

**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

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

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

11 In the Matter of the Accusation Against:

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15 **Non-Resident Pharmacy Permit No. NRP**
1325
16 **Non-Resident Sterile Compounding Permit**
No. NSC 99824

17 Respondent.

Case No. 5887

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STIPULATED SETTLEMENT AND
DISCIPLINARY ORDER FOR PUBLIC
REPROVAL

[Bus. & Prof. Code § 495]

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

20 PARTIES

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

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

I have carefully read the above Stipulated Settlement and Disciplinary Order for Public Repeval 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 Repeval 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 Repeval. I approve its form and content.

DATED: 5/23/17



STEVEN L. SIMAS
DANIEL TATICK
Attorneys for Respondent

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ENDORSEMENT

The foregoing Stipulated Settlement and Disciplinary Order for Public Repeval 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

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Exhibit A

Accusation No. 5887

1 KAMALA D. HARRIS
Attorney General of California
2 KENT D. HARRIS
Supervising Deputy Attorney General
3 DAVID E. BRICE
Deputy Attorney General
4 State Bar No. 269443
1300 I Street, Suite 125
5 P.O. Box 944255
Sacramento, CA 94244-2550
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10 **STATE OF CALIFORNIA**

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450 US Hwy 51 Bypass N
Dyersburg, TN 38024
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15 **Non-Resident Pharmacy Permit No. NRP**
1325
16 **Non-Resident Pharmacy Permit No. NSC**
99824
17 Respondent.

Case No. 5887

A C C U S A T I O N

18
19 Complainant alleges:

20 **PARTIES**

- 21 1. Virginia Herold (Complainant) brings this Accusation solely in her official capacity as
22 the Executive Officer of the Board of Pharmacy, Department of Consumer Affairs.
- 23 2. On or about May 28, 2013, the Board of Pharmacy issued Original Non-Resident
24 Pharmacy Permit Number NRP 1325 to Wells Pharmacy Network LLC (Respondent). The Non-
25 Resident Pharmacy Permit was in full force and effect at all times relevant to the charges brought
26 herein and will expire on May 1, 2017, unless renewed.
- 27 3. On or about July 1, 2013, the Board of Pharmacy issued Original Non-Resident
28 Pharmacy Permit Number NSC 99824 to Respondent to compound injectable sterile drug

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

3 **JURISDICTION**

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

7 **STATUTORY REFERENCES**

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

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

12 ...

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

17 6. Section 4300.1 of the Code states:

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

24 7. Section 4127.7 of the Code states:

25 On and after July 1, 2005, a pharmacy shall compound sterile injectable products from
26 one or more nonsterile ingredients in one of the following environments:

27 (a) An ISO class 5 laminar airflow hood within an ISO class 7 cleanroom. The
28 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.

1 **REGULATIONS**

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

5 9. 16 CCR 1751.7 states, in pertinent part:

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

10 **COST RECOVERY**

11 10. Section 125.3 of the Code states, in pertinent part, that the Board may request the
12 administrative law judge to direct a licentiate found to have committed a violation or violations of
13 the licensing act to pay a sum not to exceed the reasonable costs of the investigation and
14 enforcement of the case.

15 **FIRST CAUSE FOR DISCIPLINE**

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

17 11. Respondent is subject to disciplinary action under Code section 4127.7 and 16 CCR
18 1751(c), by and through Code section 4301(o), in that Respondent compounded sterile injectable
19 drugs from non-sterile ingredients in an improper environment. The circumstances are as follows:

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

23 **SECOND CAUSE FOR DISCIPLINE**

24 (Failure to Document Quality Assurance)

25 13. Respondent is subject to disciplinary action under 16 CCR 1751.7(c), by and through
26 Code section 4301(o), in that Respondent failed to document end product testing for sterility and
27 ///

28 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).

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

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

6 **PRAYER**

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

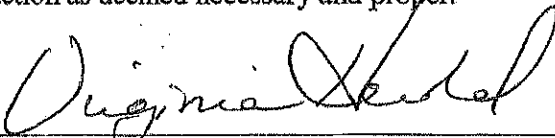
9 1. Revoking or suspending Non-Resident Pharmacy Permit Number NRP 1325, issued to
10 Wells Pharmacy Network LLC;

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

13 3. Ordering Wells Pharmacy Network LLC to pay the Board of Pharmacy the reasonable
14 costs of the investigation and enforcement of this case, pursuant to Business and Professions Code
15 section 125.3; and,

16 4. Taking such other and further action as deemed necessary and proper.

17
18 DATED: 10/14/16


19 VIRGINIA HEROLD
20 Executive Officer
21 Board of Pharmacy
22 Department of Consumer Affairs
23 State of California
24 Complainant

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