, hospitals/clinics with onsite pharmacies, distributors and reverse distributors
3 licensed by the board may offer, under the requirements in this article, specified prescription drug
4 take-back services through collection receptacles and/or mail back envelopes or packages to
5 provide options for the public to discard unwanted, unused or outdated prescription drugs. Each
6 entity must comply with regulations of the federal Drug Enforcement Administration (DEA) and
7 this article.

8 “Only California-licensed pharmacies, hospitals/clinics with onsite pharmacies, and drug
9 distributors (licensed wholesalers and third-party logistics providers) who are registered with the
10 DEA as collectors and licensed in good standing with the board may host a pharmaceutical take-
11 back receptacle as authorized under this article.”

12 **COST RECOVERY**

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

17 **DEFINITIONS**

18 18. Atenolol, also known by the brand name Tenormin, is a beta-blocker that affects the
19 heart and circulation and is a dangerous drug under Code section 4022. It is used to treat chest
20 pain and high blood pressure.

21 19. Diazepam, also known by the brand name Valium, is a Schedule II controlled
22 substance under Health and Safety Code section 11057, subdivision (d)(9), and a dangerous drug
23 under Code section 4022. It is used to treat anxiety.

24 20. Hydrocodone/Acetaminophen (APAP), also known by the brand name Norco, is a
25 Schedule II controlled substance under RSC, section 11055, subdivision (b)(1)(I), and Title 21
26 CFR, section 1308.12, subdivision (b)(1)(vi), and a dangerous drug under Code section 4022. It is
27 used for pain.

28 ///

21. Lisinopril, also known by the brand name Zestril, is an angiotensin-converting-enzyme inhibitor used to treat high blood pressure in adults and children. It is a dangerous drug under Code section 4022.

22. Morphine Sulfate, also known by the brand name MS Contin/Avinza, is a Schedule II controlled substance under Health and Safety Code section 11055, subdivision (b)(1)(L), and a dangerous drug under Code section 4022. It is used to treat pain.

23. Prochlorperazine, also known by the brand name Compazine, is an anti-psychotic medicine. It is a dangerous drug under Code section 4022 and is used to treat psychotic disorders such as schizophrenia and anxiety and to control severe nausea and vomiting.

FIRST CAUSE FOR DISCIPLINE

(Failure to Maintain Current Inventory)

24. Respondents Pharmacy and Biran have subjected their Original Pharmacy Permit and Pharmacist licenses to discipline, respectively, because Respondents failed to properly maintain their current inventory of controlled substances and dangerous drugs. (Bus. & Prof. Code, § 4081, subd. (a); Cal. Code Regs., tit. 16, § 1718.) Respondent Biran is responsible as pharmacist in charge and as owner. (Bus. & Prof. Code, §§ 4081, subd. (b), 4113, subd. (c).) The circumstances are as follows:

25. Following the February 20, 2019 inspection, the Board's inspector conducted an audit of Respondent Pharmacy's inventory of dangerous drugs based upon acquisition and disposition records Respondents provided that covered the period between January 21, 2018, and February 20, 2019. The Board's inspector determined the following inventory discrepancies for that period:

Drug	Overage/(Shortage)
Morphine Sulfate IR (30mg)	(297 tablets)
Morphine Sulfate ER (30mg)	(1 tablet)
Hydrocodone/acetaminophen (5-325mg)	56 tablets
Hydrocodone/acetaminophen (10-325mg)	(1551 tablets)
Diazepam (10mg)	(389 tablets)

1 **SECOND CAUSE FOR DISCIPLINE**

2 (Unauthorized Take-Back Services)

3 26. Respondents Pharmacy and Biran have subjected their Original Pharmacy Permit and
4 Pharmacist licenses to discipline, respectively, because Respondents accepted unused medications
5 from patients without an authorized take-back receptacle services complying with the applicable
6 DEA regulations. (Cal. Code Regs., tit. 16, § 1776.) Respondent Biran is responsible as
7 pharmacist in charge. (Bus. & Prof. Code, § 4113, subd. (c).) The circumstances are as follows:

8 27. On or about February 20, 2019, during an inspection of Respondent Pharmacy, the
9 Board's inspector found approximately six bags of returned, unused medication accepted by
10 Respondents from patients.

11 **THIRD CAUSE FOR DISCIPLINE**

12 (Labeling Requirements)

13 28. Respondents Pharmacy and Biran have subjected their Original Pharmacy Permit and
14 Pharmacist licenses to discipline, respectively, because Respondents incorrectly labeled
15 prescription bottles intended for dispensing to customers. (Bus. & Prof. Code, § 4076, subds.
16 (a)(8), (9), (11)(A).) Respondent Biran is responsible as pharmacist in charge. (Bus. & Prof.
17 Code, § 4113, subd. (c).) The circumstances are as follows:

18 29. On or about February 20, 2019, the Board's inspector inspected bags located at
19 Respondent Pharmacy waiting for pick-up by Respondents' customers, finding the following
20 incorrectly labeled prescriptions:

21 a. Diazepam, 10 milligram tablets, filled on December 13, 2018, showed an incorrect
22 expiration date of May 31, 2018, on the label;

23 b. Prochlorperazine, 10 milligram tablets, labeled with a tablet description of round,
24 yellow tablets with TF/115 markings, contained, in the same bottle, another manufacturer's brand
25 (Mylan) with round, maroon tablets with M/P2 markings;

26 c. Lisinopril, 10 milligram tablets, labeled with a tablet description of pink and round
27 with WW/267 markings, instead contained oblong pink tablets with H146 markings inside the
28 bottle;

1 d. Atenolol, 25 milligram tablets, labeled as filled with 90 tablets, but the bottle only
2 contained 85 tablets.

3 **FOURTH CAUSE FOR DISCIPLINE**

4 (Labeling of Compounded Drug Preparations)

5 30. Respondents Pharmacy and Biran have subjected their Original Pharmacy Permit and
6 Pharmacist licenses to discipline, respectively, because Respondents failed to properly label a
7 compounded drug preparation prior to dispersing. (Cal. Code Regs., tit. 16, § 1735.4, subd. (a).)
8 Respondent Biran is responsible as pharmacist in charge. (Bus. & Prof. Code, § 4113, subd. (c).)
9 The circumstances are as follows:

10 31. On or about February 20, 2019, the Board inspector found that a prescription for a
11 non-sterile compounded preparation of hydrocodone 5 milligram capsules, filled on February 15,
12 2019, did not indicate the lot number of the prescription label and indicated the beyond use date
13 was February 2020, which was beyond the allowable 180-day-beyond-use date for this
14 compounded preparation.

15 **FIFTH CAUSE FOR DISCIPLINE**

16 (Compounding Limitations and Requirements)

17 32. Respondents Pharmacy and Biran have subjected their Original Pharmacy Permit and
18 Pharmacist licenses to discipline, respectively, because Respondents incorrectly labeled a non-
19 sterile compounded drug preparation with a beyond-use date that exceeded the date allowed by
20 regulation. (Cal. Code Regs., tit. 16, § 1735.2, subd. (i)(1)(D).) Respondent Biran is responsible
21 as pharmacist in charge. (Bus. & Prof. Code, § 4113, subd. (c).) The circumstances are
22 described above in paragraph 29.

23 **SIXTH CAUSE FOR DISCIPLINE**

24 (Recordkeeping of Compounded Drug Preparations)

25 33. Respondents Pharmacy and Biran have subjected their Original Pharmacy Permit and
26 Pharmacist licenses to discipline, respectively, because Respondents failed to properly maintain a
27 complete compounding log. (Cal. Code Regs., tit. 16, § 1735.3, subd. (a)(2)(B), (H), (I).)
28

1 Respondent Biran is responsible as pharmacist in charge. (Bus. & Prof. Code, § 4113, subd. (c).)

2 The circumstances are as follows:

3 34. On or about February 20, 2019, the Board's inspector reviewed Respondent
4 Pharmacy's compounding log and found that it was missing the date of compounding, the final
5 quantity compounded, and the beyond-use date on several of the entries.

6 **SEVENTH CAUSE FOR DISCIPLINE**

7 (Variation from Prescriptions)

8 35. Respondents Pharmacy and Biran have subjected their Original Pharmacy Permit and
9 Pharmacist licenses to discipline, respectively, because Respondents deviated from the
10 requirements of a prescription. (Cal. Code Regs., tit. 16, § 1716.) Respondent Biran is
11 responsible as pharmacist in charge. (Bus. & Prof. Code, § 4113, subd. (c).) The circumstances
12 are as follows:

13 36. On or about July 10, 2018, Respondents dispensed a prescription incorrectly to a
14 patient, M.S. The prescription was written for morphine sulfate immediate release 30 milligram
15 tablets, but inside the bottle M.S. received were morphine sulfate extended release 30 milligram
16 tablets.

17 **EIGHTH CAUSE FOR DISCIPLINE**

18 (Failure to Provide Recent, Completed Compounding Self-Assessment)

19 37. Respondents Pharmacy and Biran have subjected their Original Pharmacy Permit and
20 Pharmacist licenses to discipline, respectively, because Respondents failed to provide a recent,
21 completed compounding self-assessment upon request. (Cal. Code Regs., tit. 16, § 1735.2, subd.
22 (k).) Respondent Biran is responsible as pharmacist in charge. (Bus. & Prof. Code, § 4113, subd.
23 (c).) The circumstances are as follows:

24 38. On or about February 20, 2019, during an inspection of Respondent Pharmacy, the
25 Board's inspector requested to view Respondent Pharmacy's compounding self-assessment form.
26 Respondent Biran could not locate it and could not produce the document when requested.

27 **OTHER MATTERS**

28 39. Pursuant to Code section 4307, if discipline is imposed on Original Permit Number

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

40. Pursuant to Code section 4307, if discipline is imposed on Original Permit Number PHY 48531, issued to West Marin Pharmacy Inc., while Respondent Biran and/or Jason Yoon have been an owner and had knowledge of or knowingly participated in any conduct for which the licensee was disciplined, Respondent Biran and 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 Permit Number PHY 48531 is placed on probation or until Original Permit Number PHY 48531 is reinstated if it is revoked.

DISCIPLINE CONSIDERATIONS

41. To determine the degree of discipline, if any, to be imposed on Respondent Pharmacy, Complainant 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 to pay a fine of \$3,000.00. That Citation is now final, and Board records indicate that the citation fine was paid.

42. To determine the degree of discipline, if any, to be imposed on Respondent Biran, Complainant 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 to pay a fine of \$3,000.00 and comply with an order of abatement. That Citation is now final; however, Board records indicate that citation or order of abatement has not been satisfied.

PRAYER

WHEREFORE, Complainant requests that a hearing be held on the matters alleged here, 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;

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

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

9 5. Prohibiting Jason Yoon from serving as a manager, administrator, owner, member,
10 officer, director, associate, or partner of a licensee for five years if Original Permit Number PHY
11 48531 is place on probation or until Original Permit Number PHY 48531 is reinstated if Original
12 Permit Number 48531 issued to West Marin Pharmacy Inc. is revoked.

13 6. Ordering Respondents Pharmacy and Biran to pay the Board of Pharmacy the
14 reasonable costs of the investigation and enforcement of this case, pursuant to Business and
15 Professions Code section 125.3; and,

16 7. Taking such other and further action as deemed necessary and proper.

17
18
19 DATED: November 14, 2019



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