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

In the Matter of the Accusation Against: **WELLS PHARMACY NETWORK LLC** **450 US Hwy 51, Bypass N** **Dyersburg, TN 38024** **Non-Resident Pharmacy Permit No. NRP 1325** **Non-Resident Sterile Compounding Permit No. NSC 99824** Respondent.	Case No. 5887 OAH No. 2017011087 **STIPULATED SETTLEMENT AND DISCIPLINARY ORDER FOR PUBLIC REPROVAL**

DECISION AND ORDER

The attached Stipulated Settlement and Disciplinary Order is hereby adopted by the Board of Pharmacy, Department of Consumer Affairs, as its Decision in this matter.

This Decision shall become effective at 5:00 p.m. on July 26, 2017.

It is so ORDERED on June 26, 2017.

BOARD OF PHARMACY
DEPARTMENT OF CONSUMER AFFAIRS
STATE OF CALIFORNIA

By _____
Amy Gutierrez, Pharm.D.
Board President

XAVIER BECERRA
Attorney General of California
KENT D. HARRIS
Supervising Deputy Attorney General
DAVID E. BRICE
Deputy Attorney General
State Bar No. 269443
1300 I Street, Suite 125
P.O. Box 944255
Sacramento, CA 94244-2550
Telephone: (916) 324-8010
Facsimile: (916) 327-8643
E-mail: David.Brice@doj.ca.gov
Attorneys for Complainant

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

In the Matter of the Accusation Against: **WELLS PHARMACY NETWORK LLC** **450 US Hwy 51 Bypass N** **Dyersburg, TN 38024** **Non-Resident Pharmacy Permit No. NRP 1325** **Non-Resident Sterile Compounding Permit No. NSC 99824** Respondent.	Case No. 5887 OAH No. 2017011087 **STIPULATED SETTLEMENT AND DISCIPLINARY ORDER FOR PUBLIC REPROVAL** **[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:

PARTIES

1. Virginia Herold (Complainant) is the Executive Officer of the Board of Pharmacy (Board). She brought this action solely in her official capacity and is represented in this matter by Xavier Becerra, Attorney General of the State of California, by David E. Brice, Deputy Attorney General.

2. Wells Pharmacy Network LLC (Respondent) is represented in this proceeding by attorneys Steven L. Simas and Daniel Tatick, whose address is: Simas and Associates, 3835 North Freeway Blvd., Suite 228, Sacramento, CA 95834.

JURISDICTION

3. On or about May 28, 2013, the Board issued Original Non-Resident Pharmacy Permit No. NRP 1325 to Respondent. The Non-Resident Pharmacy Permit was in full force and effect at all times relevant to the charges brought in Accusation No. 5887, expired on May 1, 2017, and has not been renewed.

4. On or about July 1, 2013, the Board issued Original Non-Resident Sterile Compounding Permit Number NSC 99824 to Respondent to compound injectable sterile drug products. The Non-Resident Sterile Compounding Permit was in full force and effect at all times relevant to the charges brought in Accusation No. 5887, expired on May 1, 2017, and has not been renewed.

5. Accusation No. 5887 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 October 21, 2016. Respondent timely filed its Notice of Defense contesting the Accusation. A copy of Accusation No. 5887 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 Accusation No. 5887. Respondent has also carefully read, fully discussed with counsel, and understands the effects of this Stipulated Settlement and Disciplinary Order for Public Reproval.

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.

CULPABILITY

9. Respondent understands and agrees that the charges and allegations in Accusation No. 5887, if proven at a hearing, constitute cause for imposing discipline upon its Non-Resident Pharmacy Permit and its Non-Resident Sterile Compounding Permit.

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

11. Respondent agrees that its Non-Resident Pharmacy Permit and its Non-Resident Sterile Compounding Permit are subject to discipline and agrees to be bound by the Disciplinary Order below.

CONTINGENCY

12. This stipulation shall be subject to approval by the Board of Pharmacy. Respondent understands and agrees that counsel for Complainant and the staff of the Board of Pharmacy may communicate directly with the Board regarding this stipulation and settlement, without notice to or participation by Respondent or its counsel. By signing the stipulation, Respondent understands and agrees that it may not withdraw its agreement or seek to rescind the stipulation prior to the time the Board considers and acts upon it. If the Board fails to adopt this stipulation as its Decision and Order, the Stipulated Settlement and Disciplinary Order for Public Reproval shall be of no force or effect, except for this paragraph, it shall be inadmissible in any legal action between the parties, and the Board shall not be disqualified from further action by 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 Portable Document Format (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 both Non-Resident Pharmacy Permit No. NRP 1325 and Non-Resident Sterile Compounding Permit No. NSC 99824 issued to Respondent Wells Pharmacy Network LLC shall be publicly reproved by the Board of Pharmacy under Business and Professions Code section 495 in resolution of Accusation No. 5887, attached as exhibit A.

Cost Recovery. Respondent shall pay $6,155.25 to the Board for its costs associated with the investigation and enforcement of this matter. Respondent shall be permitted to pay these costs in a payment plan approved by the Board. If Respondent fails to pay the Board costs as ordered, Respondent shall not be allowed to renew its Non-Resident Pharmacy Permit or its Non-Resident Sterile Compounding Permit until Respondent pays costs in full.

///

///

///

ACCEPTANCE

I have carefully read the above Stipulated Settlement and Disciplinary Order for Public Reproval and have fully discussed it with my attorneys, Steven L. Simas and Daniel Tatick. I understand the stipulation and the effect it will have on the Non-Resident Pharmacy Permit and the Non-Resident Sterile Compounding Permit held by Wells Pharmacy Network LLC. I enter into this Stipulated Settlement and Disciplinary Order for Public Reproval voluntarily, knowingly, and intelligently, and agree to be bound by the Decision and Order of the Board of Pharmacy.

DATED: 05/23/17

STACY SHAPIRO, GENERAL COUNSEL
WELLS PHARMACY NETWORK LLC
Respondent

I have read and fully discussed with Respondent Wells Pharmacy Network LLC the terms and conditions and other matters contained in the above Stipulated Settlement and Disciplinary Order for Public Reproval. I approve its form and content.

DATED: 5/23/17

STEVEN L. SIMAS
DANIEL TATICK
Attorneys for Respondent

ENDORSEMENT

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

Dated: 5/23/2017

Respectfully submitted,

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

DAVID E. BRICE
Deputy Attorney General
Attorneys for Complainant

SA2016102809
12687933.docx

Exhibit A

Accusation No. 5887

KAMALA D. HARRIS
Attorney General of California
KENT D. HARRIS
Supervising Deputy Attorney General
DAVID E. BRICE
Deputy Attorney General
State Bar No. 269443
1300 I Street, Suite 125
P.O. Box 944255
Sacramento, CA 94244-2550
Telephone: (916) 324-8010
Facsimile: (916) 327-8643
E-mail: David.Brice@doj.ca.gov
Attorneys for Complainant

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

In the Matter of the Accusation Against: **WELLS PHARMACY NETWORK LLC** **450 US Hwy 51 Bypass N** **Dyersburg, TN 38024** **Non-Resident Pharmacy Permit No. NRP 1325** **Non-Resident Pharmacy Permit No. NSC 99824** Respondent.	Case No. 5887 **ACCUSATION**

Complainant alleges:

PARTIES

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

2. On or about May 28, 2013, the Board of Pharmacy issued Original Non-Resident Pharmacy Permit Number NRP 1325 to Wells Pharmacy Network LLC (Respondent). The Non-Resident Pharmacy Permit was in full force and effect at all times relevant to the charges brought herein and will expire on May 1, 2017, unless renewed.

3. On or about July 1, 2013, the Board of Pharmacy issued Original Non-Resident Pharmacy Permit Number NSC 99824 to Respondent to compound injectable sterile drug

products. The Non-Resident Pharmacy Permit was in full force and effect at all times relevant to the charges brought herein and will expire on May 1, 2017, unless renewed.

JURISDICTION

4. This 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 unless otherwise indicated.

STATUTORY REFERENCES

5. Section 4301 of the Code states, in pertinent part:

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

6. 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.

7. Section 4127.7 of the Code states:

> On and after July 1, 2005, a pharmacy shall compound sterile injectable products from one or more nonsterile ingredients in one of the following environments:
>
> (a) An ISO class 5 laminar airflow hood within an ISO class 7 cleanroom. The cleanroom must have a positive air pressure differential relative to adjacent areas.
>
> (b) An ISO class 5 cleanroom.
>
> (c) A barrier isolator that provides an ISO class 5 environment for compounding.

REGULATIONS

8. Section 1751 of title 16 of the California Code of Regulations (16 CCR 1751) states, in pertinent part: "(c) Any pharmacy compounding a sterile injectable product from one or more non-sterile ingredients shall comply with Business and Professions Code section 4127.7."

9. 16 CCR 1751.7 states, in pertinent part:

> (c) Batch-produced sterile injectable drug products compounded from one or more non-sterile ingredients shall be subject to documented end product testing for sterility and pyrogens and shall be quarantined until the end product testing confirms sterility and acceptable levels of pyrogens.

COST RECOVERY

10. Section 125.3 of the Code states, in pertinent part, that the Board may request the administrative law judge to direct a licentiate 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.

FIRST CAUSE FOR DISCIPLINE

(Compounding Sterile from Non-Sterile Drugs in Improper Environment)

11. Respondent is subject to disciplinary action under Code section 4127.7 and 16 CCR 1751(c), by and through Code section 4301(o), in that Respondent compounded sterile injectable drugs from non-sterile ingredients in an improper environment. The circumstances are as follows:

12. On or about March 4, 2016, during an inspection of Respondent's premises, a Board inspector found that Respondent compounded non-sterile to sterile drugs in a clean room that was certified only as an ISO 7 environment, instead of the required ISO 5 environment.[1]

SECOND CAUSE FOR DISCIPLINE

(Failure to Document Quality Assurance)

13. Respondent is subject to disciplinary action under 16 CCR 1751.7(c), by and through Code section 4301(o), in that Respondent failed to document end product testing for sterility and

///

[1] Clean rooms are classified by the International Organization for Standardization (ISO) according to the size of particles permitted in the air, from ISO 1 (smallest) to ISO 9 (largest).

pyrogens of batch-produced sterile injectable drug products compounded from one or more non-sterile ingredients. The circumstances are as follows:

14. Between May 2015 and March 2016, Respondent shipped about 2,890 batch-produced non-sterile to sterile compounded injectable drug products into California without documentation of end product sterility or pyrogen testing.[2]

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 Number NRP 1325, issued to Wells Pharmacy Network LLC;

2. Revoking or suspending Non-Resident Pharmacy Permit Number NSC 99824, issued to Wells Pharmacy Network LLC;

3. Ordering Wells Pharmacy Network 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: 10/14/16

VIRGINIA HEROLD
Executive Officer
Board of Pharmacy
Department of Consumer Affairs
State of California
Complainant

SA2016102809
12442799.doc

[2] A pyrogen is any substance or agent that causes fever.