

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

In the Matter of the Accusation Against:

**ALIXA RX LLC, dba ALIXARX;
RONALD E. SILVA, MEMBER;
PAUL DEAN WALTERS, MEMBER;
WILLIAM BRADLEY SAVAGE, MEMBER;
JOHN W. DRISCOLL, PRESIDENT & CEO;
CALVIN SCOTT BROWN, SECRETARY,
Pharmacy Permit No. PHY 51693 &
Sterile Compounding License No. LSC 99953;**

and

**AMIT-KUMAR JANA,
Pharmacist License No. RPH 60363,**

Respondents

Agency Case No. 6995

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 April 13, 2022.

It is so ORDERED on March 14, 2022.

BOARD OF PHARMACY
DEPARTMENT OF CONSUMER AFFAIRS
STATE OF CALIFORNIA

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

Seung W. Oh, Pharm.D.
Board President

1 ROB BONTA
Attorney General of California
2 ANDREW M. STEINHEIMER
Supervising Deputy Attorney General
3 BRENT O. JEX
Deputy Attorney General
4 State Bar No. 235261
1300 I Street, Suite 125
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6 Telephone: (916) 210-7864
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7 *Attorneys for Complainant*

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

12
13 In the Matter of the Accusation Against:

Case No. 6995

14 **ALIXA RX LLC, DBA ALIXARX;**
15 **RONALD E. SILVA, MEMBER;**
16 **PAUL DEAN WALTERS, MEMBER;**
17 **WILLIAM BRADLEY SAVAGE, MEMBER;**
18 **JOHN W. DRISCOLL, PRESIDENT & CEO;**
19 **CALVIN SCOTT BROWN, SECRETARY**
4727 W. Shaw Avenue, Suite 104
Fresno, CA 93722

**STIPULATED SETTLEMENT AND
DISCIPLINARY ORDER**

**[RESPONDENT AMIT-KUMAR JANA
ONLY]**

20 **Pharmacy Permit No. PHY 51693; and**
21 **Sterile Compounding License No. LSC 99953**

22 **and**

23 **AMIT-KUMAR JANA**
4727 W. Shaw Avenue, Suite 104
Fresno, CA 93722
24 **Pharmacist-in-Charge**

25 **Pharmacist License No. RPH 60363**

26 Respondents.
27
28

1 IT IS HEREBY STIPULATED AND AGREED by and between Complainant and
2 Respondent Jana that the following matters are true:

3 **PARTIES**

4 1. Anne Sodergren (Complainant) is the Executive Officer of the Board of Pharmacy
5 (Board). She brought this action solely in her official capacity and is represented in this matter by
6 Rob Bonta, Attorney General of the State of California, by Brent O. Jex, Deputy Attorney
7 General.

8 2. Respondent Amit-Kumar Jana (Respondent Jana) is represented in this proceeding by
9 attorney:

10 Armond Marcarian, Esq.
11 Marcarian Law Firm, P.C.
12 21650 W. Oxnard Street, Suite 1980
Woodland Hills, CA 91367

13 3. On or about November 6, 2007, the Board issued Registered Pharmacist License
14 Number RPH 60363 to Respondent Jana. The Registered Pharmacist License was in full force
15 and effect at all times relevant to the charges brought herein and will expire on March 31, 2023,
16 unless renewed. Respondent Jana was the pharmacist-in-charge for Alixa Rx LLC, dba AlixaRx
17 (Respondent Alixa) for the period May 6, 2016 through January 9, 2020.

18 **JURISDICTION**

19 4. Accusation No. 6995 was filed before the Board, and is currently pending against
20 Respondent. The Accusation and all other statutorily required documents were properly served
21 on Respondent on November 16, 2020. Respondent Jana's Notice of Defense contesting the
22 Accusation was accepted by the Board on June 24, 2021.

23 5. A copy of Accusation No. 6995 is attached as Exhibit A and incorporated herein by
24 reference.

25 **ADVISEMENT AND WAIVERS**

26 6. Respondent Jana has carefully read, fully discussed with counsel, and understands the
27 charges and allegations in Accusation No. 6995. Respondent Jana has also carefully read, fully
28

1 discussed with counsel, and understands the effects of this Stipulated Settlement and Disciplinary
2 Order.

3 7. Respondent Jana is fully aware of his legal rights in this matter, including the right to
4 a hearing on the charges and allegations in the Accusation; the right to confront and cross-
5 examine the witnesses against him; the right to present evidence and to testify on his own behalf;
6 the right to the issuance of subpoenas to compel the attendance of witnesses and the production of
7 documents; the right to reconsideration and court review of an adverse decision; and all other
8 rights accorded by the California Administrative Procedure Act and other applicable laws.

9 8. Respondent Jana voluntarily, knowingly, and intelligently waives and gives up each
10 and every right set forth above.

11 **CULPABILITY**

12 9. Respondent Jana understands and agrees that the charges and allegations in
13 Accusation No. 6995, if proven at a hearing, constitute cause for imposing discipline upon his
14 Registered Pharmacist License.

15 10. For the purpose of resolving the Accusation without the expense and uncertainty of
16 further proceedings, Respondent Jana agrees that, at a hearing, Complainant could establish a
17 factual basis for the charges in the Accusation, and that Respondent Jana hereby gives up his right
18 to contest those charges.

19 **CONTINGENCY**

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

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

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

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

DISCIPLINARY ORDER

IT IS HEREBY ORDERED that Registered Pharmacist License Number RPH 60363 issued to Respondent Jana is revoked. However, the revocation is stayed, and Respondent Jana is placed on probation for three (3) years on the following terms and conditions:

1. Obey All Laws

Respondent Jana shall obey all state and federal laws and regulations.

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

a. An arrest or issuance of a criminal complaint for violation of any provision of the Pharmacy Law, state and federal food and drug laws, or state and federal controlled substances laws;

b. A plea of guilty, or nolo contendere, no contest, or similar, in any state or federal criminal proceeding to any criminal complaint, information or indictment;

c. A conviction of any crime; and

d. The filing of a disciplinary pleading, issuance of a citation, or initiation of another administrative action filed by any state or federal agency which involves respondent's license or

1 which is related to the practice of pharmacy or the manufacturing, obtaining, handling,
2 distributing, billing, or charging for any drug, device or controlled substance.

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

4 **2. Report to the Board**

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

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

14 **3. Interview with the Board**

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

20 **4. Cooperate with Board Staff**

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

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1 **5. Continuing Education**

2 Respondent Jana shall provide evidence of efforts to maintain skill and knowledge as a
3 pharmacist as directed by the board or its designee.

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

5 During the period of probation, Respondent Jana shall notify all present and prospective
6 employers of the decision in case number 6995 and the terms, conditions and restrictions imposed
7 on Respondent Jana by the decision, as follows:

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

20 Within thirty (30) days of the effective date of this decision, and within fifteen (15) days of
21 Respondent Jana undertaking any new employment, Respondent Jana shall cause (a) his direct
22 supervisor, (b) his pharmacist-in-charge, designated representative-in-charge, responsible
23 manager, or other compliance supervisor, and (c) the owner or owner representative of his
24 employer, to report to the board in writing acknowledging that the listed individual(s) has/have
25 read the decision in case number 6995, and terms and conditions imposed thereby. If one person
26 serves in more than one role described in (a), (b), or (c), the acknowledgment shall so state. It
27 shall be t Respondent Jana's responsibility to ensure that these acknowledgment(s) are timely
28 submitted to the board. In the event of a change in the person(s) serving the role(s) described in

1 (a), (b), or (c) during the term of probation, Respondent Jana shall cause the person(s) taking over
2 the role(s) to report to the board in writing within fifteen (15) days of the change acknowledging
3 that he or she has read the decision in case number 6995, and the terms and conditions imposed
4 thereby.

5 If Respondent Jana works for or is employed by or through an employment service,
6 Respondent Jana must notify the person(s) described in (a), (b), and (c) above at every entity
7 licensed by the board of the decision in case number 6995, and the terms and conditions imposed
8 thereby in advance of Respondent Jana commencing work at such licensed entity. A record of
9 this notification must be provided to the board upon request.

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

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

19 "Employment" within the meaning of this provision includes any full-time, part-time,
20 temporary, relief, or employment/management service position as a pharmacist, or any position
21 for which a pharmacist is a requirement or criterion for employment, whether Respondent Jana is
22 an employee, independent contractor or volunteer.

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

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

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

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

2 During the period of probation, Respondent Jana shall not supervise any intern pharmacist,
3 be the pharmacist-in-charge, designated representative-in-charge, responsible manager or other
4 compliance supervisor of any entity licensed by the board, nor serve as a consultant. Assumption
5 of any such unauthorized supervision responsibilities shall be considered a violation of probation.

6 **9. Reimbursement of Board Costs**

7 As a condition precedent to successful completion of probation, Respondent Jana shall pay
8 to the board its costs of investigation and prosecution in the amount of \$7,000. Respondent Jana
9 shall be permitted to pay these costs in a payment plan approved by the board or its designee, so
10 long as full payment is completed no later than one (1) year prior to the end date of probation.

11 **10. Probation Monitoring Costs**

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

16 **11. Status of License**

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

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

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

26 Following the effective date of this decision, should Respondent Jana cease practice due to
27 retirement or health, or be otherwise unable to satisfy the terms and conditions of probation,
28 Respondent Jana may relinquish his license, including any indicia of licensure issued by the

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

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

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

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

20 If Respondent Jana does not practice as a pharmacist in California for the minimum number
21 of hours in any calendar month, for any reason (including vacation), Respondent Jana shall notify
22 the board in writing within ten (10) days of the conclusion of that calendar month. This
23 notification shall include at least: the date(s), location(s), and hours of last practice; the reason(s)
24 for the interruption or reduction in practice; and the anticipated date(s) on which Respondent Jana
25 will resume practice at the required level. Respondent Jana shall further notify the board in
26 writing within ten (10) days following the next calendar month during which Respondent Jana
27 practices as a pharmacist in California for the minimum of hours. Any failure to timely provide
28 such notification(s) shall be considered a violation of probation.

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

5 **14. Violation of Probation**

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

13 If Respondent Jana violates probation in any respect, the board, after giving Respondent
14 Jana notice and an opportunity to be heard, may revoke probation and carry out the disciplinary
15 order that was stayed. If a petition to revoke probation or an accusation is filed against
16 Respondent Jana during probation, or the preparation of an accusation or petition to revoke
17 probation is requested from the Office of the Attorney General, the board shall have continuing
18 jurisdiction and the period of probation shall be automatically extended until the petition to
19 revoke probation or accusation is heard and decided, and the charges and allegations in
20 Accusation No. 6995 shall be deemed true and correct.

21 **15. Completion of Probation**

22 Upon written notice by the board or its designee indicating successful completion of
23 probation, Respondent Jana's license will be fully restored.

24 **16. Remedial Education**

25 Within 60 days of the effective date of this decision, Respondent Jana shall submit to the
26 board or its designee, for prior approval, an appropriate program of remedial education related to
27 the grounds for discipline in Accusation No. 6995. The program of remedial education shall
28 consist of at least 10 hours per year in USP 797, for each year Respondent Jana is subject to these

1 probationary terms, including at least 5 hours by live webinar or in-person instruction. The
2 education shall be completed at Respondent Jana 's own expense. All remedial education shall be
3 in addition to, and shall not be credited toward, continuing education (CE) courses used for
4 license renewal purposes for pharmacists.

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

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

14 17. **Ethics Course**

15 Within sixty (60) calendar days of the effective date of this decision, Respondent Jana shall
16 enroll in a course in ethics, at Respondent Jana's expense, approved in advance by the board or its
17 designee that complies with Title 16 California Code of Regulations section 1773.5. Respondent
18 Jana shall provide proof of enrollment upon request. Within five (5) days of completion,
19 Respondent Jana shall submit a copy of the certificate of completion to the board or its designee.
20 Failure to timely enroll in an approved ethics course, to initiate the course during the first year of
21 probation, to successfully complete it before the end of the second year of probation, or to timely
22 submit proof of completion to the board or its designee, shall be considered a violation of
23 probation.

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ACCEPTANCE

I have carefully read the above Stipulated Settlement and Disciplinary Order and have fully discussed it with my attorney, Armond Marcarian, Esq. 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: _____
AMIT-KUMAR JANA
Respondent

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

DATED: _____
ARMOND MARCARIAN, ESQ.
Attorney for Respondent

1 ACCEPTANCE

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

7
8 DATED: 1/24/2022


9 AMIT-KUMAR JANA
Respondent

10
11 I have read and fully discussed with Respondent Amit-Kumar Jana the terms and conditions
12 and other matters contained in the above Stipulated Settlement and Disciplinary Order. I approve
13 its form and content.

14
15 DATED: 1/24/2022


16 ARMOND MARCARIAN, ESQ.
Attorney for Respondent

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ENDORSEMENT

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

DATED: _____

Respectfully submitted,

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

BRENT O. JEX
Deputy Attorney General
Attorneys for Complainant

ENDORSEMENT

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

DATED: February 17, 2022

Respectfully submitted,

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

/s/ Brent O. Jex

BRENT O. JEX
Deputy Attorney General
Attorneys for Complainant

Exhibit A

Accusation No. 6995

1 XAVIER BECERRA
Attorney General of California
2 KENT D. HARRIS
Supervising Deputy Attorney General
3 BRENT O. JEX
Deputy Attorney General
4 State Bar No. 235261
1300 I Street, Suite 125
5 P.O. Box 944255
Sacramento, CA 94244-2550
6 Telephone: (916) 210-7864
Facsimile: (916) 327-8643
7 *Attorneys for Complainant*

8
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16 **WILLIAM BRADLEY SAVAGE, MEMBER;**
17 **JOHN W. DRISCOLL, PRESIDENT & CEO;**
CALVIN SCOTT BROWN, SECRETARY
4727 W. Shaw Avenue, Suite 104
Fresno, CA 93722

ACCUSATION

18 **Pharmacy Permit No. PHY 51693; and**
19 **Sterile Compounding License No. LSC 99953**

20 **and**

21 **AMIT-KUMAR JANA**
4727 W. Shaw Avenue, Suite 104
Fresno, CA 93722
22 **Pharmacist-in-Charge**

23 **Pharmacist License No. RPH 60363**

24 Respondents.

1 **PARTIES**

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

4 2. On or about December 18, 2013, the Board issued Pharmacy Permit Number PHY
5 51693 to Alixa Rx LLC, dba AlixaRx (Respondent Alixa), with Ronald E. Silva, Member; Paul
6 Dean Walters, Member; and William Bradley Savage, Member. John W. Driscoll served as
7 President and CEO of Respondent Alixa from April 1, 2015 through December 18, 2018. Calvin
8 Scott Brown has served as Secretary of Respondent Alixa from April 1, 2015 through the filing of
9 this Accusation. On or about June 16, 2014, the Board issued Sterile Compounding Permit
10 Number LSC 99953 to Respondent Alixa. The Pharmacy Permit and Sterile Compounding Permit
11 were in full force and effect at all times relevant to the charges brought herein and will expire on
12 December 1, 2020, unless renewed.

13 3. On or about November 6, 2007, the Board issued Registered Pharmacist License
14 Number RPH 60363 to Amit-Kumar Jana (Respondent Jana). The Registered Pharmacist License
15 was in full force and effect at all times relevant to the charges brought herein and will expire on
16 March 31, 2021, unless renewed. Respondent Jana was the pharmacist-in-charge for Respondent
17 Alixa for the period May 6, 2016 through January 9, 2020.

18 4. Respondent Alixa and Respondent Jana are referred to herein collectively as
19 Respondents.

20 **JURISDICTION**

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

24 6. Code section 4300 provides, in pertinent part:

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

26 (b) The board shall discipline the holder of any license issued by the board,
27 whose default has been entered or whose case has been heard by the board and found
guilty, by any of the following methods:

28 (1) Suspending judgment.

- 1 (2) Placing him or her upon probation.
- 2 (3) Suspending his or her right to practice for a period not exceeding one year.
- 3 (4) Revoking his or her license.
- 4 (5) Taking any other action in relation to disciplining him or her as the board in
its discretion may deem proper.

5 ...

6 7. Code section 4300.1 states:

7 The expiration, cancellation, forfeiture, or suspension of a board-issued license
8 by operation of law or by order or decision of the board or a court of law, the
9 placement of a license on a retired status, or the voluntary surrender of a license by a
10 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.

11 8. Code section 4307 provides, in pertinent part:

12 (a) Any person who has been denied a license or whose license has been
13 revoked or is under suspension, or who has failed to renew his or her license
14 while it was under suspension, or who has been a manger, administrator,
15 owner, member, officer, director, associate, partner, or any other person with
16 management or control of any partnership, corporation, trust, firm, or
17 association whose application for a license has been denied or revoked, is
18 under suspension or has been placed on probation, and while acting as the
19 manger, 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 probations, 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:

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

23 (2) Where the license is denied or revoked, the prohibition shall continue
24 until the license is issued or reinstated.

25 (b) Manager, administrator, owner, member, officer, director, associate,
26 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.

27 ...

STATUTORY PROVISIONS

9. Code section 4022 provides:

Dangerous drug or dangerous device means any drug or device unsafe for self-use in humans or animals, and includes the following:

(a) Any drug that bears the legend: Caution: federal law prohibits dispensing without prescription, Rx only, or words of similar import.

(b) Any device that bears the statement: Caution: federal law restricts this device to sale by or on the order of a _____, Rx only, or words of similar import, the blank to be filled in with the designation of the practitioner licensed to use or order use of the device.

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

10. Code section 4081, subdivision (a) provides, in pertinent part:

(a) All records of manufacture and of sale, acquisition, receipt, shipment, or disposition of dangerous drugs or dangerous devices shall be at all times during business hours open to inspection by authorized officers of the law, and shall be preserved for at least three years from the date of making. A current inventory shall be kept by every manufacturer, wholesaler, third-party logistics provider, pharmacy, veterinary food-animal drug retailer, outsourcing facility, physician, dentist, podiatrist, veterinarian, laboratory, licensed correctional clinic, as defined in Section 4187, clinic, hospital, institution, or establishment holding a currently valid and unrevoked certificate, license, permit, registration, or exemption under Division 2 (commencing with Section 1200) of the Health and Safety Code or under Part 4 (commencing with Section 16000) of Division 9 of the Welfare and Institutions Code who maintains a stock of dangerous drugs or dangerous devices.

...

11. Code section 4104, subdivisions (c)(2) and (c)(6) provide, in pertinent part:

...

(c) Every pharmacy shall report and provide to the board, within 14 days of the receipt or development thereof, the following information with regard to any licensed individual employed by or with the pharmacy:

...

(2) Any admission by a licensed individual of theft, diversion, or self-use of dangerous drugs.

...

(6) Any termination of a licensed individual based on theft, diversion, or self-use of dangerous drugs.

...

1 12. Code section 4113 provides, in pertinent part, that every pharmacy shall designate a
2 pharmacist-in-charge who shall be responsible for the pharmacy's compliance with all state and
3 federal laws and regulations pertaining to the practice of pharmacy.

4 13. Code section 4115, subdivision (f)(1) provides, in pertinent part:

5 ...

6 (f)(1) A pharmacy with only one pharmacist shall have no more than one pharmacy
7 technician performing the tasks specified in subdivision (a). The ratio of pharmacy
8 technicians performing the tasks specified in subdivision (a) to any additional
9 pharmacist shall not exceed 2:1, except that this ratio shall not apply to personnel
10 performing clerical functions pursuant to Section 4116 or 4117. This ratio is
11 applicable to all practice settings, except for an inpatient of a licensed health facility,
a patient of a licensed home health agency, as specified in paragraph (2), an inmate of
a correctional facility of the Department of Corrections and Rehabilitation, and for a
person receiving treatment in a facility operated by the State Department of State
Hospitals, the State Department of Developmental Services, or the Department of
Veterans Affairs.

12 14. Code section 4301 provides, in pertinent part:

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

15 ...

16 (f) The commission of any act involving moral turpitude, dishonesty, fraud,
17 deceit, or corruption, whether the act is committed in the course of relations as a
licensee or otherwise, and whether the act is a felony or misdemeanor or not.

18 ...

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

21 ...

22 (o) Violating or attempting to violate, directly or indirectly, or assisting in or
23 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.

24 (p) Actions or conduct that would have warranted denial of a license.

25 ...

26 ///

27 ///

REGULATORY PROVISIONS

15. California Code of Regulations (CCR), title 16, section 1714, subdivision (b) provides, in pertinent part:

...

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

...

16. CCR, title 16, section 1735.2, subdivision (k) provides, in pertinent part:

...

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

...

17. CCR, title 16, section 1751.1, subdivision (a)(9) provides, in pertinent part:

(a) In addition to the records required by section 1735.3, any pharmacy engaged in any compounding of sterile drug preparations shall maintain the following records, which must be readily retrievable, within the pharmacy:

...

(9) Other facility quality control records specific to the pharmacy's policies and procedures (e.g., cleaning logs for facilities and equipment).

...

18. CCR, title 16, section 1751.4, subdivision (d) provides, in pertinent part, that cleaning shall be done using a germicidal detergent and sterile water.

19. CCR, title 16, section 1751.6, provides, in pertinent part:

...

(b) The pharmacist-in-charge shall ensure that all pharmacy personnel engaging in compounding sterile drug preparations have training and demonstrated competence in the safe handling and compounding of sterile drug preparations, including hazardous agents if the pharmacy compounds products with hazardous agents.

...

(e) Pharmacies that compound sterile drug preparations must comply with the following training requirements:

(1) The pharmacy must establish and follow a written program of training and performance evaluation designed to ensure that each person working in the designated area has the knowledge and skills necessary to perform their assigned tasks properly. This program of training and performance evaluation must address at least the following:

...

(H) Cleaning, sanitizing, and maintaining of the equipment and the controlled area.

...

(2) Each person engaged in sterile compounding must successfully complete practical skills training in aseptic technique and aseptic area practices using models that are comparable to the most complex manipulations to be performed by the individual. Each pharmacist responsible for, or directly supervising and controlling, aseptic techniques or practices, must demonstrate the skills needed to ensure the sterility of compounded drug preparations. Evaluation must include written testing and a written protocol of periodic routine performance checks involving adherence to aseptic area policies and procedures. Each person's proficiency and continuing training needs must be reassessed at least every 12 months. Results of these assessments must be documented and retained in the pharmacy for three years.

20. CCR, title 16, section 1751.7 provides, in pertinent part:

...

(b)(1) The pharmacy and each individual involved in the compounding of sterile drug preparations must successfully demonstrate competency on aseptic technique and aseptic area practices before being allowed to prepare sterile drug preparations. The validation process shall be carried out in the same manner as normal production, except that an appropriate microbiological growth medium is used in place of the actual product used during sterile preparation. The validation process shall be representative of the types of manipulations, products and batch sizes the individual is expected to prepare and include a media-fill test. The validation process shall be as complicated as the most complex manipulations performed by staff and contain the same amount or greater amount of volume transferred during the compounding process. The same personnel, procedures, equipment, and materials must be used in the testing. Media used must have demonstrated the ability to support and promote growth. Completed medium samples must be incubated in a manner consistent with the manufacturer's recommendations. If microbial growth is detected, then each

individual's sterile preparation process must be evaluated, corrective action taken and documented, and the validation process repeated.

(2) Each individual's competency must be revalidated at least every twelve months for sterile to sterile compounding and at least every six months for individuals compounding sterile preparations from non-sterile ingredients.

...

(d) Re-evaluation of garbing and gloving competency shall occur at least every 12 months for personnel compounding products made from sterile ingredients and at least every six months for personnel compounding products from non-sterile ingredients.

...

COST RECOVERY

21. 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.

DEFINITIONS

22. **Percocet** is the brand name of a combination medication containing acetaminophen and oxycodone, a Schedule II controlled substance, as designated by Health and Safety Code section 11055, subdivision (b)(1)(M). Percocet is a dangerous drug under Code section 4022.

23. **Norco** is the brand name of a combination medication containing 325 milligrams (mg) of acetaminophen and 10 mg of hydrocodone bitartrate, a Schedule II controlled substance, as designated by Health and Safety Code section 11055, subdivision (b)(1)(i). Norco is a dangerous drug under Code section 4022.

24. **Alprazolam** is a Schedule IV controlled substance, as designated by Health and Safety Code section 11057, subdivision (d)(1). Alprazolam is a dangerous drug under Code section 4022.

25. **Ondansetron** is a dangerous drug under Code section 4022.

26. A **sporicidal agent** is a cleaning product that kills bacterial and fungal spores.

27. **Sporicidin®** is a cleaning solution utilizing buffered phenol and sodium phenate as the active ingredients for cleaning, disinfecting, and detergency. Sporicidin is not a sporicidal agent.

28. A **media-fill test** means a test used to measure the efficacy of compounding personnel in aseptic techniques whereby compounding procedures are mimicked using a growth-based media and then the resulting preparation is evaluated for sterility. The media-fill test must mimic the most complex compounding procedures performed by the pharmacy.

29. **Gloved fingertip sampling** means a process whereby compounding personnel lightly press each fingertip and thumb of each hand onto appropriate growth media, which are then incubated at a temperature and for a time period conducive to multiplication of microorganisms, and then examined for growth of microorganisms. Gloved fingertip sampling is used to evaluate the competency of personnel in performing hand hygiene and garbing procedures.

FACTUAL ALLEGATIONS

30. Respondent Alixa owns and operates a pharmacy located at 4727 West Shaw Avenue, Suite 104, in the city of Fresno (Pharmacy).

Pharmacy Inspection: September 7, 2018

31. On or about September 7, 2018, Board Inspector J.F. conducted an inspection of the Pharmacy.

32. During this inspection, Respondent Jana was the only pharmacist on duty, and there were four Pharmacy Technicians actively performing and engaging in Pharmacy Technician duties, including the manipulation of vials in the IV hood of the Pharmacy's sterile compounding room, pulling and returning medications from the active drug shelves, and packing and filling medication canisters.

33. After the inspection, Inspector J.F. conducted an audit on three controlled substance medications using records obtained from the inspection. The audit revealed that between May 6, 2016 and September 7, 2018, Respondent Alixa incurred a loss of 28 tablets of Percocet, and 1,425 tablets of Norco. Additionally, during the same time period, the inventory had a surplus of 47 tablets of alprazolam 2 mg.

34. During the inspection, Inspector J.F. obtained physician records from the Pharmacy. The records showed Respondents' staff utilized and recorded out-of-state addresses for multiple California-based physicians. These physicians were ordering and/or prescribing medications for patients of skilled nursing home facilities serviced by Respondent Alixa.

35. Pharmacy records also revealed that on July 7, 2018, Respondent Jana was notified of the theft and consumption of one tablet of ondansetron 8 mg by a staff pharmacist employed by Respondent Alixa, whose employment was thereafter terminated by Respondent Alixa.

Pharmacy Inspection: July 17, 2019

36. On or about July 17, 2019, Board Inspectors M.V. and P.S. completed a Sterile Compounding License renewal inspection of the Pharmacy.

37. During this inspection, the Inspectors requested a compounding self-assessment for 2019, but Respondents did not have a compounding self-assessment for the year 2019 completed. Instead, Respondent Jana completed a compounding self-assessment during the inspection, and backdated the self-assessment to July 1, 2019.

38. Also during this inspection, the Inspectors requested to see training documentation for the compounding staff. The documentation provided by Respondents revealed that from 2017 to 2018, the continuing training needs of Pharmacy Technician V. and Pharmacist S. were not reassessed every 12 months.

39. The documentation from the inspection also revealed that Pharmacist S. had not completed a media fill test since 2017.

40. The documentation from the inspection also revealed that Pharmacy Technician V. completed his annual gloved fingertip sampling on September 17, 2019, which was approximately 18 months after his March 1, 2018 sampling. Additionally, Pharmacist S. completed her annual gloved fingertip sampling on August 29, 2019, which was approximately 15 months after her May 2, 2018 sampling.

41. Finally, the inspection revealed that Respondents had been cleaning the Pharmacy with Sporidicin® as their sporicidal agent. However, Sporidicin® does not have sporicidal activity. Board Inspectors M.V. and P.S. informed Respondent Jana that Sporidicin® was not a

1 sporicidal agent, and Respondent Jana was issued an order of correction for not using a sporicidal
2 agent on at least a monthly basis.

3 **Pharmacy Inspection: December 20, 2019**

4 42. On or about December 20, 2019, Board Inspector M.V. inspected the Pharmacy in
5 response to a confidential complaint received by the Board. During the inspection, Board
6 Inspector M.V. learned that on September 4, 2019, Pharmacy Technician R.V. had sustained a
7 needle stick injury while reconstituting an injectable vial. R.V. did not have an initial media fill
8 test completed before being allowed to prepare sterile drug preparations. The test date for R.V.'s
9 media fill test was September 13, 2019, which was nine days after the needle stick injury
10 occurred.

11 43. The inspection revealed that neither Pharmacist J.S.D., nor Pharmacy Technician
12 R.V. had been informed of any updates to the Compounding Room Maintenance Log.
13 Additionally, R.V. had not been trained to document on the Compounding Room Maintenance
14 Log. The inspection further revealed that compounding staff were inadequately trained on the use
15 of the Facilities Humidity Log, and where to properly document differential room pressures.
16 Finally, although Respondent Jana provided a statement after the inspection regarding the
17 Pharmacy's change in cleaning agents, the statement did not state whether Respondent Jana had
18 provided training on the new cleaning agent or new Compounding Room Maintenance Log.

19 44. During the inspection on December 20, 2019, the Compounding Room Maintenance
20 Logs for July 2019 through September 2019, and November 2019 through January 2020 were not
21 available.

22 45. The inspection on December 20, 2019 further revealed no documentation showing
23 that the Pharmacy had used a sporicidal agent for cleaning all surfaces of the IV room on at least
24 a monthly basis.

25 46. During the inspection on December 20, 2019, Respondent Amit-Kumar Jana provided
26 a check-off list to Board Inspector M.V. for compounding staff that indicated all compounding
27 staff had completed and passed gloved fingertip sampling, media-fill testing, and written testing.
28 However, an analysis of the training records showed that as of October 29, 2019, two of the

1 compounding staff had outstanding media fill tests, and at least one of the compounding staff had
2 not completed his or her written test.

3 **FIRST CAUSE FOR DISCIPLINE**

4 (Fraud and Dishonesty)

5 47. Respondent Amit-Kumar Jana is subject to disciplinary action under Code section
6 4301, subdivisions (f), (o) and (p). As set forth in paragraph 36, above, Respondent Amit-Kumar
7 Jana completed a compounding self-assessment during the July 17, 2019 inspection, and
8 intentionally backdated the self-assessment to July 1, 2019.

9 48. Additionally, as set forth in paragraph 46, during the inspection on December 20,
10 2019, Respondent Amit-Kumar Jana provided a check-off list to Board Inspector M.V. for
11 compounding staff that indicated all compounding staff had completed and passed gloved
12 fingertip sampling, media-fill testing, and written testing. However, an analysis of the training
13 records showed that as of October 29, 2019, two of the compounding staff had outstanding media
14 fill tests, and at least one of the compounding staff had not completed his or her written test.

15 **SECOND CAUSE FOR DISCIPLINE**

16 (Failure to Uphold Pharmacist to Pharmacy Technician Ratio)

17 49. Respondents Alixa Rx LLC, dba AlixaRx and Amit-Kumar Jana are subject to
18 disciplinary action under Code sections 4113 and 4301, subdivision (o), in that Respondent Alixa
19 failed to comply with Code section 4115, subdivision (f). As set forth in paragraph 31 above,
20 during an inspection of the Pharmacy on September 7, 2018, the Pharmacy had only one
21 Pharmacist on duty, with four Pharmacy Technicians actively performing and engaging in
22 Pharmacy Technician duties, including the manipulation of vials in the IV hood of the
23 Pharmacy's sterile compounding room, pulling and returning medications from the active drug
24 shelves, and packing and filling medication canisters.

25 ///

26 ///

1 **THIRD CAUSE FOR DISCIPLINE**

2 (Failure to Maintain Inventory Accountability of Dangerous Drugs)

3 50. Respondents Alixa Rx LLC, dba AlixaRx and Amit-Kumar Jana are subject to
4 disciplinary action under Code sections 4113 and 4301, subdivisions (j) and (o) for violating
5 California Code of Regulations (CCR), title 16, section 1714, subdivision (b). As set forth in
6 paragraph 32 above, an audit conducted on three controlled substance medications after an
7 inspection of the Pharmacy on September 7, 2018 revealed that between May 6, 2016 and
8 September 7, 2018, Respondent Alixa incurred a loss of 28 tablets of Percocet, and 1,425 tablets
9 of Norco, both Schedule II controlled substances. Additionally, during the same time period, the
10 inventory had a surplus of 47 tablets of alprazolam 2 mg, a Schedule IV controlled substance.

11 **FOURTH CAUSE FOR DISCIPLINE**

12 (Failure to Maintain Accurate Prescription Records)

13 51. Respondents Alixa Rx LLC, dba AlixaRx and Amit-Kumar Jana are subject to
14 disciplinary action under Code sections 4113 and 4301, subdivisions (j) and (o) for violating
15 Code section 4081, subdivision (a). As set forth in paragraph 33 above, during an inspection of
16 the Pharmacy on September 7, 2018, physician records from the Pharmacy computer system were
17 obtained. The records show Respondents' staff utilized and recorded out-of-state addresses for
18 multiple California-based physicians ordering and/or prescribing medications for patients of
19 skilled nursing home facilities serviced by Respondent Alixa.

20 **FIFTH CAUSE FOR DISCIPLINE**

21 (Failure to Report to the Board)

22 52. Respondents Alixa Rx LLC, dba AlixaRx and Amit-Kumar Jana are subject to
23 disciplinary action under Code sections 4113 and 4301, subdivision (o) for violating Code section
24 4104, subdivisions (c)(2) and (c)(6). As set forth in paragraph 34 above, on July 7, 2018,
25 Respondent Amit-Kumar Jana was notified of the theft and consumption of one tablet of
26 ondansetron 8 mg, a prescription drug, by a staff pharmacist employed by Respondent Alixa,
27 whose employment was thereafter terminated by Respondent Alixa. Respondents Alixa and
28

1 Amit-Kumar Jana failed to report the theft, consumption, and termination of employment to the
2 Board.

3 **SIXTH CAUSE FOR DISCIPLINE**

4 (Failure to Complete Compounding Self-Assessment)

5 53. Respondents Alixa Rx LLC, dba AlixaRx and Amit-Kumar Jana are subject to
6 disciplinary action under Code sections 4113 and 4301, subdivision (o) for violating CCR, title
7 16, section 1735.2, subdivision (k). As set forth in paragraph 26 above, a compounding self-
8 assessment for the year 2019 was not completed nor available at the July 17, 2019 inspection of
9 the Pharmacy.

10 **SEVENTH CAUSE FOR DISCIPLINE**

11 (Failure to Timely Reassess Training Needs of Compounding Staff)

12 54. Respondents Alixa Rx LLC, dba AlixaRx and Amit-Kumar Jana are subject to
13 disciplinary action under Code sections 4113 and 4301, subdivision (o) for violating CCR, title
14 16, section 1751.6, subdivision (e)(2). As set forth in paragraph 37 above, from 2017 to 2018,
15 written training records for Pharmacy Technician V. and Pharmacist S. show that each person's
16 continuing training needs were not reassessed every 12 months, but were done approximately 18
17 months later.

18 **EIGHTH CAUSE FOR DISCIPLINE**

19 (Failure to Timely Revalidate Staff Competency on Aseptic Technique)

20 55. Respondents Alixa Rx LLC, dba AlixaRx and Amit-Kumar Jana are subject to
21 disciplinary action under Code sections 4113 and 4301, subdivision (o) for violating CCR, title
22 16, section 1751.7, subdivisions (b)(1) and (b)(2). As set forth in paragraph 38 above, Pharmacist
23 S. completed a media-fill test in 2017, but did not complete one for 2018 or 2019.

24 **NINTH CAUSE FOR DISCIPLINE**

25 (Failure to Timely Re-Evaluate Gloving Practices)

26 56. Respondents Alixa Rx LLC, dba AlixaRx and Amit-Kumar Jana are subject to
27 disciplinary action under Code sections 4113 and 4301, subdivision (o) for violating CCR, title
28 16, section 1751.7, subdivision (d). As set forth in paragraph 39 above, Pharmacy Technician V.

1 completed his annual gloved fingertip sampling on September 17, 2019, which was
2 approximately 18 months after his March 1, 2018 sampling. Additionally, Pharmacist S.
3 completed her annual gloved fingertip sampling on August 29, 2019, which was approximately
4 15 months after her May 2, 2018 sampling.

5 **TENTH CAUSE FOR DISCIPLINE**

6 (Failure to Use a Monthly Sporicidal Agent)

7 57. Respondents Alixa Rx LLC, dba AlixaRx and Amit-Kumar Jana are subject to
8 disciplinary action under Code sections 4113 and 4301, subdivision (o) for violating CCR, title
9 16, section 1751.4, subdivision (d). As set forth in paragraph 41 above, the Pharmacy was using
10 Sporicidin® as their sporicidal agent. However, Sporicidin® does not have sporicidal activity.

11 58. Additionally, as set forth in paragraph 45 above, even after Respondent Jana was
12 issued an order of correction for not using a sporicidal agent on at least a monthly basis, the
13 inspection on December 20, 2019 revealed no evidence that the Pharmacy had been using a
14 sporicidal agent for the cleaning of all surfaces of the IV room on at least a monthly basis.

15 **ELEVENTH CAUSE FOR DISCIPLINE**

16 (Failure to Complete Initial Competencies Before Compounding)

17 59. Respondents Alixa Rx LLC, dba AlixaRx and Amit Kumar Jana are subject to
18 disciplinary action under Code sections 4113 and 4301, subdivision (o) for violating CCR, title
19 16, section 1751.7, subdivision (b)(1). As set forth in paragraph 42 above, on September 4, 2019,
20 Pharmacy Technician R.V. sustained a needle stick injury while reconstituting an injectable vial.
21 R.V. did not have an initial media fill test completed before being allowed to prepare sterile drug
22 preparations.

23 **TWELFTH CAUSE FOR DISCIPLINE**

24 (Failure to Ensure Proper Training of Compounding Staff)

25 60. Respondents Alixa Rx LLC, dba AlixaRx and Amit Kumar Jana are subject to
26 disciplinary action under Code sections 4113 and 4301, subdivision (o) for violating CCR, title
27 16, section 1751.6, subdivision (e)(1)(H). As set forth in paragraph 43 above, the inspection on
28 December 20, 2019 revealed that neither Pharmacist J.S.D., nor Pharmacy Technician R.V. had

1 been informed of any updates to the Compounding Room Maintenance Log. Additionally, R.V.
2 had not been trained to document on the Compounding Room Maintenance Log. The inspection
3 further revealed that compounding staff were inadequately trained on the use of the Facilities
4 Humidity Log, and where to properly document differential room pressures. Finally, although
5 Respondent Jana provided a statement after the inspection regarding the Pharmacy's change in
6 cleaning agents, the statement did not state whether Respondent Jana had provided training on the
7 new cleaning agent or new Compounding Room Maintenance Log.

8 **THIRTEENTH CAUSE FOR DISCIPLINE**

9 (Failure to Maintain Cleaning Logs)

10 61. Respondents Alixa Rx LLC, dba AlixaRx and Amit Kumar Jana are subject to
11 disciplinary action under Code sections 4113 and 4301, subdivision (o) for violating CCR, title
12 16, section 1751.1, subdivision (a)(9). As set forth in paragraph 44 above, during the inspection
13 on December 20, 2019, the Compounding Room Maintenance Logs for July 2019 through
14 September 2019, and November 2019 through January 2020 were not available.

15 **MATTERS IN AGGRAVATION**

16 62. To determine the degree of discipline to be assessed against Respondents,
17 Complainant alleges that on or about September 20, 2017, the Board issued the following
18 citations and fine numbers for violating California Code of Regulations (CCR), title 16, section
19 1751.4, subdivision (d) [failure to comply with requirements regarding disinfecting facilities and
20 equipment];

- 21 a. CI 2017 76700 against pharmacy permit PHY 51693;
- 22 b. CI 2016 72895 against sterile compounding permit LSC 99953; and
- 23 c. CI 2017 76701 against pharmacist license number RPH 60363.

24 63. Additionally, on or about September 8, 2017, the Board issued citation and fine
25 number CI 2014 63679 against pharmacy permit PHY 51693 for violating CCR, title 16, section
26 1715.6 [reporting drug loss]; CCR, title 16, section 1714, subdivision (b) [operational standards
27 and security]; Business and Professions Code section 4081, subdivisions (a) and (b) and CCR,
28 title 16, section 1718 [records of dangerous drugs and devices kept open for inspection]; and

Code of Federal Regulations, title 21, section 1304.11, subdivisions (a) and (d) [general requirements for inventories].

OTHER MATTERS

64. Under Code section 4307, if the Board disciplines pharmacy permit number PHY 51693, issued to Alixa RX LLC dba AlixaRx, and/or Sterile Compounding Permit number LSC 99953, issued to Alixa RX LLC dba AlixaRx, and/or pharmacist license number RPH 60363, issued to Amit-Kumar Jana, then the disciplined Respondent(s) shall be prohibited from serving as a manager, administrator, owner, member, officer, director, associate, or partner of a licensee for five years if Respondent(s) are placed on probation, or, if revoked, until Respondent(s) are reinstated.

65. Under Code section 4307, if the Board disciplines pharmacy permit number PHY 51693, issued to Alixa RX LLC dba AlixaRx, and/or Sterile Compounding Permit number LSC 99953, issued to Alixa RX LLC dba AlixaRx, while Respondents Ronald E. Silva, Paul Dean Walters, William Bradley Savage, John W. Driscoll, and/or Calvin Scott Brown, has/have been an officer or owner, and had knowledge of, or knowingly participated in, any conduct for which the licensee is disciplined, Respondent(s) 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 51693, and/or Sterile Compounding Permit number LSC 99953, is/are placed on probation, or until pharmacy permit number PHY 51693 and/or Sterile Compounding Permit number LSC 99953, is/are reinstated if revoked.

PRAYER

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

1. Revoking or suspending Pharmacy Permit Number PHY 51693, issued to Alixa Rx LLC, dba AlixaRx;

2. Revoking or suspending Sterile Compounding License Number LSC 99953, issued to Alixa Rx LLC, dba AlixaRx;

1 3. Revoking or suspending Registered Pharmacist License Number RPH 60363, issued
2 to Amit-Kumar Jana;

3 4. Ordering Respondent Alixa Rx LLC, dba AlixaRx and Amit-Kumar Jana to pay the
4 Board of Pharmacy the reasonable costs of the investigation and enforcement of this case,
5 pursuant to Business and Professions Code section 125.3;

6 5. Prohibiting Alixa Rx LLC, dba AlixaRx from serving as a manager, administrator,
7 owner, member, officer, director, associate, or partner of a licensee for five years if Pharmacy
8 Permit Number PHY 51693 and/or Sterile Compounding License number LSC 99953 is placed
9 on probation, or until Pharmacy Permit Number PHY 51693 and/or Sterile Compounding License
10 Number LSC 99953 is reinstated if revoked;

11 6. Prohibiting Respondent Amit-Kumar Jana from serving as a manager, administrator,
12 owner, member, officer, director, associate, or partner of a licensee for five years if Pharmacist
13 License Number RPH 60363 is placed on probation, or until Pharmacist License Number RPH
14 60363 is reinstated if revoked;

15 7. Prohibiting Ronald E. Silva from serving as a manager, administrator, owner
16 member, officer, director, associate, or partner of a licensee for five years if pharmacy permit
17 number PHY 51693 and/or Sterile Compounding Permit Number LSC 99953 is/are placed on
18 probation, or until pharmacy permit number PHY 51693 and/or Sterile Compounding Permit
19 Number LSC 99953 is/are reinstated if pharmacy permit number PHY 51693 and/or Sterile
20 Compounding Permit Number LSC 99953 is/are revoked;

21 8. Prohibiting Paul Dean Walters from serving as a manager, administrator, owner
22 member, officer, director, associate, or partner of a licensee for five years if pharmacy permit
23 number PHY 51693 and/or Sterile Compounding Permit Number LSC 99953 is/are placed on
24 probation, or until pharmacy permit number PHY 51693 and/or Sterile Compounding Permit
25 Number LSC 99953 is/are reinstated if pharmacy permit number PHY 51693 and/or Sterile
26 Compounding Permit Number LSC 99953 is/are revoked;

27 9. Prohibiting William Bradley Savage from serving as a manager, administrator, owner
28 member, officer, director, associate, or partner of a licensee for five years if pharmacy permit

number PHY 51693 and/or Sterile Compounding Permit Number LSC 99953 is/are placed on probation, or until pharmacy permit number PHY 51693 and/or Sterile Compounding Permit Number LSC 99953 is/are reinstated if pharmacy permit number PHY 51693 and/or Sterile Compounding Permit Number LSC 99953 is/are revoked;

10. Prohibiting John W. Driscoll from serving as a manager, administrator, owner member, officer, director, associate, or partner of a licensee for five years if pharmacy permit number PHY 51693 and/or Sterile Compounding Permit Number LSC 99953 is/are placed on probation, or until pharmacy permit number PHY 51693 and/or Sterile Compounding Permit Number LSC 99953 is/are reinstated if pharmacy permit number PHY 51693 and/or Sterile Compounding Permit Number LSC 99953 is/are revoked;

11. Prohibiting Calvin Scott Brown from serving as a manager, administrator, owner member, officer, director, associate, or partner of a licensee for five years if pharmacy permit number PHY 51693 and/or Sterile Compounding Permit Number LSC 99953 is/are placed on probation, or until pharmacy permit number PHY 51693 and/or Sterile Compounding Permit Number LSC 99953 is/are reinstated if pharmacy permit number PHY 51693 and/or Sterile Compounding Permit Number LSC 99953 is/are revoked; and

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

DATED: 11/4/2020

Signature on File

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