

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

In the Matter of the Second Amended Accusation Against:

**SNP PHARMACY LLC doing business as
SKILLED NURSING PHARMACY;
BRENDA MANDELBAUM, BENTZION
MANDELBAUM, and MICHELLE
MANDELBAUM, Owners**

**Original Pharmacy Permit No. PHY 49974,
Sterile Compounding Permit No. LSC 99561,**

and

MINA NASR AYAD NASR

Original Pharmacist License No. RPH 78315,

Respondents.

Agency Case No. 6975

OAH No. 2021090385

DECISION AND ORDER

The attached Stipulated Settlement and Disciplinary Order for Public Reprimand 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 May 25, 2022.

It is so ORDERED on April 25, 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.

Seung W. Oh, Pharm.D.
Board President

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Attorney General of California
2 DIANN SOKOLOFF
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Attorneys for Complainant

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

13 In the Matter of the Accusation Against:

14 **SNP PHARMACY LLC doing business as**
15 **SKILLED NURSING PHARMACY;**
16 **BRENDA MANDELBAUM, BENTZION**
17 **MANDELBAUM, and MICHELLE**
18 **MANDELBAUM, Owners**
19 **21150 Cabot Blvd.**
20 **Hayward, CA 94545**

21 **Original Pharmacy Permit No. PHY 49974,**
22 **Sterile Compounding Permit No. LSC 99561**

23 **and**

24 **MINA NASR AYAD NASR**
25 **5045 Valley Crest Drive, #210**
26 **Concord, CA 94521**

27 **Original Pharmacist License No. RPH 78315**

28 Respondents.

Case No. 6975

OAH No. 2021090385

**STIPULATED SETTLEMENT AND
DISCIPLINARY ORDER FOR PUBLIC
REPROVAL REGARDING MINA NASR
AYAD NASR**

[Bus. & Prof. Code § 495]

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

1 **PARTIES**

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

6 2. Respondent Mina Nasr Ayad Nasr (Respondent) is represented in this proceeding by
7 attorney Tony J. Park of California Pharmacy Lawyers and Law Offices of Tony J. Park, PC,
8 located at 9090 Irvine Center Dr, Irvine, CA 92618-4658.

9 **JURISDICTION**

10 3. On or about March 27, 2018, the Board of Pharmacy issued Original Pharmacist
11 License Number RPH 78315 to Mina Nasr Ayad Nasr (Respondent Nasr). The Original
12 Pharmacist License will expire on August 31, 2023, unless renewed.

13 4. Second Amended Accusation No. 6975 was filed before the Board of Pharmacy
14 (Board), Department of Consumer Affairs and is currently pending against Respondent. The
15 Second Amended Accusation and all other statutorily required documents were properly served
16 on Respondent on or about January 24, 2022. Respondent had previously timely filed his Notice
17 of Defense contesting the Second Amended Accusation. A copy of Second Amended Accusation
18 No. 6975 is attached as exhibit A and incorporated by reference.

19 **ADVISEMENT AND WAIVERS**

20 5. Respondent has carefully read, fully discussed with counsel, and understands the
21 charges and allegations in Accusation No. 6975. Respondent has also carefully read, fully
22 discussed with counsel, and understands the effects of this Stipulated Settlement and Disciplinary
23 Order for Public Repeval.

24 6. Respondent is fully aware of his legal rights in this matter, including the right to a
25 hearing on the charges and allegations in the Accusation; the right to be represented by counsel at
26 its own expense; the right to confront and cross-examine the witnesses against him; the right to
27 present evidence and to testify on his own behalf; the right to the issuance of subpoenas to compel
28 the attendance of witnesses and the production of documents; the right to reconsideration and

1 court review of an adverse decision; and all other rights accorded by the California
2 Administrative Procedure Act and other applicable laws.

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

5 **CULPABILITY**

6 8. Respondent understands and agrees that the charges and allegations in Second
7 Amended Accusation No. 6975, if proven at a hearing, constitute cause for imposing discipline
8 upon his Original Pharmacist License.

9 9. For the purpose of resolving the Second Amended Accusation without the expense
10 and uncertainty of further proceedings, Respondent agrees that, at a hearing, Complainant could
11 establish a factual basis for the charges in the Second Amended Accusation, and that Respondent
12 hereby gives up his right to contest those charges.

13 10. Respondent further agrees that his Original Pharmacist License is subject to discipline
14 and he agrees to be bound by the Disciplinary Order below.

15 11. In addition, if the Board files an Accusation against Respondent in a future action,
16 then the charges and allegations in Second Amended Accusation No. 6975 shall be deemed to be
17 true and correct.

18 **CONTINGENCY**

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

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

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

15. 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 Original Pharmacist License No. RPH 78315, issued to Mina Nasr Ayad Nasr (Respondent) shall be publicly reproved by the Board of Pharmacy under Business and Professions Code section 495 in resolution of Accusation No. 6975, attached as exhibit A.

Remedial Education

Within thirty (30) days of the effective date of this decision, Respondent shall submit to the Board or its designee, for prior approval, an appropriate program of remedial education consisting of 10 hours in compounding (USP 797) presented by live webinar or in person. The remedial education shall be completed within one year from the effective date of the decision at Respondent's own expense. Respondent shall submit to the Board the original transcripts or certificates of completion for the above-required course(s). All remedial education shall be in addition to, and shall not be credited toward, continuing education (CE) courses used for license renewal purposes for pharmacists.

1 **Full Compliance**

2 As a resolution of the charges in Accusation No. 6975, this stipulated settlement is
3 contingent upon Respondent's full compliance with all conditions of this Order. If Respondent
4 fails to satisfy any of these conditions, such failure to comply constitutes cause for discipline,
5 including outright revocation, of Respondent's Original Pharmacist Permit.

6 **ACCEPTANCE**

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

12
13 DATED: _____

14 MINA NASR AYAD NASR
 Respondent

15 I have read and fully discussed with Respondent Mina Nasr Ayad Nasr the terms and
16 conditions and other matters contained in the above Stipulated Settlement and Disciplinary Order
17 for Public Reproval. I approve its form and content.

18
19 DATED: _____

20 TONY J. PARK
 Attorney for Respondent

1 **Full Compliance**

2 As a resolution of the charges in Accusation No. 6975, this stipulated settlement is
3 contingent upon Respondent's full compliance with all conditions of this Order. If Respondent
4 fails to satisfy any of these conditions, such failure to comply constitutes cause for discipline,
5 including outright revocation, of Respondent's Original Pharmacist Permit.

6 **ACCEPTANCE**

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

12
13 DATED: 03/2/22

14 Mina Nasr
 MINA NASR AYAD NASR
 Respondent

15 I have read and fully discussed with Respondent Mina Nasr Ayad Nasr the terms and
16 conditions and other matters contained in the above Stipulated Settlement and Disciplinary Order
17 for Public Repeval. I approve its form and content.

18
19 DATED: _____

20 TONY J. PARK
 Attorney for Respondent

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ACCEPTANCE

DATED:

DATED: 03/02/2022

5

ENDORSEMENT

The foregoing Stipulated Settlement and Disciplinary Order for Public Reapproval 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
DIANN SOKOLOFF
Supervising Deputy Attorney General

ASPASIA A. PAPAVALASSILOU
Deputy Attorney General
Attorneys for Complainant

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ENDORSEMENT

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

DATED: March 2, 2022

Respectfully submitted,

ROB BONTA
Attorney General of California
DIANN SOKOLOFF
Supervising Deputy Attorney General



ASPASIA A. PAPA VASSILIOU
Deputy Attorney General
Attorneys for Complainant

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Exhibit A

Accusation No. 6975

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2 DIANN SOKOLOFF
Supervising Deputy Attorney General
3 ASPASIA A. PAPAVALASSILOU
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7 E-mail: aspasia.papavassiliou@doj.ca.gov
Attorneys for Complainant

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24 **MINA NASR AYAD NASR**
25 **5045 Valley Crest Drive, #210**
26 **Concord, CA 94521**

27 **Original Pharmacist License No. RPH 78315**

28 Respondents.

Case No. 6975

OAH No. 2021090385

SECOND AMENDED
ACCUSATION

PARTIES

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

2. On or about December 21, 2009, the Board of Pharmacy issued Original Pharmacy Permit Number PHY 49974 and Sterile Compounding Permit Number LSC 99561 to SNP Pharmacy Inc., doing business as Skilled Nursing Pharmacy, with Brenda Mandelbaum as 50-percent shareholder; Bentzion Mandelbaum as President and 25-percent shareholder, and Michelle Mandelbaum as Director and 25-percent shareholder. On April 22, 2019, SNP Pharmacy, Inc. changed its corporate name to SNP Pharmacy LLP (Respondent SNP). The Original Pharmacy Permit and Sterile Compounding Permit were in full force and effect at all times relevant to the charges brought here and will expire on December 1, 2022, unless renewed.

3. On or about March 27, 2018, the Board of Pharmacy issued Original Pharmacist License Number RPH 78315 to Mina Nasr Ayad Nasr (Respondent Nasr). The Original Pharmacist License was in full force and effect at all times relevant to the charges brought here and will expire on August 31, 2023, unless renewed.

4. Respondent Nasr has been designated as Respondent SNP's Pharmacist-in-Charge (PIC) since December 31, 2018.

JURISDICTION

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

6. Section 4011 of the Code states, in pertinent part:

The board shall administer and enforce this chapter and the Uniform Controlled Substances Act (Division 10 (commencing with Section 11000) of the Health and Safety Code).

7. Section 4300 of the Code states:

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

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

(1) Suspending judgment.

(2) Placing him or her upon probation.

(3) Suspending his or her right to practice for a period not exceeding one year.

(4) Revoking his or her license.

(5) Taking any other action in relation to disciplining him or her as the board in its discretion may deem proper.

(c) The board may refuse a license to any applicant guilty of unprofessional conduct. The board may, in its sole discretion, issue a probationary license to any applicant for a license who is guilty of unprofessional conduct and who has met all other requirements for licensure. The board may issue the license subject to any terms or conditions not contrary to public policy, including, but not limited to, the following:

(1) Medical or psychiatric evaluation.

(2) Continuing medical or psychiatric treatment.

(3) Restriction of type or circumstances of practice.

(4) Continuing participation in a board-approved rehabilitation program.

(5) Abstention from the use of alcohol or drugs.

(6) Random fluid testing for alcohol or drugs.

(7) Compliance with laws and regulations governing the practice of pharmacy.

(d) The board may initiate disciplinary proceedings to revoke or suspend any probationary certificate of licensure for any violation of the terms and conditions of probation. Upon satisfactory completion of probation, the board shall convert the probationary certificate to a regular certificate, free of conditions.

(e) The proceedings under this article shall be conducted in accordance with Chapter 5 (commencing with Section 11500) of Part 1 of Division 3 of the Government Code, and the board shall have all the powers granted therein. The action shall be final, except that the propriety of the action is subject to review by the superior court pursuant to Section 1094.5 of the Code of Civil Procedure.

8. Section 4300.1 of the Code states:

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

9. Section 4307, subdivision (a), of the Code states:

“Any person who has been denied a license or whose license has been revoked or is under suspension, or who has failed to renew his or her license while it was under suspension, or who

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

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

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

14 **STATUTORY PROVISIONS**

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

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

18 11. Section 4126.8 of the Code states:

19 The compounding of drug preparations by a pharmacy for furnishing, distribution, or
20 use in this state shall be consistent with standards established in the pharmacy
21 compounding chapters of the current version of the United States Pharmacopeia-National
22 Formulary, including relevant testing and quality assurance. The board may adopt
23 regulations to impose additional standards for compounding drug preparations.

24 12. Section 4301 of the Code states:

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

28 . . .

(o) Violating or attempting to violate, directly or indirectly, or assisting in or
abetting the violation of or conspiring to violate any provision or term of this chapter
or of the applicable federal and state laws and regulations governing pharmacy,

including regulations established by the board or by any other state or federal regulatory agency.

13. Section 4306.5 states, in pertinent part:

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

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

(b) Acts or omissions that involve, in whole or in part, the failure to exercise or implement his or her best professional judgment or corresponding responsibility with regard to the dispensing or furnishing of controlled substances, dangerous drugs, or dangerous devices, or with regard to the provision of services.

REGULATORY PROVISIONS

14. California Code of Regulations, title 16, section 1714, subdivision (b), states:

“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.”

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

...

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

...

(4) Inactive ingredients to be used.

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

...

(g) The pharmacist performing or supervising compounding is responsible for the integrity, potency, quality, and labeled strength of a compounded drug preparation until the beyond use date indicated on the label, so long as label instructions for storage and handling are followed after the preparation is dispensed.

1 16. California Code of Regulations, title 16, section 1735.3 states, in pertinent part:

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

3 . . .

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

6 . . .

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

8 17. California Code of Regulations, title 16, section 1751.7 states, in pertinent part:

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

18 . . .

19 (3) The pharmacy's validation process on aseptic technique and aseptic area
20 practices must be revalidated whenever:

21 . . .

22 (B) there is any change in the compounding process, the Primary Engineering
23 Control (PEC), or the compounding environment. For purposes of this subsection, a
24 change includes, but is not limited to, when the PEC is moved, repaired or replaced,
when the facility is modified in a manner that affects airflow or traffic patterns, or
when improper aseptic techniques are observed.

24 **COST RECOVERY**

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

1 **DRUG DEFINITION**

2 19. Vancomycin is an antibiotic that when taken orally is used to treat bacterial intestinal
3 infections. It is designated as a dangerous drug under Business and Professions Code section
4 4022.

5 **FACTUAL ALLEGATIONS**

6 **VANCOMYCIN COMPOUNDING**

7 20. From December 1, 2018, to February 1, 2019, Respondents reconstituted vancomycin
8 5gram vials to compound at least 335 sterile compounded preparations with the incorrect amount
9 of sterile water. Moreover, the compounding logs lacked documentation of the identity of the
10 pharmacist who performed the quality review of the final product; the master formula for
11 vancomycin in sodium chloride 0.9% sterile compounds failed to include the sterile water used
12 for reconstitution of the vancomycin powder vial used in compounding; and the master formula
13 failed to include directions for reconstituting the vancomycin vial used in compounding.

14 **REFRIGERATOR TEMPERATURE**

15 21. From January 1, 2020, to October 31, 2020, Respondent SNP's refrigerator
16 temperature recordings were out of the range of the 36 to 46 degrees Fahrenheit required for the
17 proper storage of medications for 239 out of 305 days.

18 **CLEANROOM RENOVATIONS**

19 22. From April 28, 2021, the date after completion of renovations of Respondent SNP's
20 cleanroom, including replacement of the floor and work on the ante room ceiling, as well as
21 replacement of the laminar flow hood, to May 14, 2021, the date when SNP received
22 environmental sampling results, SNP compounded at least 180 sterile preparations, including at
23 least 17 total parenteral nutrition (medium risk compounds). Moreover, from April 28, 2021,
24 after the Primary Engineering Control (PEC) was replaced, to May 20, 2021, the date of the first
25 results of employee testing to validate aseptic technique in the new PEC, Respondent SNP
26 compounded at least 200 sterile preparations, of which at least 25 were total parental nutrition
27 (medium risk compounds).
28

1 **CAUSES FOR DISCIPLINE AGAINST RESPONDENT SNP**

2 **FIRST CAUSE FOR DISCIPLINE - SNP**

3 **(Incorrect Reconstitution of Compounded Drug Preparation)**
4 **(Bus. & Prof. Code, § 4301, subd. (o); Cal. Code Regs., tit. 16, § 1735.2, subd. (g))**

5 23. Respondent SNP's Original Pharmacy Permit and Sterile Compounding Permit are
6 subject to disciplinary action because Respondent SNP compounded at least 335 vancomycin
7 sterile preparations with vancomycin 5gram vials which were reconstituted with 50mls of sterile
8 water rather than the manufacturer's FDA approved package insert instructions of 100mls of
9 sterile water. The circumstances are set forth in paragraph 20, above. (Bus. & Prof. Code, §
4301, subd. (o); Cal. Code Regs., tit. 16, § 1735.2, subd. (g).)

10 **SECOND CAUSE FOR DISCIPLINE - SNP**

11 **(Incomplete Compounding Records)**
12 **(Bus. & Prof. Code, § 4301, subd. (o); Cal. Code Regs., tit. 16, § 1735.3, subd. (a)(2)(D))**

13 24. Respondent SNP's Original Pharmacy Permit and Sterile Compounding Permit are
14 subject to disciplinary action because Respondent SNP failed to keep complete compounding
15 records, as set forth in paragraph 20, above. (Bus. & Prof. Code, § 4301, subd. (o); Cal. Code
16 Regs., tit. 16, § 1735.3, subd. (a)(2)(D).)

17 **THIRD CAUSE FOR DISCIPLINE - SNP**

18 **(Incomplete Master Formula)**
19 **(Bus. & Prof. Code, § 4301, subd. (o); Cal. Code Regs., tit. 16, § 1735.2,**
20 **subds. (e)(4) and (e)(5))**

21 25. Respondent SNP's Original Pharmacy Permit and Sterile Compounding Permit are
22 subject to disciplinary action because Respondent SNP failed to prepare a written master formula
23 document that includes inactive ingredients to be used, and specific and essential compounding
24 steps used to prepare the drug, before compounding a drug preparation, as set forth in paragraph
20, above. (Bus. & Prof. Code, § 4301, subd. (o); Cal. Code Regs., tit. 16, § 1735.3, subds. (e)(4)
and (e)(5).)

25 **FOURTH CAUSE FOR DISCIPLINE - SNP**

26 **(Failure to Maintain Operational Standards and Security)**
27 **(Bus. & Prof. Code, § 4301, subd. (o); Cal. Code Regs., tit. 16, § 1714, subd. (b))**

28 26. Respondent SNP's Original Pharmacy Permit and Sterile Compounding Permit are
subject to disciplinary action because Respondent SNP failed to maintain operational standards

1 and security. (Bus. & Prof. Code, §§ 4301, subd. (o), 4306.5, subds. (a) and (b); Cal. Code Regs.,
2 tit. 16, § 1714, subd. (b).) The circumstances are set forth in paragraph 21, above.

3 **FIFTH CAUSE FOR DISCIPLINE - SNP**
4 **(Compounding after Renovation without Environmental Sampling)**
5 **(Bus. & Prof. Code, §§ 4301, subd. (o), and 4126.8)**

6 27. Respondent SNP's Original Pharmacy Permit and Sterile Compounding Permit are
7 subject to disciplinary action because it engaged compounding sterile preparations after
8 compounding room renovations without waiting for environmental sampling results as required
9 by United States Pharmacopeia-National Formulary (USP), which states that environmental
10 sampling shall occur as part of a comprehensive quality management program and shall occur
11 minimally under any of the following conditions: as part of the commissioning and certification
12 of new facilities and equipment and following any servicing of facilities and equipment. (Bus. &
13 Prof. Code, §§ 4301, subd. (o), and 4126.8.) The circumstances are described in paragraph 22,
14 above

15 **SIXTH CAUSE FOR DISCIPLINE - SNP**
16 **(Compounding after PEC Change without Validation of Compounding Personnel)**
17 **(Bus. & Prof. Code, § 4301, subd. (o); Cal. Code Regs., tit. 16, § 1751.7, subd. (b)(3)(B))**

18 28. Respondent SNP's Original Pharmacy Permit and Sterile Compounding Permit are
19 subject to disciplinary action because it engaged in compounding of sterile preparations after a
20 change in the Primary Engineering Control or compounding environment without first ensuring
21 that compounding personnel demonstrated competency on aseptic technique and aseptic area
22 practices. The circumstances are described in paragraph 22, above. (Bus. & Prof. Code, § 4301,
23 subd. (o); Cal. Code Regs., tit. 16, § 1751.7, subd. (b)(3)(B).)

24 **CAUSES FOR DISCIPLINE AGAINST RESPONDENT NASR**

25 **FIRST CAUSE FOR DISCIPLINE - NASR**
26 **(Incorrect Reconstitution of Compounded Drug Preparation)**
27 **(Bus. & Prof. Code, §§ 4113, subd. (c), 4301, subd. (o), 4306.5, subds. (a) and (b); Cal. Code**
28 **Regs., tit. 16, § 1735.2, subd. (g))**

29 29. Respondent Nasr's Original Pharmacist License is subject to disciplinary action
30 because between December 31, 2018 and February 1, 2019, while Respondent Nasr was PIC,
31 Respondent SNP compounded at least 149 vancomycin sterile preparations with vancomycin

5gram vials which were reconstituted with 50mls of sterile water rather than the manufacturer's instructions of 100mls of sterile water. The circumstances are set forth in paragraph 20, above. (Bus. & Prof. Code, §§ 4113, subd. (c), 4301, subd. (o), 4306.5, subds. (a) and (b); Cal. Code Regs., tit. 16, § 1735.2, subd. (g).)

**SECOND CAUSE FOR DISCIPLINE - NASR
(Incomplete Compounding Records)
(Bus. & Prof. Code, §§ 4113, subd. (c), 4301, subd. (o), 4306.5, subds. (a) and (b); Cal. Code Regs., tit. 16, § 1735.3, subd. (a)(2)(D))**

30. Respondent Nasr's Original Pharmacist License is subject to disciplinary action because between December 31, 2018, and February 1, 2019, while Respondent Nasr was PIC, Respondent SNP failed to keep complete compounding records, as set forth in paragraph 20, above. (Bus. & Prof. Code, §§ 4113, subd. (c), 4301, subd. (o), 4306.5, subds. (a) and (b); Cal. Code Regs., tit. 16, § 1735.3, subd. (a)(2)(D).)

**THIRD CAUSE FOR DISCIPLINE - NASR
(Incomplete Master Formula)
(Bus. & Prof. Code, §§ 4113, subd. (c), 4301, subd. (o), 4306.5, subds. (a) and (b); Cal. Code Regs., tit. 16, § 1735.2, subds. (e)(4) and (e)(5))**

31. Respondent Nasr's Original Pharmacist License is subject to disciplinary action because between December 31, 2018 and February 1, 2019, while Respondent Nasr was PIC, Respondent SNP failed to prepare a written master formula document that includes inactive ingredients to be used, and specific and essential compounding steps used to prepare the drug, before compounding a drug preparation, as set forth in paragraph 20, above. (Bus. & Prof. Code, §§ 4113, subd. (c), 4301, subd. (o), 4306.5, subds. (a) and (b); Cal. Code Regs., tit. 16, § 1735.2, subds. (e)(4) and (e)(5).)

**FOURTH CAUSE FOR DISCIPLINE - NASR
(Failure to Maintain Operational Standards and Security)
(Bus. & Prof. Code, §§ 4113, subd. (c), 4301, subd. (o), 4306.5, subds. (a) and (b); Cal. Code Regs., tit. 16, § 1714, subd. (b))**

32. Respondent Nasr's Original Pharmacist License is subject to disciplinary action because he failed to maintain operational standards and security while as PIC of Respondent SNP. (Bus. & Prof. Code, §§ 4113, subd. (c), 4301, subd. (o), 4306.5, subds. (a) and (b); Cal. Code

1 Regs., tit. 16, § 1714, subd. (b).) The circumstances are set forth in paragraph 21, above.

2 **FIFTH CAUSE FOR DISCIPLINE - NASR**
3 **(Compounding after Renovation without Environmental Sampling)**
4 **(Bus. & Prof. Code, §§ 4113, subd. (c), 4301, subd. (o), and 4126.8)**

5 33. Respondent Nasr's Original Pharmacist License is subject to disciplinary action
6 because as PIC of Respondent SNP he authorized compounding sterile preparations after
7 compounding room renovations without waiting for environmental sampling results as required
8 by United States Pharmacopeia-National Formulary (USP), which states that environmental
9 sampling shall occur as part of a comprehensive quality management program and shall occur
10 minimally under any of the following conditions: as part of the commissioning and certification
11 of new facilities and equipment and following any servicing of facilities and equipment. (Bus. &
12 Prof. Code, §§ 4113, subd. (c), 4301, subd. (o), and 4126.8.) The circumstances are described in
13 paragraph 22, above.

14 **SIXTH CAUSE FOR DISCIPLINE - NASR**
15 **(Compounding after PEC Change without Validation of Compounding Personnel)**
16 **(Bus. & Prof. Code, §§ 4113, subd. (c), and 4301, subd. (o); Cal. Code Regs., tit. 16, § 1751.7,**
17 **subd. (b)(3)(B))**

18 34. Respondent Nasr's Original Pharmacist License is subject to disciplinary action
19 because as PIC of Respondent PIC he authorized compounding of sterile preparations after a
20 change in the Primary Engineering Control or compounding environment without first ensuring
21 that compounding personnel demonstrated competency on aseptic technique and aseptic area
22 practices. The circumstances are described in paragraph 22, above. (Bus. & Prof. Code, §§ 4113,
23 subd. (c), 4301, subd. (o); Cal. Code Regs., tit. 16, § 1751.7, subd. (b)(3)(B).)

24 **DISCIPLINE CONSIDERATIONS**

25 To determine the degree of discipline to be imposed on Respondents, Complainant
26 further alleges that the Board issued Respondents the below-listed citations, which are now final.

27 **RESPONDENT SNP ONLY**

28 35. On or about August 16, 2017, Respondent SNP was issued Citation No. CI 2017
75997 for its pharmacy permit and Citation No. CI 2016 7286 for its sterile compounding permit
for the following violations, discovered during an inspection on or about November 2, 2016:

- The annual review of compounding policies and procedures had not been documented as reviewed by the Pharmacist in Charge, in violation of California Code of Regulations, title 16, section 1735.5, subdivision (b);
- The weekly cleaning of the walls, ceilings, floors, shelves, tables and stools had not been documented from March 2016 to October 2016, in violation of California Code of Regulations, title 16, section 1751.4(d);
- The refrigerator temperatures were outside the stated acceptable temperature range approximately 38 times between March 2016 and October 2016, in violation of California Code of Regulations, title, section 1714, subdivision (b);
- Prescription number 7235121 failed to list the inactive ingredient and amount used to reconstitute the active ingredient, in violation of the California Code of Regulations, title 16, section 1735.3(a)(5); and
- Prescription number 7235121 failed to list the inactive ingredient manufacturer, lot number and expiration date used to reconstitute the active ingredient, in violation of California Code of Regulations, title 16, section 1735.3(a)(6).

36. On or about May 14, 2020, Respondent SNP was issued Citation No. CI 2018 82624 regarding its pharmacy permit for failing to review a patient's drug therapy and medication record, in violation of California Code of Regulations, title 16, section 1707.3, and for failing to verify an uncertain or erroneous prescription, in violation of California Code of Regulations, title 16, section 1761. Specifically, on July 11, 2018, SNP pharmacist CN failed to screen for severe potential drug therapy problems while reviewing RX# 7958076 and dispensing the prescription to ME without contacting the prescriber to validate the uncertain direction of daily dosing of methotrexate for the treatment of rheumatoid arthritis; and on July 24, 2018, SNP pharmacist AD failed to screen for severe potential drug therapy problems while reviewing RX# 7973015 and dispensing the prescription to ME without contacting the prescriber to validate the uncertain direction of daily dosing of methotrexate for the treatment of rheumatoid arthritis. ME was dispensed methotrexate 2.5 mg with directions to take one tablet daily instead of four tablets weekly, and subsequently suffered from methotrexate toxicity, ultimately resulting in patient

1 death. Additionally, RX# 7958076 and RX# 7973015 were dispensed pursuant to faxed discharge
2 instructions, and not a valid chart order or telephone order from the facility. Furthermore, the
3 dispensing pharmacist failed to contact the prescriber to obtain an oral order or to verify the
4 uncertain order prior to dispensing the prescription.

5 **RESPONDENTS SNP AND NASR**

6 37. On or about May 21, 2020, Respondent SNP was issued Citation No. CI 2019 87894
7 for its pharmacy permit and Citation No. CI 2019 86128 its sterile compounding permit, and
8 Respondent Nasr was issued Citation No. CI 2019 87893. The basis for the citations was that on
9 or about October 30, 2019, Respondents failed to ensure that all equipment used in the designated
10 area or cleanroom was made of a material that could be easily cleaned and disinfected (Cal. Code
11 Regs., tit. 16, § 1751.4, subds. (c) and (e)); and Respondents failed to ensure adequate training of
12 sterile injectable compounding staff (Cal. Code Regs., tit. 16, § 1751.6, subd. (e)(1)).
13 Specifically, a technician failed to properly demonstrate the cleaning of the laminar air flow
14 workbench (LAFW) and did not know the cleaning agents required and their dwell times for use.
15 In addition, the technician failed to clean the ceiling and back wall of the LAFW and there was no
16 ceiling panel covering the light fixture allowing staff to clean the ceiling. Furthermore, the
17 pharmacy also had a hole in the ceiling making the ISO 7 buffer room exposed to outside air and
18 a rolling stool with a plastic bag covering the seat making these areas not cleanable surfaces.
19 Finally, the pharmacy failed to have complete training records for all their compounding staff.

20 **OTHER MATTERS**

21 38. Pursuant to section 4307 of the Code, if discipline is imposed on Original Pharmacy
22 Permit Number PHY 49974, issued to SNP Pharmacy LLC., doing business as Skilled Nursing
23 Pharmacy with Brenda Mandelbaum as 50-percent shareholder, Bentzion Mandelbaum as
24 President and 25-percent shareholder, and Michelle Mandelbaum as Director and 25-percent
25 shareholder, while Brenda Mandelbaum, Bentzion Mandelbaum, and Michelle Mandelbaum were
26 shareholders of Skilled Nursing Pharmacy and had knowledge of or knowingly participated in
27 any conduct for which Original Pharmacy Permit Number PHY 49974 was disciplined, Brenda
28 Mandelbaum, Bentzion Mandelbaum, and Michelle Mandelbaum shall be prohibited from serving

as a manager, administrator, owner, member, officer, director, associate, or partner of a licensee for five years if Original Pharmacy Permit Number PHY 49974 is placed on probation or until Original Permit Number PHY 49974 is reinstated if it is revoked.

PRAYER

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

1. Revoking or suspending Original Pharmacy Permit Number PHY 49974, issued to SNP Pharmacy LLC doing business as Skilled Nursing Pharmacy;
2. Revoking or suspending Sterile Compounding Permit Number LSC 99561, issued to SNP Pharmacy LLC doing business as Skilled Nursing Pharmacy;
3. Revoking or suspending Original Pharmacist License Number RPH 78315, issued to Mina Nasr Ayad Nasr;
4. Prohibiting Brenda Mandelbaum, Bentzion Mandelbaum, and Michelle Mandelbaum from serving as a manager, administrator, owner, member, officer, director, associate, or partner of a licensee for five years if Original Pharmacy Permit Number PHY 49974 is placed on probation or until Original Pharmacy Permit Number PHY 49974 is reinstated if Original Pharmacy Permit Number 49974 issued to SNP Pharmacy LLC doing business as Skilled Nursing Pharmacy, is revoked;
5. Ordering SNP Pharmacy LLC and Mina Nasr Ayad Nasr 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,
6. Taking such other and further action as deemed necessary and proper.

DATED: 1/24/2022

Signature on File

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

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