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Attorneys for the Arizona State Board of Pharmacy

**BEFORE THE ARIZONA STATE BOARD OF PHARMACY**

In the Matter of  
  
**Wells Pharmacy Network,**  
  
Holder of Pharmacy Permit No. Y005709  
in the State of Arizona.

Board Case No. 14-0019-PHR  
  
**CONSENT AGREEMENT FOR  
PROBATION, CIVIL PENALTY,  
COSTS AND INSPECTION**

In the interest of a prompt and judicious settlement of this case, consistent with the public interest, statutory requirements and the responsibilities of the Arizona State Board of Pharmacy ("Board") under A.R.S. § 32-1901, *et. seq.*, Wells Pharmacy Network, holder of Pharmacy Permit Number Y005709 in the State of Arizona ("Respondent"), and the Board enter into the following Recitals, Findings of Fact, Conclusions of Law and Order ("Consent Agreement") as a final disposition of this matter.

RECITALS

1  
2           1.     Respondent has read and understands this Consent Agreement and has had  
3 the opportunity to discuss this Consent Agreement with an attorney, or has waived the  
4 opportunity to discuss this Consent Agreement with an attorney.

5           2.     Respondent understands that it has a right to a public administrative hearing  
6 concerning the above-captioned matter, at which hearing it could present evidence and  
7 cross examine witnesses. By entering into this Consent Agreement, Respondent  
8 knowingly and voluntarily relinquishes all right to such an administrative hearing, as well  
9 as rights of rehearing, review, reconsideration, appeal, judicial review or any other  
10 administrative and/or judicial action, concerning the matters set forth herein.

11          3.     Respondent affirmatively agrees that this Consent Agreement shall be  
12 irrevocable.

13          4.     Respondent understands that this Consent Agreement or any part of the  
14 agreement may be considered in any future disciplinary action by the Board.

15          5.     Respondent understands this Consent Agreement deals with Board  
16 Complaint No. 4338 involving allegations of unethical conduct against Respondent. The  
17 investigation into these allegations against Respondent shall be concluded upon the  
18 Board's adoption of this Consent Agreement.

19          6.     Respondent understands that this Consent Agreement does not constitute a  
20 dismissal or resolution of any other matters currently pending before the Board, if any,  
21 and does not constitute any waiver, express or implied, of the Board's statutory authority  
22 or jurisdiction regarding any other pending or future investigation, action or proceeding.

23          7.     Respondent also understands that acceptance of this Consent Agreement  
24 does not preclude any other agency, subdivision, or officer of this State from instituting  
25 any other civil or criminal proceedings with respect to the conduct that is the subject of  
26 this Consent Agreement.

1           8.     Respondent acknowledges and agrees that, upon signing this Consent  
2 Agreement and returning this document to the Board's Executive Director, it may not  
3 revoke its acceptance of the Consent Agreement or make any modifications to the  
4 document regardless of whether the Consent Agreement has been signed by the  
5 Executive Director. Any modification to this original document is ineffective and void  
6 unless mutually agreed by the parties in writing.

7           9.     This Consent Agreement is subject to the approval of the Board and is  
8 effective only when accepted by the Board and signed by the Board's Executive Director.  
9 In the event that the Board does not approve this Consent Agreement, it is withdrawn and  
10 shall be of no evidentiary value and shall not be relied upon nor introduced in any action  
11 by any party, except that the parties agree that should the Board reject this Consent  
12 Agreement and this case proceeds to hearing, Respondent shall assert no claim that the  
13 Board was prejudiced by its review and discussion of this document or any records  
14 relating thereto.

15           10.    If a court of competent jurisdiction rules that any part of this Consent  
16 Agreement is void or otherwise unenforceable, the remainder of the Consent Agreement  
17 shall remain in full force and effect.

18           11.    Respondent understands that this Consent Agreement is a public record that  
19 may be publicly disseminated as a formal action of the Board and may be reported as  
20 required by law to the National Practitioner Data Bank and the Healthcare Integrity and  
21 Protection Data Bank.

22           12.    Respondent understands that any violation of this Consent Agreement  
23 constitutes unethical conduct and may result in disciplinary action. A.R.S. §§ 32-  
24 1901.01(A) and A.R.S. § 32-1927.02(A).

25           13.    Respondent agrees that the Board will adopt the following Findings of Fact,  
26 Conclusions of Law and Order.

1 ACCEPTED AND AGREED BY RESPONDENT

2  
3 Wells Pharmacy Network

Dated: 3 31 15

4 by Ben David, CEO on behalf of Wells Pharmacy Network

5  
6 Subscribed and sworn to before me in the County of Palm Beach, State of  
7 Florida, this 31st day of March, 2014, by  
Ben David, on behalf of Wells Pharmacy Network. 2015



8 **BRET JONATHAN PHILLIPS**  
9 **NOTARY PUBLIC**  
**STATE OF FLORIDA**  
**Comm# FF173881**  
**Expires 11/4/2018**

Bret J Phillips  
10 **NOTARY PUBLIC**

My Commission expires: 11/4/2018

11 **FINDINGS OF FACT**

12 1. The Board is the duly constituted authority for licensing and regulating the  
13 practice of pharmacy in the State of Arizona.

14 2. Respondent is the holder of Pharmacy Permit Number Y005709.

15 3. From February 21, 2014 through March 7, 2014 representatives of the  
16 United States Food and Drug Administration ("FDA") conducted an inspection of  
17 Respondent's facility located at 1210 SW 33<sup>rd</sup> Ave., Ocala, Florida. As a result of that  
18 inspection, the FDA issued a report on March 7, 2014 which contained eleven (11)  
19 observations detailing potential violations. Based upon its concerns regarding the  
20 observations identified in the FDA report the Board directed its staff to conduct an  
21 inspection of Respondent's facility in Ocala, Florida.  
22

23 4. On or about October 7 and 8, 2014 Board compliance officers conducted an  
24 inspection of Respondent's facility located at 1210 SW 33<sup>rd</sup> Ave., Ocala Florida and on  
25  
26

1 October 10, 2014 requested additional documents which were provided by Respondent  
2 on October 15, 2014.

3 5. At the October 7 and 8, 2014 inspection Board compliance officers  
4 observed a technician working at Respondent's facility exiting and re-entering the ante  
5 room without re-garbing and later observed the same technician working in the ante room  
6 without gloves or a mask both activities were not in compliance with Respondent's  
7 standard operating procedures.  
8

9 6. At the October 7 and 8, 2014 inspection Board compliance officers noted  
10 that the pharmacist in the general compounding area was not performing or documenting  
11 a verification of the components or weights prior to the completion of the finished  
12 product.  
13

14 7. At the October 7 and 8, 2014 inspection Board compliance officers  
15 conducted a random sampling of the compounding records regarding the "Beyond Use  
16 Date" (BUD) for several lots of Trimix injectable.  
17

18 8. At the October 7 and 8, 2014 inspection Board compliance officers  
19 observed discrepancies in Respondent's compliance with sterility, endotoxin and sterile  
20 filtration testing results records.

21 9. At the October 7 and 8, 2014 inspection Board compliance officers  
22 observed that Respondent's employees were not following Respondent's standard  
23 operating procedures regarding patient counseling of compounded preparations,  
24 sterilization and depyrogenation and pharmacist preparation of the first formulation of a  
25  
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1 complex preparation which is then verified and approved by a pharmacist (quality  
2 manager).

3 10. At the October 7 and 8, 2014 inspection Board compliance officers  
4 reviewed ten (10) random prescription/orders from the Arizona report which revealed  
5 Respondent failed to maintain proper compounding records of quality assurance  
6 verification, documentation of procedures for obtaining samples for testing,  
7 documentation of filter lot number/expiration date and bubble point testing in the  
8 compounding record, documentation of the sampling plan for sterility/endotoxin testing  
9 and failure to follow proper procedures/protocols for sterility and endotoxin testing  
10 sampling.  
11

12 11. Board compliance officers reviewed additional documents requested from  
13 Respondent and received on or about October 15, 2014 which revealed additional  
14 discrepancies regarding the records, documentation, compliance with standard operating  
15 procedures, testing procedures, sampling procedures and shipping procedures involving  
16 Rx 6009925, Rx 6038319, Rx 6038321, Rx 6021313, Rx 605 1741 and Rx 6004621 as  
17 more fully set forth in the compliance officers' report dated October 15, 2014, a copy of  
18 which is attached and is incorporated by this reference.  
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### 21 CONCLUSIONS OF LAW

22 1. The Board possesses jurisdiction over the subject matter and over  
23 Respondent pursuant to A.R.S. § 32-1901 *et seq.*

24 2. The Board may discipline permit holder if the Board determines that the  
25 permittee or the permittee's employee has engaged in unethical conduct. A.R.S. § 32-  
26 1927.02(A) (1).



1 required unannounced random inspection in paragraph 4 of this Order prior to the  
2 expiration of the one (1) year probationary period, Respondent may petition the Board for  
3 early termination of the probation by submitting such a request in writing and appearing  
4 before the Board at a regularly scheduled meeting.

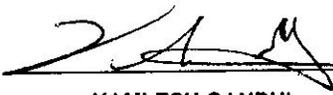
5 6. If Respondent violates this Order in any way or fails to fulfill the  
6 requirements of this Order, the Board, after giving the Respondent notice and the  
7 opportunity to be heard, make take disciplinary action against Respondent's permit. The  
8 issue at such a hearing will be limited solely to whether this Order has been violated.

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DATED this 09 day of June, ~~2014~~ 2015

ARIZONA STATE BOARD OF PHARMACY

(Seal)

By:   
KAMLESH GANDHI  
EXECUTIVE DIRECTOR

ORIGINAL OF THE FOREGOING FILED  
this 09 day of June, ~~2014~~ 2015 with:

Arizona State Board of Pharmacy  
1616 W. Adams St.  
Phoenix, Arizona 85007

COPY OF THE FOREGOING MAILED  
BY CERTIFIED MAIL

this 09 day of June, ~~2014~~ 2015

Wells Pharmacy Network  
1210 SW 33<sup>rd</sup> Ave.  
Ocala, Florida 34474  
Respondent

1 COPY OF THE FOREGOING MAILED  
2 this *09* day of *June*, ~~2014~~ to:  
*2015*

3 Montgomery Lee  
4 Assistant Attorney General  
5 1275 W. Washington Street, CIV/LES  
6 Phoenix, Arizona 85007  
7 Attorney for the State of Arizona

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