

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

In the Matter of the Accusation Against:

UNITED PHARMACY LLC,

**Non-Resident Pharmacy Permit No. NRP 1278 and Non-Resident
Sterile Compounding Permit No. NSC 99795;**

Respondent

Agency Case No. 6969

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 March 26, 2021.

It is so ORDERED on February 24, 2021.

BOARD OF PHARMACY
DEPARTMENT OF CONSUMER AFFAIRS
STATE OF CALIFORNIA

A handwritten signature in black ink, appearing to read "Greg Lippe", is written over the printed name.

By

Greg Lippe
Board President

1 XAVIER BECERRA
Attorney General of California
2 KENT D. HARRIS
Supervising Deputy Attorney General
3 MABEL LEW
Deputy Attorney General
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7 *Attorneys for Complainant*

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

12 In the Matter of the Accusation Against:

13 **UNITED PHARMACY LLC**
14 **3951 N. Haverhill Road, Ste. 120-121**
West Palm Beach, FL 33417

15 **Non-Resident Pharmacy Permit No. NRP 1278**
16 **Non-Resident Sterile Compounding Permit No. NSC 99795**

17 Respondent.

Case No. 6969

**STIPULATED
SETTLEMENT AND
DISCIPLINARY ORDER
FOR PUBLIC REPROVAL
AND STIPULATED
SURRENDER**

[Bus. & Prof. Code § 495]

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19
20 IT IS HEREBY STIPULATED AND AGREED by and between the parties to the above-
21 entitled proceedings that the following matters are true:

22 **PARTIES**

23 1. Anne Sodergren (Complainant) is the Executive Officer of the Board of Pharmacy
24 (Board). She brought this action solely in her official capacity and is represented in this matter by
25 Xavier Becerra, Attorney General of the State of California, by Mabel Lew, Deputy Attorney
26 General.

27 2. Respondent United Pharmacy LLC (Respondent) does not have a licensed California
28 attorney as its representative in this proceeding.

3. On or about December 24, 2012, the Board issued Non-Resident Pharmacy Permit Number NRP 1278 to Respondent. The Non-Resident Pharmacy Permit was in full force and effect at all times relevant to the charges brought in Accusation No. 6969 and will expire on December 1, 2020, unless renewed.

4. On or about March 14, 2013, the Board issued Non-Resident Sterile Compounding Permit Number NSC 99795 to Respondent. The Non-Resident Sterile Compounding Permit was in full force and effect at all times relevant to the charges brought in Accusation No. 6969 and will expire on December 1, 2020, unless renewed.

JURISDICTION

5. Accusation No. 6969 (Accusation) was filed before the Board and is currently pending against Respondent. The Accusation and all other statutorily required documents were properly served on Respondent on August 7, 2020. Respondent timely filed its Notice of Defense contesting the Accusation. A copy of Accusation No. 6969 is attached as exhibit A and incorporated herein by reference.

ADVISEMENT AND WAIVERS

6. Respondent has carefully read, fully discussed with counsel, and understands the charges and allegations in the Accusation. Respondent has also carefully read, and understands the effects of this Stipulated Settlement and Disciplinary Order for Public Reprimand and Stipulated Surrender.

7. Respondent is fully aware of its legal rights in this matter, including the right to a hearing on the charges and allegations in the Accusation; the right to be represented by counsel at its own expense; the right to confront and cross-examine the witnesses against them; the right to present evidence and to testify on its own behalf; the right to the issuance of subpoenas to compel the attendance of witnesses and the production of documents; the right to reconsideration and court review of an adverse decision; and all other rights accorded by the California Administrative Procedure Act and other applicable laws.

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

1 **CULPABILITY**

2 9. Respondent understands and agrees that the charges and allegations in the
3 Accusation, if proven at a hearing, constitute cause for imposing discipline upon its Non-Resident
4 Pharmacy Permit Number NRP 1278 and Non-Resident Sterile Compounding Permit Number
5 NSC 99795.

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

10 11. Respondent understands that by signing this Stipulated Settlement and Disciplinary
11 Order for Public Reprimand and Stipulated Surrender (Stipulation), it enables the Board to issue an
12 order accepting the surrender of Non-Resident Sterile Compounding Permit Number NSC 99795.
13 Respondent agrees that its Non-Resident Pharmacy Permit Number NRP 1278 is subject to
14 discipline and agrees to be bound by the Disciplinary Order below.

15 **CONTINGENCY**

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

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

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

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

13 **DISCIPLINARY ORDER**

14 IT IS HEREBY ORDERED that Non-Resident Pharmacy Permit Number NRP 1278 issued
15 to Respondent shall be publicly reapproved by the Board of Pharmacy under Business and
16 Professions Code section 495 in resolution of Accusation No. 6969, attached as exhibit A.

17 **Cost Recovery.** Respondent shall pay \$14,864.25 to the Board for its costs associated with
18 the investigation and enforcement of this matter. Respondent shall be permitted to pay these
19 costs in a payment plan approved by the Board. If Respondent fails to pay the Board costs as
20 ordered, Respondent shall not be allowed to renew its Non-Resident Pharmacy Permit NRP 1278
21 until Respondent pays costs in full.

22 IT IS HEREBY FURTHER ORDERED that Non-Resident Sterile Compounding Permit
23 Number NSC 99795, issued to Respondent, is surrendered and accepted by the Board.

24 1. Respondent surrenders Non-Resident Sterile Compounding Permit Number NSC
25 99795 as of the effective date of this Decision.

26 2. The surrender of Respondent's Non-Resident Sterile Compounding Permit Number
27 NSC 99795 and acceptance of the surrendered license by the Board shall constitute the imposition
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1 of discipline against Respondent. This Stipulation constitutes a record of discipline and shall
2 become a part of Respondent's license history with the Board of Pharmacy.

3 3. Respondent shall lose all rights and privileges as a non-resident sterile compounding
4 pharmacy in California as of the effective date of the Board's Decision and Order.

5 4. Respondent shall cause to be delivered to the Board its pocket licenses and, if one
6 was issued, its wall certificates on or before the effective date of the Decision and Order.

7 5. Respondent may not reapply or petition the Board for reinstatement of the
8 surrendered permit for three years from the effective date of this Decision and Order.

9 6. If Respondent ever applies for an application for a licensed sterile compounding
10 permit or a petition for reinstatement in the State of California, the Board shall treat it as a new
11 application for a permit. Respondent must comply with all the laws, regulations, and procedures
12 for licensure in effect at the time the application or petition is filed, and all of the charges and
13 allegations contained in Accusation No. 6969 shall be deemed to be true, correct and admitted by
14 Respondent when the Board determines to grant or deny the application or petition.

15
16 **ACCEPTANCE**

17 I have carefully read the above Stipulated Settlement and Disciplinary Order for Public
18 Reproval and Stipulated Surrender. I understand the stipulation and the effect it will have on
19 Non-Resident Pharmacy Permit NRP 1278, and Non-Resident Sterile Compounding Permit NSC
20 99795. I enter into this Stipulated Settlement and Disciplinary Order for Public Reproval and
21 Stipulated Surrender voluntarily, knowingly, and intelligently, and agree to be bound by the
22 Decision and Order of the Board of Pharmacy.

23
24 DATED: _____

25 MINA BANOUB, PHARMACIST-IN-CHARGE
26 UNITED PHARMACY LLC
27 *Respondent*
28

1 of discipline against Respondent. This Stipulation constitutes a record of discipline and shall
2 become a part of Respondent's license history with the Board of Pharmacy.

3 3. Respondent shall lose all rights and privileges as a non-resident sterile compounding
4 pharmacy in California as of the effective date of the Board's Decision and Order.

5 4. Respondent shall cause to be delivered to the Board its pocket licenses and, if one
6 was issued, its wall certificates on or before the effective date of the Decision and Order.


7 5. Respondent may not reapply or petition the Board for reinstatement of the
8 surrendered permit for three years from the effective date of this Decision and Order.

9 6. If Respondent ever applies for an application for a licensed sterile compounding
10 permit or a petition for reinstatement in the State of California, the Board shall treat it as a new
11 application for a permit. Respondent must comply with all the laws, regulations, and procedures
12 for licensure in effect at the time the application or petition is filed, and all of the charges and
13 allegations contained in Accusation No. 6969 shall be deemed to be true, correct and admitted by
14 Respondent when the Board determines to grant or deny the application or petition.

15
16 ACCEPTANCE

17 I have carefully read the above Stipulated Settlement and Disciplinary Order for Public
18 Reproval and Stipulated Surrender. I understand the stipulation and the effect it will have on
19 Non-Resident Pharmacy Permit NRP 1278, and Non-Resident Sterile Compounding Permit NSC
20 99795. I enter into this Stipulated Settlement and Disciplinary Order for Public Reproval and
21 Stipulated Surrender voluntarily, knowingly, and intelligently, and agree to be bound by the
22 Decision and Order of the Board of Pharmacy.

23
24 DATED: 1/20/21


25 MINA BANOUB, PHARMACIST-IN-CHARGE
26 UNITED PHARMACY LLC
27 Respondent
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ENDORSEMENT

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

DATED: _____

Respectfully submitted,

XAVIER BECERRA
Attorney General of California
KENT D. HARRIS
Supervising Deputy Attorney General

MABEL LEW
Deputy Attorney General
Attorneys for Complainant

SA2020301620

1 ENDORSEMENT

2 The foregoing Stipulated Settlement and Disciplinary Order for Public Repeval and
3 Stipulated Surrender is hereby respectfully submitted for consideration by the Board of Pharmacy
4 of the Department of Consumer Affairs.

5 DATED: 1/25/2021

6 Respectfully submitted,

7 XAVIER BECERRA
8 Attorney General of California
9 KENT D. HARRIS
10 Supervising Deputy Attorney General

11 
12 MABEL LEW
13 Deputy Attorney General
14 Attorneys for Complainant

15 SA2020301620

Exhibit A

Accusation No. 6969

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2 KENT D. HARRIS
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9 **BEFORE THE**
BOARD OF PHARMACY
10 **DEPARTMENT OF CONSUMER AFFAIRS**
11 **STATE OF CALIFORNIA**

12 In the Matter of the Accusation Against:

Case No. 6969

13 **UNITED PHARMACY LLC**
14 **3951 N. Haverhill Road, Suite 120-121**
West Palm Beach, FL 33417

ACCUSATION

15 **Non-Resident Pharmacy Permit No. NRP 1278**
16 **Non-Resident Sterile Compounding Permit**
No. NSC 99795

17 Respondent.
18

19 Complainant alleges:

20 **PARTIES**

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

23 2. On or about December 24, 2012, the Board issued Non-Resident Pharmacy Permit
24 Number NRP 1278 to United Pharmacy LLC (Respondent). The Non-Resident Pharmacy Permit
25 was in full force and effect at all times relevant to the charges brought herein and will expire on
26 December 1, 2020, unless renewed.
27
28

3. On or about March 14, 2013, the Board issued Non-Resident Sterile Compounding Permit Number NSC 99795 to Respondent. The Non-Resident Sterile Compounding Permit was in full force and effect at all times relevant to the charges brought herein and will expire on December 1, 2020, unless renewed.

JURISDICTION

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

5. Code section 4300 states in pertinent part:

(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....

6. Code section 4300.1 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.

STATUTORY AND REGULATORY PROVISIONS

7. Code section 4022 states:

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

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

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

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

5 8. Code section 4301 states in pertinent part:

6 The board shall take action against any holder of a license who is guilty
7 of unprofessional conduct Unprofessional conduct shall include, but is not limited
to, any of the following:

8

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

11

12 (o) Violating or attempting to violate, directly or indirectly, or assisting in
13 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
14 pharmacy, including regulations established by the board or by any other state or
federal regulatory agency . . .

15 9. Code section 4307 (a) states in pertinent part:

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

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

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

27

10. Health and Safety Code section 11056 states in pertinent part:

(a) The controlled substances listed in this section are included in Schedule III.

....

(f) Anabolic steroids and chorionic gonadotropin. Any material, compound, mixture, or preparation containing chorionic gonadotropin or an anabolic steroid (excluding anabolic steroid products listed in the "Table of Exempt Anabolic Steroid Products" (Section 1308.54 of Title 21 of the Code of Federal Regulations), as exempt from federal Controlled Substances Act (Section 801 and following of Title 21 of the United States Code)), including, but not limited to the following:

....

(30) Testosterone.

....

(32) Human chorionic gonadotropin (hCG), except when possessed by, sold to, purchased by, transferred to, or administered by a licensed veterinarian, or a licensed veterinarian's designated agent, exclusively for veterinary use.

....

11. Health & Safety Code section 11165 states:

....

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

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

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

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

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

(5) Quantity of the controlled substance dispensed.

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

(7) Number of refills ordered.

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

(9) Date of origin of the prescription.

(10) Date of dispensing of the prescription.

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

12. California Code of Regulations section 1735.1(k) states:

....

(k) "Copy or essentially a copy" of a commercially available drug product includes all preparations that are comparable in active ingredients to commercially available drug products, except it does not include any preparations in which there has been a change, made for an identified individual patient, which produces for that patient a clinically significant difference, as determined by a prescribing practitioner, between that compounded preparation and the comparable commercially available drug product.

13. California Code of Regulations section 1735.2 provides in pertinent part:

....

(i) Every compounded drug preparation shall be given a beyond use date representing the date or date and time beyond which the compounded drug preparation should not be used, stored, transported or administered, and determined based on the professional judgment of the pharmacist performing or supervising the compounding.

....

(3) For sterile compounded drug preparations, extension of a beyond use date is only allowable when supported by the following:

(A) Method suitability test,

(B) Container Closure Integrity Test, and

(C) Stability Studies

(4) In addition to the requirements of paragraph three (3), the drugs or compounded drug preparations tested and studied shall be identical in ingredients, specific and essential compounding steps, quality reviews, and packaging as the finished drug or compounded drug preparation.

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COST RECOVERY

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

DRUG CLASSIFICATIONS

15. *Human Chorionic Gonadotropin* is a hormone and is indicated for use as a growth hormone. It is a Schedule III controlled substance under Health & Safety Code section 11056, and is a dangerous drug pursuant to Code section 4022.

16. *Sermorelin* is a hormone and is indicated for use as a growth hormone. It is a dangerous drug pursuant to Code section 4022.

17. *Testosterone cypionate* and *testosterone propionate* are anabolic steroids and are indicated for use as growth hormones. Testosterone is a Schedule III controlled substance under Health & Safety Code section 11056, and is a dangerous drug pursuant to Code section 4022.

FACTUAL ALLEGATIONS

18. On October 24, 2019, Board Inspector SD conducted an annual sterile compounding inspection of Respondent Pharmacy. During the inspection, it was found that between January 1, 2019 and September 30, 2019, Respondent dispensed and shipped into California the following final compounded drugs with extended beyond use dates¹ from a non-sterile source: Human Chorionic Gonadotropin (HCG)², Sermorelin³, and Testosterone Cypionate/Propionate⁴ (California drugs).

19. An additional investigation revealed that during that same period, Respondent extended beyond use dates on those California drugs without a Container Closure Integrity Test. The Stability Study and Method Suitability Test were conducted by a laboratory in India, but

¹ A “beyond use date” is the date after which a compounded medication should be discarded.

² 612 prescriptions for HCG 12,000 Units, 149 prescriptions HCG 5000 Units, and 692 prescriptions for HCG 6000 Units.

³ 64 prescriptions for Sermorelin 15mg, and 88 prescriptions for Sermorelin 6mg.

⁴ 84 prescriptions for Testosterone Cypionate/Propionate 175/25mg.

1 provided no data ensuring that the testing was accurate or precise or would be eligible to extend a
2 beyond use date. The manufacturers were different for several of the product's raw materials.
3 Since identical materials were not used, the stability testing data was inaccurate. The studies
4 conducted were not with identical ingredients, specific and essential compounding steps, quality
5 reviews and packaging as the finished drug or compounded drug preparations.

6 20. The investigation also revealed the HCG it dispensed and shipped to patients in
7 California were essentially a copy of the FDA-approved commercially available HCG product
8 (manufacturer drug), without any proof of clinical differences⁵ or shortage of the manufacturer
9 drug. Respondent did not provide any prescriber attestation with the original prescription
10 requesting Respondent's product for a clinically significant difference over the commercially
11 available product – a requirement for every prescription sent to patients in California.
12 Respondent also did not provide documentation of clinical significance as to the medical
13 necessity for its subcutaneous (SQ) injection drug versus the commercially available drug for
14 intramuscular (IM) injection.

15 21. The investigation further revealed that between January 1, 2018 and November 26,
16 2019, Respondent did not report its dispensing of the HCG and Testosterone drugs⁶ to California
17 patients to the Department of Justice. Specifically, Respondent failed to report dispensing data
18 concerning the HCG and Testosterone Cypionate/Propionate drugs to the California Controlled
19 Substance Utilization Review and Evaluation System of the Prescription Drug Monitoring
20 Program (CURES)⁷. In fact, a CURES compliance report showed Respondent did not begin
21 reporting until December 20, 2019.

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25 ⁵ A different strength, such as 6000 or 12000 units of HCG, does not exempt a pharmacy's
product from being essentially a copy of a commercially available FDA-approved product.

26 ⁶ Pursuant to Health and Safety Code section 11056, HCG and Testosterone are Schedule
III controlled substances.

27 ⁷ CURES is California's prescription drug monitoring program which is maintained by the
Department of Justice. Since January 1, 2005, Schedule III controlled substances dispensed to
28 patients in California are required to be reported to CURES by pharmacies and direct dispensers.
The purpose of such reporting is to help identify and prevent/deter drug abuse and diversion.

1 **FIRST CAUSE FOR DISCIPLINE**

2 (Unlawful Extending Beyond Use Date Without Appropriate Studies)

3 22. Respondent is subject to disciplinary action under Code section 4301 subdivision (o)
4 and California Code of Regulations section 1735.2 subdivision (i)(3) in that, in violation of
5 Pharmacy Law, Respondent dispensed and extended the beyond use date without any of the
6 required studies for patients in California, as set forth in paragraphs 18-19 above, which are
7 incorporated herein by reference.

8 **SECOND CAUSE FOR DISCIPLINE**

9 (Unlawful Extending Beyond Use Date Without Appropriate Testing)

10 23. Respondent is subject to disciplinary action under Code section 4301 subdivision (o)
11 and California Code of Regulations section 1735.2 subdivision (i)(4) in that, in violation of
12 Pharmacy Law, Respondent extended the beyond use date of the prescriptions without any of the
13 required studies as set forth in paragraph 22, and conducted tests which were not identical in
14 ingredients, specific and essential compounding steps, quality reviews and packaging as the
15 finished drug or compounded drug preparation, as set forth in paragraphs 18-19 above, which are
16 incorporated herein by reference.

17 **THIRD CAUSE FOR DISCIPLINE**

18 (Unlawful Compounding of Essentially a Copy of Manufacturer Drug
19 Without Proof of Medical Necessity)

20 24. Respondent is subject to disciplinary action under Code section 4301 subdivision (o)
21 and California Code of Regulations section 1735.2 subdivision (d), in that, in violation of
22 Pharmacy Law, Respondent compounded and dispensed HCG prescriptions which were
23 essentially copies of the HCG manufacturer drug for subcutaneous injections without appropriate
24 documentations as to the medical necessity for an identified individual patient, as set forth in
25 paragraphs 18-20 above, which are incorporated herein by reference.

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1 **FOURTH CAUSE FOR DISCIPLINE**

2 (Failure to Report CURES Data)

3 25. Respondent is subject to disciplinary action under Code section 4301(o) and Health
4 and Safety Code section 11165 subdivision (d), in that, in violation of Pharmacy Law, between
5 January 1, 2018 and November 26, 2019, Respondent did not report to the Department of Justice
6 the Schedule III controlled substances (HCG and Testosterone) it dispensed to California patients,
7 as set forth in paragraphs 18-21.

8 **OTHER MATTERS**

9 26. Pursuant to Code section 4307, if discipline is imposed on Non-Resident Pharmacy
10 Permit No. NRP 1278 issued to United Pharmacy LLC, United Pharmacy LLC shall be prohibited
11 from serving as a manager, administrator, owner, member, officer, director, associate, or partner
12 of a licensee for five years if Non-Resident Pharmacy Permit No. NRP 1278 is placed on
13 probation or until Non-Resident Pharmacy Permit No. NRP 1278 is reinstated if it is revoked.

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PRAYER

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

1. Revoking or suspending Non-Resident Pharmacy Permit No. NRP 1278, issued to United Pharmacy LLC;
2. Revoking or suspending Non-Resident Sterile Compounding Permit No. NSC 99795, issued to United Pharmacy LLC;
3. Ordering United Pharmacy LLC 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,
4. Taking such other and further action as deemed necessary and proper.

DATED: August 3, 2020

Anne Sodergren

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

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