

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

In the Matter of the Accusation Against:

**ARROW-MED RX INC. DBA JANA HEALTHCARE PHARMACY,
ALEXANDR AKOPNIK,
Pharmacy Permit Number PHY 50759,
Compounding Permit Number LSC 100684;**

and

**DEMAR LEWIS, III
Pharmacist License Number RPH 37541,**

Respondents.

Agency Case No. 6904

OAH No. 2021060182

DECISION AND ORDER

The attached Stipulated Surrender of License and 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" being clearly legible, and "W." in the middle.

Seung W. Oh, Pharm.D.
Board President

1 ROB BONTA
Attorney General of California
2 THOMAS L. RINALDI
Supervising Deputy Attorney General
3 LESLIE A. WALDEN
Deputy Attorney General
4 State Bar No. 196882
300 So. Spring Street, Suite 1702
5 Los Angeles, CA 90013
Telephone: (213) 269-6293
6 Facsimile: (916) 731-2126
Attorneys for Complainant
7

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

12 In the Matter of the Accusation Against:

13 **ARROW-MED RX INC. DBA JANA**
14 **HEALTHCARE PHARMACY,**
15 **ALEXANDR AKOPNIK**
16 **5233 Melrose Avenue**
17 **Los Angeles, CA 90038**

18 **Permit No. PHY 50759,**
19 **Compounding Permit No. LSC 100684**

20 **and**

21 **DEMAR LEWIS**
22 **265 Chateaux Elise, #G**
23 **Santa Barbara, CA 93109**

24 **Pharmacist License No. RPH 37541**

25 Respondents.

Case No. 6904

OAH No. 2021060182

STIPULATED SURRENDER OF
LICENSE AND ORDER AS TO
COMPOUNDING PERMIT NO. LSC
100684

1 IT IS HEREBY STIPULATED AND AGREED by and between the parties to the above-
2 entitled proceedings 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 Leslie A. Walden, Deputy Attorney
7 General.

8 2. Arrow-Med Rx Inc. dba Jana Healthcare Pharmacy, Alexandr Akopnik (Respondent)
9 is represented in this proceeding by attorney Herbert L. Weinberg, Esq., whose address is: 1990
10 South Bundy Drive, Suite 777, Los Angeles, CA 90025..

11 3. On or about December 30, 2014, the Board issued Compounding Permit No. PHY
12 100684 to Respondent. The Permit was in full force and effect at all times relevant to the charges
13 brought in the First Amended Accusation No. 6904 and expired on July 19, 2019.

14 **JURISDICTION**

15 4. Accusation No. 6904 was filed before the Board on September 19, 2020. A First
16 Amended Accusation was subsequently filed on January 21, 2021, and is currently pending
17 against Respondent. The First Amended Accusation and all other statutorily required documents
18 were properly served on Respondent on February 22, 2021. Respondent timely filed its Notice of
19 Defense contesting the Accusation. A copy of the First Amended Accusation No. 6904 is
20 attached as Exhibit A and incorporated by reference.

21 **ADVISEMENT AND WAIVERS**

22 5. Respondent has carefully read, fully discussed with counsel, and understands the
23 charges and allegations in the First Amended Accusation No. 6904. Respondent also has
24 carefully read, fully discussed with counsel, and understands the effects of this Stipulated
25 Surrender of License and Order as to Compounding Permit No. LSC 100684.

26 6. Respondent is fully aware of its legal rights in this matter, including the right to a
27 hearing on the charges and allegations in the Accusation; the right to confront and cross-examine
28 the witnesses against them; the right to present evidence and to testify on its own behalf; the right

1 to the issuance of subpoenas to compel the attendance of witnesses and the production of
2 documents; the right to reconsideration and court review of an adverse decision; and all other
3 rights accorded by the California Administrative Procedure Act and other applicable laws.

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

6 **CULPABILITY**

7 8. Respondent understands that the charges and allegations in the First Amended
8 Accusation No. 6904, if proven at a hearing, constitute cause for imposing discipline upon its
9 Permit.

10 9. For the purpose of resolving the First Amended Accusation without the expense and
11 uncertainty of further proceedings, Respondent agrees that, at a hearing, Complainant could
12 establish a factual basis for the charges in the First Amended Accusation and that those charges
13 constitute cause for discipline. Respondent hereby gives up their right to contest that cause for
14 discipline exists based on those charges.

15 10. Respondent understands that by signing this stipulation Respondent enables the Board
16 to issue an order accepting the surrender of their Permit without further process.

17 **CONTINGENCY**

18 11. This stipulation shall be subject to approval by the Board. Respondent understands
19 and agrees that counsel for Complainant and the staff of the Board may communicate directly
20 with the Board regarding this stipulation and surrender, without notice to or participation by
21 Respondent or its counsel. By signing the stipulation, Respondent understands and agrees that
22 they may not withdraw its agreement or seek to rescind the stipulation prior to the time the Board
23 considers and acts upon it. If the Board fails to adopt this stipulation as its Decision and Order,
24 the Stipulated Surrender of License and Order as to Compounding Permit No. LSC 100684 shall
25 be of no force or effect, except for this paragraph, it shall be inadmissible in any legal action
26 between the parties, and the Board shall not be disqualified from further action by having
27 considered this matter.
28

12. The parties understand and agree that Portable Document Format (PDF) and facsimile copies of this Stipulated Surrender of License and Order as to Compounding Permit No. LSC 100684, including PDF and facsimile signatures thereto, shall have the same force and effect as the originals.

13. This Stipulated Surrender of License and Order as to Compounding Permit No. LSC 100684 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 Surrender of License and Order as to Compounding Permit No. LSC 100684 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 Order:

ORDER

IT IS HEREBY ORDERED that Compounding Permit No. LSC 100684, issued to Respondent Arrow-Med Rx Inc. dba Jana Healthcare Pharmacy, Alexandr Akopnik, is surrendered and accepted by the Board.

1. The surrender of Respondent's Compounding Permit and the acceptance of the surrendered license by the Board shall constitute the imposition of discipline against Respondent. This stipulation constitutes a record of the discipline and shall become a part of Respondent's license history with the Board.

2. Respondent shall lose all rights and privileges to practice under the Compounding Permit in California as of the effective date of the Board's Decision and Order.

3. Respondent shall cause to be delivered to the Board its pocket license and, if one was issued, its wall certificate on or before the effective date of the Decision and Order.

4. If they ever applies for licensure or petitions for reinstatement in the State of California, the Board shall treat it as a new application for licensure. Respondent must comply with all the laws, regulations and procedures for licensure in effect at the time the application or

petition is filed, and all of the charges and allegations contained in First Amended Accusation No. 6904 shall be deemed to be true, correct and admitted by Respondent when the Board determines whether to grant or deny the application or petition. Respondent may not apply for any new license from the board for three (3) years from the effective date of the surrender. Respondent shall meet all requirements applicable to the license sought as of the date the application for that license is submitted to the board.

5. Respondent shall pay the agency its costs of investigation and enforcement in the amount of \$8,470.00 prior to issuance of a new or reinstated license.

ACCEPTANCE

I have carefully read the above Stipulated Surrender of License and Order as to Compounding Permit No. LSC 100684 and have fully discussed it with my attorney Herbert L. Weinberg, Esq. I understand the stipulation and the effect it will have on my Compounding Permit. I enter into this Stipulated Surrender of License and Order as to Compounding Permit No. LSC 100684 voluntarily, knowingly, and intelligently, and agree to be bound by the Decision and Order of the Board of Pharmacy.

DATED: _____

ARROW-MED RX INC. DBA JANA
HEALTHCARE PHARMACY, ALEXANDR
AKOPNIK
Respondent

I have read and fully discussed with Respondent Arrow-Med Rx Inc. dba Jana Healthcare Pharmacy, Alexandr Akopnik the terms and conditions and other matters contained in this Stipulated Surrender of License and Order as to Compounding Permit No. LSC 100684. I approve its form and content.

DATED: _____

HERBERT L. WEINBERG, ESQ.
Attorney for Respondent


1 petition is filed, and all of the charges and allegations contained in First Amended Accusation No.
2 6904 shall be deemed to be true, correct and admitted by Respondent when the Board determines
3 whether to grant or deny the application or petition. Respondent may not apply for any new
4 license from the board for three (3) years from the effective date of the surrender. Respondent
5 shall meet all requirements applicable to the license sought as of the date the application for that
6 license is submitted to the board.

7 5. Respondent shall pay the agency its costs of investigation and enforcement in the
8 amount of \$8,470.00 prior to issuance of a new or reinstated license.

9 ACCEPTANCE


10 I have carefully read the above Stipulated Surrender of License and Order as to
11 Compounding Permit No. LSC 100684 and have fully discussed it with my attorney Herbert L.
12 Weinberg, Esq. I understand the stipulation and the effect it will have on my Compounding
13 Permit. I enter into this Stipulated Surrender of License and Order as to Compounding Permit
14 No. LSC 100684 voluntarily, knowingly, and intelligently, and agree to be bound by the Decision
15 and Order of the Board of Pharmacy.

16
17 DATED: 10/5/2021


ARROW-MED RX INC. DBA JANA
HEALTHCARE PHARMACY, ALEXANDR
AKOPNIK
Respondent

21 I have read and fully discussed with Respondent Arrow-Med Rx Inc. dba Jana Healthcare
22 Pharmacy, Alexandr Akopnik the terms and conditions and other matters contained in this
23 Stipulated Surrender of License and Order as to Compounding Permit No. LSC 100684. I
24 approve its form and content.

25
26 DATED: 10/5/2021


HERBERT L. WEINBERG, ESQ.
Attorney for Respondent

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ENDORSEMENT

The foregoing Stipulated Surrender of License and Order as to Compounding Permit No. LSC 100684 is hereby respectfully submitted for consideration by the Board of Pharmacy of the Department of Consumer Affairs.

DATED: _____

Respectfully submitted,

ROB BONTA
Attorney General of California
THOMAS L. RINALDI
Supervising Deputy Attorney General

LESLIE A. WALDEN
Deputy Attorney General
Attorneys for Complainant

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ENDORSEMENT

The foregoing Stipulated Surrender of License and Order as to Compounding Permit No. LSC 100684 is hereby respectfully submitted for consideration by the Board of Pharmacy of the Department of Consumer Affairs.

DATED: October 5, 2021

Respectfully submitted,

ROB BONTA
Attorney General of California
THOMAS L. RINALDI
Supervising Deputy Attorney General

Leslie Walden

LESLIE A. WALDEN
Deputy Attorney General
Attorneys for Complainant

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Exhibit A

Accusation No. 6904

1 XAVIER BECERRA
Attorney General of California
2 THOMAS L. RINALDI
Supervising Deputy Attorney General
3 LESLIE A. WALDEN
Deputy Attorney General
4 State Bar No. 196882
300 So. Spring Street, Suite 1702
5 Los Angeles, CA 90013
Telephone: (213) 269-6293
6 Facsimile: (916) 731-2126
E-mail: leslie.walden@doj.ca.gov
7 *Attorneys for Complainant*

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

12 In the Matter of the First Amended Accusation
13 Against:

14 **ARROW-MED RX INC. DBA JANA**
15 **HEALTHCARE PHARMACY,**
ALEXANDR AKOPNIK, OWNER
16 **MIRA ZEFFREN**

5233 Melrose Avenue
Los Angeles, CA 90038

17 Pharmacy Permit No. PHY 50759,
18 Compounding Permit No. LSC 100684

19 and

20 **DEMAR LEWIS III**

21 6121 Shoup Ave. #6
Woodland Hills, CA 91367

22 Pharmacist License No. RPH 37541

23 Respondents.
24

Case No. 6904

FIRST AMENDED ACCUSATION

1 **PARTIES**

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

5 2. On or about October 4, 2011, the Board of Pharmacy issued Permit Number PHY
6 50759 to Arrow-Med Rx Inc. dba Jana Healthcare Pharmacy with Alexandr Akopnik as President
7 and 100% Shareholder (Respondent Jana Healthcare). Demar Lewis III was the Pharmacist in
8 Charge from August 15, 2018 to May 20, 2019. The Permit was in full force and effect at all
9 times relevant to the charges brought herein and will expire on October 1, 2021, unless renewed.

10 3. On or about December 30, 2014, the Board of Pharmacy issued Sterile Compounding
11 Permit Number LSC 100684 to Respondent Jana Healthcare. Demar Lewis III was the
12 Pharmacist in Charge from August 15, 2018 to May 20, 2019. The Permit was in full force and
13 effect at all times relevant to the charges brought herein and expired on July 19, 2019.

14 4. On or about February 9, 1983, the Board of Pharmacy issued Pharmacist License
15 Number RPH 37541 to Demar Lewis III (Respondent Lewis). The Pharmacist License was in
16 full force and effect at all times relevant to the charges brought herein and will expire on June 30,
17 2022, unless renewed.

18 5. On or about September 26, 1987, the Board of Pharmacy issued Pharmacist License
19 Number RPH 41239 to Mira J. Zeffren. The Pharmacist License was revoked on November 6,
20 2015 *In the Matter of the First Amended Accusation against Mira J. Zeffren*, Board of Pharmacy,
21 Case Number AC 5070. Respondent acted as an undisclosed officer, associate and/or person with
22 management or control of Respondent Pharmacy.

23 **JURISDICTION**

24 6. This First Amended Accusation is brought before the Board of Pharmacy (Board),
25 Department of Consumer Affairs, under the authority of the following laws. All section
26 references are to the Business and Professions Code (Code) unless otherwise indicated.

27 7. Section 4113 of the Code states in pertinent part:

28

1 “(d) Every pharmacy shall notify the board in writing, on a form designed by the board,
2 within 30 days of the date when a pharmacist-in-charge ceases to act as the pharmacist-in-charge,
3 and shall on the same form propose another pharmacist to take over as the pharmacist-in-charge.
4 The proposed replacement pharmacist-in-charge shall be subject to approval by the board. If
5 disapproved, the pharmacy shall propose another replacement within 15 days of the date of
6 disapproval and shall continue to name proposed replacements until a pharmacist-in-charge is
7 approved by the board.

8 (e) If a pharmacy is unable, in the exercise of reasonable diligence, to identify within 30
9 days a permanent replacement pharmacist-in-charge to propose to the board on the notification
10 form, the pharmacy may instead provide on that form the name of any pharmacist who is an
11 employee, officer, or administrator of the pharmacy or the entity that owns the pharmacy and who
12 is actively involved in the management of the pharmacy on a daily basis, to act as the interim
13 pharmacist-in-charge for a period not to exceed 120 days. The pharmacy, or the entity that owns
14 the pharmacy, shall be prepared during normal business hours to provide a representative of the
15 board with the name of the interim pharmacist-in-charge with documentation of the active
16 involvement of the interim pharmacist-in-charge in the daily management of the pharmacy, and
17 with documentation of the pharmacy’s good faith efforts prior to naming the interim pharmacist-
18 in-charge to obtain a permanent pharmacist-in-charge. By no later than 120 days following the
19 identification of the interim pharmacist-in-charge, the pharmacy shall propose to the board the
20 name of a pharmacist to serve as the permanent pharmacist-in-charge. The proposed permanent
21 pharmacist-in-charge shall be subject to approval by the board. If disapproved, the pharmacy shall
22 propose another replacement within 15 days of the date of disapproval, and shall continue to
23 name proposed replacements until a pharmacist-in-charge is approved by the board.”

24 8. Section 4110 of the Code subdivision (a) states:

25 “(a) No person shall conduct a pharmacy in the State of California unless he or she has
26 obtained a license from the board. A license shall be required for each pharmacy owned or
27 operated by a specific person. A separate license shall be required for each of the premises of any
28 person operating a pharmacy in more than one location. The license shall be renewed annually.

1 The board may, by regulation, determine the circumstances under which a license may be
2 transferred.”

3 9. Section 4116 of the Code subdivision (a) states in pertinent part:

4 “(a) No person other than a pharmacist, an intern pharmacist, an authorized officer of the
5 law, or a person authorized to prescribe shall be permitted in that area, place, or premises
6 described in the license issued by the board wherein controlled substances or dangerous drugs or
7 dangerous devices are stored, possessed, prepared, manufactured, derived, compounded,
8 dispensed, or repackaged. However, a pharmacist shall be responsible for any individual who
9 enters the pharmacy for the purposes of receiving consultation from the pharmacist or performing
10 clerical, inventory control, housekeeping, delivery, maintenance, or similar functions relating to
11 the pharmacy if the pharmacist remains present in the pharmacy during all times as the authorized
12 individual is present.”

13 10. Section 4301 of the Code states:

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

17

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

22 11. Section 4037 subdivision (a) of the Code states in pertinent part:

23 “Pharmacy” means an area, place, or premises licensed by the board in which the
24 profession of pharmacy is practiced and where prescriptions are compounded. “Pharmacy”
25 includes, but is not limited to, any area, place, or premises described in a license issued by the
26 board wherein controlled substances, dangerous drugs, or dangerous devices are stored,
27 possessed, prepared, manufactured, derived, compounded, or repackaged, and from which the
28

1 controlled substances, dangerous drugs, or dangerous devices are furnished, sold, or dispensed at
2 retail.

3 12. Section 4305 of the Code states in pertinent part:

4 “(a) Failure by any pharmacist to notify the board in writing that he or she has ceased to act
5 as the pharmacist-in-charge of a pharmacy, or by any pharmacy to notify the board in writing that
6 a pharmacist-in-charge is no longer acting in that capacity, within the 30-day period specified in
7 Sections 4101 and 4113 shall constitute grounds for disciplinary action.

8 (b) Operation of a pharmacy for more than 30 days without supervision or management by
9 a pharmacist-in-charge shall constitute grounds for disciplinary action.”

10 13. Section 4307 of the Code states in pertinent part:

11 (a) Any person who has been denied a license or whose license has been revoked or is
12 under suspension, or who has failed to renew his or her license while it was under suspension, or
13 who has been a manager, administrator, owner, member, officer, director, associate, partner, or
14 any other person with management or control of any partnership, corporation, trust, firm, or
15 association whose application for a license has been denied or revoked, is under suspension or has
16 been placed on probation, and while acting as the manager, administrator, owner, member,
17 officer, director, associate, partner, or any other person with management or control had
18 knowledge of or knowingly participated in any conduct for which the license was denied,
19 revoked, suspended, or placed on probation, shall be prohibited from serving as a manager,
20 administrator, owner, member, officer, director, associate, partner, or in any other position with
21 management or control of a licensee as follows:

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

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

26 (b) Manager, administrator, owner, member, officer, director, associate, partner, or any
27 other person with management or control of a license as used in this section and Section 4308,
28 may refer to a pharmacist or to any other person who serves in such capacity in or for a licensee.

1 (c) The provisions of subdivision (a) may be alleged in any pleading filed pursuant to
2 Chapter 5 (commencing with Section 11500) of Part 1 of Division 3 of the Government Code.
3 However, no order may be issued in that case except as to a person who is named in the caption,
4 as to whom the pleading alleges the applicability of this section, and where the person has been
5 given notice of the proceeding as required by Chapter 5 (commencing with Section 11500) of Part
6 1 of Division 3 of the Government Code. The authority to proceed as provided by this subdivision
7 shall be in addition to the board's authority to proceed under Section 4339 or any other provision
8 of law.

9 14. Section 4329 of the Code states in pertinent part:

10 "Any nonpharmacist who takes charge of or acts as supervisor, manager, or pharmacist-in-
11 charge of any pharmacy, or who compounds or dispenses a prescription or furnishes dangerous
12 drugs except as otherwise provided in this chapter, is guilty of a misdemeanor."

13 15. Section 4105 of the Code states in pertinent part:

14 "(a) All records or other documentation of the acquisition and disposition of dangerous
15 drugs and dangerous devices by any entity licensed by the board shall be retained on the licensed
16 premises in a readily retrievable form.

17"

18 **HEALTH AND SAFETY CODE**

19 16. Section 11165 subdivision (d) of the Health and Safety Code states:

20 "(d) For each prescription for a Schedule II, Schedule III, or Schedule IV controlled
21 substance, as defined in the controlled substances schedules in federal law and regulations,
22 specifically Sections 1308.12, 1308.13, and 1308.14, and respectively, of Title 21 of the Code of
23 Federal Regulations, the dispensing pharmacy, clinic, or other dispenser shall report the following
24 information to the Department of Justice as soon as reasonably possible, but not more than seven
25 days after the date a controlled substance is dispensed, in a format specified by the Department of
26 Justice:

1 (1) Full name, address, and, if available, telephone number of the ultimate user or research
2 subject, or contact information as determined by the Secretary of the United States Department of
3 Health and Human Services, and the gender, and date of birth of the ultimate user.

4 (2) The prescriber's category of licensure, license number, national provider identifier
5 (NPI) number, the federal controlled substance registration number, and the state medical license
6 number of any prescriber using the federal controlled substance registration number of a
7 government-exempt facility, if provided.

8 (3) Pharmacy prescription number, license number, NPI number, and federal controlled
9 substance registration number.

10 (4) National Drug Code (NDC) number of the controlled substance dispensed.

11 (5) Quantity of the controlled substance dispensed.

12 (6) International Statistical Classification of Diseases, 9th revision (ICD-9) or 10th revision
13 (ICD-10) Code, if available.

14 (7) Number of refills ordered.

15 (8) Whether the drug was dispensed as a refill of a prescription or as a first-time request.

16 (9) Date of origin of the prescription.

17 (10) Date of dispensing of the prescription.

18 (11) The serial number for the corresponding prescription form, if applicable."

19 **REGULATIONS**

20 17. California Code of Regulations, title 16, section 1707.4 subdivision (a) states in
21 pertinent part:

22 "A pharmacy licensed by the board may process a request for refill of a prescription
23 received by a pharmacy within this state, provided:..."

24 18. California Code of Regulations, title 16, section 1717.1 subdivision (a) states:

25 "(a) For dangerous drugs other than controlled substances: Two or more pharmacies may
26 establish and use a common electronic file to maintain required dispensing information.
27 Pharmacies using such a common file are not required to transfer prescriptions or information for
28

1 dispensing purposes between or among pharmacies participating in the same common
2 prescription file.”

3 19. California Code of Regulations, title 16, section 1714 states in pertinent part:

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

8

9 (d) Each pharmacist while on duty shall be responsible for the security of the prescription
10 department, including provisions for effective control against theft or diversion of dangerous
11 drugs and devices, and records for such drugs and devices. Possession of a key to the pharmacy
12 where dangerous drugs and controlled substances are stored shall be restricted to a pharmacist.”

13 (e) The pharmacy owner, the building owner or manager, or a family member of a
14 pharmacist owner (but not more than one of the aforementioned) may possess a key to the
15 pharmacy that is maintained in a tamper evident container for the purpose of 1) delivering the key
16 to a pharmacist or 2) providing access in case of emergency. An emergency would include fire,
17 flood or earthquake. The signature of the pharmacist-in-charge shall be present in such a way that
18 the pharmacist may readily determine whether the key has been removed from the container.

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

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

26 Only California-licensed pharmacies, hospitals/clinics with onsite pharmacies, and drug
27 distributors (licensed wholesalers and third-party logistics providers) who are registered with the
28

1 DEA as collectors and licensed in good standing with the board may host a pharmaceutical take-
2 back receptacle as authorized under this article.”

3 21. California Code of Regulations, title 16, section 1776.1 subdivision (h) states:

4 “(h) A pharmacy must be registered with the federal DEA as a collector for purposes of
5 maintaining a prescription drug take-back collection receptacle. Such pharmacies cannot employ
6 anyone convicted of a felony related to controlled substances, or anyone who has had a DEA
7 permit denied, surrendered or revoked.”

8 22. California Code of Regulations, title 16, section 1776.4 subdivision (b) states in
9 pertinent part:

10 “(b) Only pharmacies and hospitals/clinics with onsite pharmacies may establish collection
11 receptacles in skilled nursing facilities for the collection and ultimate disposal of unwanted
12 prescription drugs. A pharmacy and hospital/clinic with an onsite pharmacy maintaining a
13 collection receptacle in a skilled nursing facility shall:

14 (1) Be registered and maintain registration with the DEA as a collector.

15 (2) Notify the board in writing within 30 days of establishing a collection receptacle.

16 (3) Notify the board in writing within 30 days when they cease to maintain the collection
17 receptacle.

18 (4) Notify the board in writing within 14 days of any tampering of the collection receptacle
19 or theft of deposited drugs.

20 (5) Notify the board in writing within 14 days of any tampering, damage or theft of a
21 removed liner.

22 (6) List all collection receptacles it maintains annually at the time of renewal of the
23 pharmacy license.”

24 23. California Code of Regulations, title 16, section 1793.3 states in pertinent part:

25 “(a) In addition to employing a pharmacy technician to perform the tasks specified in
26 section 1793.2, a pharmacy may employ a non-licensed person to type a prescription label or
27 otherwise enter prescription information into a computer record system, but the responsibility for
28 the accuracy of the prescription information and the prescription as dispensed lies with the

1 registered pharmacist who initials the prescription or prescription record. At the direction of the
2 registered pharmacist, a non-licensed person may also request and receive refill authorization.”

3 24. California Code of Regulations, title 16, section 1751.5 states in pertinent part:

4 “(a) When compounding sterile drug preparations the following standards must be met:

5 ...

6 (5) Sterile gloves that have been tested for compatibility with disinfection with isopropyl
7 alcohol are required. Hand cleansing with a persistently active alcohol-based product followed by
8 the donning of sterile gloves may occur within the ante or cleanroom. Gloves are to be routinely
9 disinfected with sterile 70 percent isopropyl alcohol before entering or re-entering the PEC and
10 after contact with non-sterile objects. Gloves shall also be routinely inspected for holes,
11 punctures, or tears and replaced immediately if such are detected.

12”

13 25. California Code of Regulations, title 16, section 1735.5 states in pertinent part:

14 “(a) Any pharmacy engaged in compounding shall maintain written policies and procedures
15 for compounding that establishes procurement procedures, methodologies for the formulation and
16 compounding of drugs, facilities and equipment cleaning, maintenance, operation, and other
17 standard operating procedures related to compounding. Any material failure to follow the
18 pharmacy's written policies and procedures shall constitute a basis for disciplinary action.

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

22 26. California Code of Regulations, title 16, section 1751.1 states in pertinent part:

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

26 (1) Documents evidencing training and competency evaluations of employees in
27 sterile drug preparation policies and procedures.

28 ...

1 (3) Results of assessments of personnel for aseptic techniques including results of
2 media-fill tests and gloved fingertip testing performed in association with media-fill tests.

3 ...

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

6”

7 27. California Code of Regulations, title 16, section 1751.4 states in pertinent part:

8 ...”

9 (j) Viable surface sampling shall be done at least every six months for all sterile-to-sterile
10 compounding and quarterly for all non-sterile-to-sterile compounding. Viable air sampling shall
11 be done by volumetric air sampling procedures which test a sufficient volume of air (400 to 1,000
12 liters) at each location and shall be done at least once every six months. Viable surface and viable
13 air sampling shall be performed by a qualified individual who is familiar with the methods and
14 procedures for surface testing and air sampling. Viable air sampling is to be performed under
15 dynamic conditions that simulate actual production. Viable surface sampling is to be performed
16 under dynamic conditions of actual compounding. When the environmental monitoring action
17 levels are exceeded, the pharmacy shall identify the CFUs at least to the genus level in addition to
18 conducting an investigation pursuant to its policies and procedures. Remediation shall include, at
19 minimum, an immediate investigation of cleaning and compounding operations and facility
20 management.

21”

22 **COST RECOVERY**

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

27 ////

1 **FIRST CAUSE FOR DISCIPLINE**

2 (Failure to Timely File Reports to CURES)

3 29. Respondents Jana Healthcare and Lewis are subject to disciplinary action under
4 Business and Professions Code section 4301, subdivision (o) in conjunction with Health and
5 Safety Code section 11165 subdivision (d) in that Respondents failed to timely report information
6 for each prescription for Schedule II, Schedule III, or Schedule IV controlled substances to the
7 Department of Justice for reporting in its Controlled Substance Utilization Review and Evaluation
8 System (CURES). The information was required to have been reported to the CURES program
9 within seven (7) days after the prescription is dispensed. The circumstances are as follows:

10 30. On or about January 31, 2019 Respondent Lewis provided confirmation that
11 Respondent Jana Healthcare Pharmacy sent a cumulative report to the CURES program where it
12 stated that it had dispensed controlled substances as follows::

13 75 controlled substance prescriptions in June 2018

14 245 controlled substance prescriptions in July 2018

15 254 controlled substance prescriptions in August 2018

16 286 controlled substance prescriptions in September 2018

17 307 controlled substance prescriptions in October 2018

18 279 controlled substance prescriptions in November 2018

19 308 controlled substance prescriptions in December 2018

20 263 controlled substance prescriptions in January 2019

21 **SECOND CAUSE FOR DISCIPLINE**

22 (Unprofessional Conduct – Unlicensed Pharmacy Activity)

23 31. Respondents Jana Healthcare and Lewis are subject to disciplinary action under
24 Business and Professions Code section 4301 subdivision (o), 4037 subdivision (a) in conjunction
25 with title 16 of the California Code of Regulations sections 1707.4 subdivision (a), 1717.1
26 subdivision (a), 1714 subdivisions (b) and (d), 1793.3 subdivision (a), and section 4110 in that on
27
28

1 or before January 24, 2019, pharmacy technician TT¹, using remote access, processed new and
2 refill prescriptions from an unlicensed location (her residence).

3 **THIRD CAUSE FOR DISCIPLINE**

4 (Failure to Obtain Drug Take-Back Registration)

5 32. Respondents Jana Healthcare and Lewis are subject to disciplinary action under
6 Business and Professions Code section 4301, subdivision (o) in conjunction with title 16 of the
7 California Code of Regulations sections 1776, 1776.1 subdivision (h) and 1776.4 subdivision (b)
8 in that on or before September 18, 2018, the pharmacy provided drug take-back services to a
9 skilled nursing facility it serviced without prior registration with the DEA as a collector.

10 **FOURTH CAUSE FOR DISCIPLINE**

11 (Pharmacy Security)

12 33. Respondents Jana Healthcare and Lewis are subject to disciplinary action under
13 Business and Professions Code sections 4116 subdivision (a), title 16 California Code of
14 Regulations section 1714 subdivisions (b), (e) and (d) in that on or about October 28, 2018, and
15 on or about December 13, 2018, MZ² who worked as an operations manager at Respondent Jana
16 Healthcare Pharmacy, was in possession of a key to Respondent Jana Healthcare Pharmacy,
17 however she was not a licensed pharmacist at the time. MZ used the key to open the pharmacy
18 and allow technicians SR and IS to access and enter the pharmacy drug area where dangerous
19 drugs and devices, including controlled substances, were maintained without a pharmacist
20 present.

21 **FIFTH CAUSE FOR DISCIPLINE**

22 (Pharmacist-in-Charge Notification to the Board)

23 34. Respondent Jana Healthcare is subject to disciplinary action under Business and
24 Professions Code sections 4113 subdivisions (d) and (e), and 4305 subdivision (a) and (b) in that
25 on or about on May 20, 2019, Respondent Lewis disassociated as the pharmacist-in charge of
26 Respondent Jana Pharmacy, however Respondent Jana Healthcare Pharmacy did not provide

27 ¹ Initials of non-parties are used in lieu of full names.

28 ² MZ was a licensed pharmacist; however her pharmacy license was revoked as of
November 6, 2015.

written notification of the disassociation to the Board within 30 days. Moreover, Respondent Jana Healthcare Pharmacy continued to operate without a pharmacist-in-charge or an interim pharmacist-in-charge until on or about August 15, 2019 when a new pharmacist-in-charge was proposed to the Board.

SIXTH CAUSE FOR DISCIPLINE

(Unprofessional Conduct - Non-pharmacist taking charge)

35. Respondent Jana Healthcare is subject to disciplinary action under Business and Professions Code sections 4301 subdivision (o) and 4329 in that MZ, an individual whose pharmacist license was revoked as of November 6, 2015 and was not subsequently licensed by the Board, took charge of or acted as a supervisor, manager, or pharmacist-in-charge for Respondent Jana Healthcare.

SEVENTH CAUSE FOR DISCIPLINE

(Failure to Comply with Facility and Equipment Standards for Sterile Compounding)

36. Respondents Jana Healthcare and Lewis are subject to disciplinary action under Business and Professions Code sections 4301 subdivision (o) in conjunction with title 16 of California Code of Regulations section 1751.4 subsection (j) in that after viable sampling performed on or about December 21, 2018 and on or about June 26, 2019 yielded out of specification results, Respondents failed to conduct an investigation and to perform remediation and resampling pursuant to its policies and procedures which require an investigation into the source of the contamination, and once determined, elimination of the contamination source; and cleaning and re-sampling. The table below lists the highly pathogenic microorganisms identified during each instance of sampling.

Highly Pathogenic Microorganisms Identification:

Date of Sampling	Location of sampling	Total Microbial count	Highly Pathogenic Microorganism	Number of colony forming units
12/21/2018	Air in anteroom on rack	12 cfu	Non-sporulating hyaline fungus	2 cfu
12/21/2018	Surface of anteroom wall	<2 cfu	Chaetomium species	1 cfu

6/26/2019	Air in anteroom on rack	128 cfu	Non-sporulating hyaline fungus	4 cfu
			Scopulariopsis species	102 cfu
			Aspergillus species	2 cfu
6/26/2019	Air in IV room on metal table	2 cfu	Scopulariopsis species	2 cfu

EIGHTH CAUSE FOR DISCIPLINE

(Failure to Comply with Sterile Compounding Attire)

37. Respondent Jana Healthcare failed to comply with Business and Professions Code sections 4301 subdivision (o) in conjunction with title 16 of the California Code of Regulations section 1751.5 subsection (a)(5) in that during an inspection on or about July 31, 2019, Respondent Jana Healthcare failed to perform hand cleansing with a persistently active alcohol-based product followed by donning of sterile gloves; no persistently active alcohol-based product was available in the pharmacy; RPH YA and TCH SR were unfamiliar with the concept; and the hand hygiene and garbing policy and procedures did not provide for the use of a persistently active alcohol based product before donning sterile gloves.

NINTH CAUSE FOR DISCIPLINE

(Failure to Comply with Compounding Policies and Procedure)

38. Respondent Jana Healthcare failed to comply with Business and Professions Code sections 4301 subdivision (o) in conjunction with title 16 of the California Code of Regulations section 1735.5 subsection (b) in that between on or about July 31, 2019 and on or about March 9, 2020, Respondent Jana Healthcare failed to provide a documentation of performance of an annual review of the compounding policies and procedures and the last documentation of review of policies and procedures by a pharmacist-in-charge was in 2017 by PIC PM.

TENTH CAUSE FOR DISCIPLINE

(Failure to Comply with Sterile Compounding Recordkeeping Requirements)

39. Respondent Jana Healthcare failed to comply with Business and Professions Code sections 4301 subdivision (o) in conjunction with title 16 of the California Code of Regulations

1 section 1751.1 subsection (a)(1) in that during an inspection on or about July 31, 2019, and as of
2 or about August 13, 2020, Respondent Jana Healthcare Pharmacy failed to provide documents
3 evidencing training, i.e. records of competency on hand hygiene and garbing and on cleaning and
4 disinfection practices for the following:

5 a. RPH GC, who had compounded at least five compounded sterile preparations
6 for Meropenem 2gm/normal saline 100ml, Rx #826847, on or about February 6, 9 and 12, 2019;
7 and

8 b. PIC Demar Lewis, who had compounded at least two compounded sterile
9 preparations for Meropenem 2gm/normal saline 100ml, Rx# 826847, on or about February 7,
10 2019.

11 **ELEVENTH CAUSE FOR DISCIPLINE**

12 (Failure to Comply with Sterile Compounding Recordkeeping Requirements)

13 40. Respondent Jana Healthcare failed to comply with Business and Professions Code
14 sections 4301 subdivision (o) in conjunction with title 16 of the California Code of Regulations
15 section 1751.1 subsection (a)(3) in that during an inspection on or about July 31, 2019, and as of
16 on or about August 3, 2020, Respondent Jana Healthcare failed to provide records of media-fill
17 tests and gloved fingertip testing performed in association with media-fill tests for PIC Demar
18 Lewis, who had compounded at least two compounded sterile preparations for Meropenem
19 2gm/normal saline 100ml, Rx# 826847 on or about February 7, 2019.

20 **TWELFTH CAUSE FOR DISCIPLINE**

21 (Failure to Comply with Sterile Compounding Recordkeeping Requirements)

22 41. Respondent Jana Healthcare failed to comply with Business and Professions Code
23 sections 4301 subdivision (o) in conjunction with title 16 of the California Code of Regulations
24 section 1751.1 subsection (a)(9) in that during an inspection on or about July 31, 2019, and as of
25 on or about August 3, 2020, Respondent Jana Healthcare failed provide records of daily cleaning
26 of facilities and equipment for the months of January 2019, April 2019, June 2019 and July 2019
27 and provided only partial records for May 2019. Additionally, Respondent Jana Healthcare did
28

not document monthly cleaning of walls, ceilings, storage shelving, tables, using a sporicidal agent for the months of December 2018, February 2019, March 2019 and May 2019.

THIRTEENTH CAUSE FOR DISCIPLINE

(Failure to Retain/Maintain Records of Dangerous Drugs and Devices)

42. Respondent Jana Healthcare failed to comply with Business and Professions Code section 4105 subsection (a) in that Respondent Jana Healthcare Pharmacy failed upon initial request dated on or about July 31, 2019, and until or about August 13, 2020, to provide records of disposition of compounded sterile preparations dispensed between July 1, 2018 and July 1, 2019.

DISCIPLINE CONSIDERATIONS

43. To determine the degree of discipline, if any, to be imposed on Respondents Jana Healthcare Pharmacy and Lewis, Complainant alleges as follows:

a. On or about October 21, 2019, in a prior action, the Board of Pharmacy issued Citation Number CI 2019 85511 to Jana Healthcare Pharmacy, PHY 50759 based on violations of Bus. & Prof. Code § 4113(d) [Every pharmacy shall notify the board in writing within 30 (d) days of the date of a change in pharmacist-in-charge] and Bus. & Prof. Code § 4305(b) [Operation of a pharmacy for more than 30 days without supervision or management by a pharmacist-in-charge shall constitute grounds for disciplinary action.] That Citation has been paid and is now final and is incorporated by reference as if fully set forth.

b. On or about December 24, 2014, *In the Matter of the Accusation Against DEMAR LEWIS, III*, Case No. 4658 and OAH No. 2014020154, the Board of Pharmacy issued a Decision and Order adopting the Stipulated Settlement and Disciplinary Order wherein Pharmacist License No. RPH 37541 issued to Demar Lewis III, was issued a letter of public reproof and required to pay costs of \$2,180.05. The circumstances of the discipline were the out of state discipline described as follows:

i. On or about June 17, 2004, in the case entitled *In the Matter of Disciplinary Proceedings Regarding the License to Practice Pharmacy in the State of Colorado of Demar Lewis, R.PH., License NO 13773, Case No. RG PH DLRAU*, Respondent was found by the CBP to be in violation of Colorado pharmacy law for numerous violations of record keeping,

1 labeling and dispensing practices. The action taken by CBP resulted in the suspension of
2 Respondent's license for 14 days followed by three (3) years' probation. Respondent was further
3 restricted from serving as a pharmacist manager, supervisor or consultant at any Colorado outlet,
4 was required to take and pass jurisprudence and professional competency examinations, and
5 provide a complete copy of the disciplinary order to each pharmacy manager and immediate
6 pharmacy supervisor at each location that he practiced.

7 ii. On or about September 1, 2005, in the matter entitled *In the Matter of*
8 *Disciplinary Proceedings Regarding the License to Practice Pharmacy in the State of Colorado*
9 *of Demar Lewis, R.PH., License NO 13773, Case No. RG PH DLVBB*, Respondent was found by
10 the CBP to be in violation of the terms and conditions of his probation under the order taken on
11 June 17, 2004 in Case No. RG PH DLRAU. As a result, the CBP suspended his license for three
12 months, followed by five (5) years' probation with certain terms and conditions.

13 iii. On or about April 1, 2008, in the matter entitled *In the Matter of*
14 *Disciplinary Proceedings Regarding the License to Practice Pharmacy in the State of Colorado*
15 *of Demar Lewis III, R.PH., License NO 13773, Case No. PH 2007-0008*, Respondent was found
16 by the CBP to be in violation of the terms and conditions of his probation under the order taken
17 September 1, 2005 in Case No. RG PH DLVBB. As a result, through a Stipulation and Final
18 Agency Order, the CBP ordered Respondent's license relinquished and cancelled, which has the
19 same force and effect as a revocation ordered by the Board.

20 iv. On or about on July 18, 2018, Citation CI 2014 64366 was issued to Jana
21 Healthcare Pharmacy by the Board for violations of Code sections 4301(g) and (o), 111255 and
22 72371. The citation has been affirmed.

23 **OTHER MATTERS**

24 44. Pursuant to Code section 4307, if discipline is imposed on Pharmacy Permit
25 Number PHY 50759 issued to Jana Healthcare Pharmacy while Demar Lewis III had been an
26 officer and owner and had knowledge of or knowingly participated in any conduct for which the
27 licensee was disciplined, Demar Lewis III shall be prohibited from serving as a manager,
28 administrator, owner, member, officer, director, associate, or partner of a licensee for five years if

Pharmacy Permit Number PHY 50759 is placed on probation or until Pharmacy Permit Number PHY 50759 is reinstated if it is revoked.

45. Pursuant to Code section 4307, if discipline is imposed on Pharmacy Permit Number PHY 50759 issued to Jana Healthcare Pharmacy while Alexandr Akopnik had been an officer and owner and had knowledge of or knowingly participated in any conduct for which the licensee was disciplined, Alexandr Akopnik 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 50759 is placed on probation or until Pharmacy Permit Number PHY 50759 is reinstated if it is revoked.

46. Pursuant to Code section 4307, if discipline is imposed on Pharmacy Permit Number PHY 50759 issued to Jana Healthcare Pharmacy while Mira J. Zeffren had been an undisclosed officer, associate and/or person with management or control and had knowledge of or knowingly participated in any conduct for which the licensee was disciplined, Mira J. Zeffren 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 50759 is placed on probation or until Pharmacy Permit Number PHY 50759 is reinstated if it is revoked.

PRAYER

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

1. Revoking or suspending Pharmacy Permit Number PHY 50759, issued to Arrow-Med Rx Inc. dba Jana Healthcare Pharmacy;

2. Revoking or suspending Sterile Compounding Permit Number LSC 100684, issued to Arrow-Med Rx Inc. dba Jana Healthcare Pharmacy;

3. Revoking or suspending Pharmacist License Number RPH 37541 issued to Demar Lewis III;

4. Prohibiting Demar Lewis III from serving as a manager, administrator, owner, member, officer, director, associate, or partner of a licensee for five years if Pharmacy Permit

Number PHY 50759 is placed on probation or until Pharmacy Permit Number PHY 50759 is reinstated if it is revoked;

5. Prohibiting Alexandr Akopnik from serving as a manager, administrator, owner, member, officer, director, associate, or partner of a licensee for five years if Pharmacy Permit Number PHY 50759 is placed on probation or until Pharmacy Permit Number PHY 50759 is reinstated if it is revoked;

6. Prohibiting Mira J. Zeffren from serving as a manager, administrator, owner, member, officer, director, associate, or partner of a licensee for five years if Pharmacy Permit Number PHY 50759 is placed on probation or until Pharmacy Permit Number PHY 50759 is reinstated if it is revoked;

7. Ordering Arrow-Med Rx Inc. dba Jana Healthcare Pharmacy, and Demar Lewis III, jointly and severally, to pay the Board of Pharmacy the reasonable costs of the investigation and enforcement of this case, pursuant to Business and Professions Code section 125.3; and

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

DATED: 1/19/2021

Signature on File

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

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