

BEFORE THE KANSAS BOARD OF PHARMACY

In the Matter of)
)
HOPEWELL PHARMACY) Case No. 21-013
)
Registration No. 22-107712)

STIPULATION AND CONSENT ORDER

IT IS HEREBY STIPULATED AND AGREED by and between the Kansas Pharmacy Board (“Board”) and Hopewell Pharmacy, a licensed non-resident pharmacy located in Hopewell, New Jersey (“Respondent”) as follows:

1. The Board is represented herein by its attorney, Brenda L. Head of Frieden & Forbes, LLP, 1414 SW Ashworth Place, Suite 201, Topeka, Kansas 66604. The Respondent is represented herein by its attorney, Bradley W. Howard or Brown & Fortunato, PC at 905 S. Fillmore, Suite 400, Amarillo, Texas 79101.

2. The Board is the Kansas agency vested with the authority to carry out and enforce the provisions of the Kansas Pharmacy Law, K.S.A. 65-1626 *et seq.*, (“Act”) including conducting hearings and proceedings to revoke, suspend or otherwise discipline a Kansas registration to operate a pharmacy.

3. On May 3, 2019, the Board issued a Summary Order in Case No. 19-116 to the Respondent, holding Registration number 22-107712, which placed the Respondent on Probation for a period of five (5) years with a condition for the Respondent to submit a new inspection report that meets the requirements of K.A.R. 68-7-12(a)(3) showing that the deficiencies had been corrected and no further deficiencies were identified that could result in patient harm for approval of its 2019 registration renewal. The Summary Order suspended \$3,000.00 of a \$5,500.00 administrative fine pending continued compounding operations within the guidelines

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of New Jersey and federal laws, regulations and guidelines for the duration of the probationary period.

4. On December 7, 2020, Respondent notified the Board of a recent penalty assessed against Respondent by the New Jersey Board of Pharmacy relating to certain deficiencies identified in the Respondent's routine inspection conducted September 26, 2019, by the New Jersey Board. The deficiencies noted in the inspection and resulting in the penalty include:

- | | |
|--------------------------|--|
| N.J.A.C. 13:39-7.18 | (that medication found in the active drug stock |
| N.J.A.C. 13:39-6.2(f)7 | inventory were found to be outdated from 1 |
| N.J.A.C. 13:39-7.16(c)6 | day-4 months (2 items); misbranded (1 item),
over-fills (1 item) |
| N.J.A.C. 13:39-5.8(a)1 | (the pharmacy's library was deficient in the
reference text category for the General
Practice of Pharmacy) |
| N.J.A.C. 13:39-11.24(a)6 | (air and surface sampling for microbial
organisms in ISO Class 5 primary engineering
controls shall be certified by an independent
certification company every six (6) months
and at any time when microbial contamination
is suspected. The pharmacy failed to have an
independent certification company collect air
and surface samples every six (6) months.) |
| N.J.A.C. 13:39-11.5(a) | (the surfaces of the fixtures, specifically, the
wall outlet and vents, were not smooth,
impervious, free from cracks and crevices,
and non-shedding, thereby minimizing spaces
in which microorganisms and other
contaminants may accumulate.) |
| N.J.A.C. 13:39-4.8(a) | (the pharmacy did not notify the Board thirty
(30) days prior to any remodeling that entails
a change within the premises of the location
or the size of the prescription area, or a change
in dimensions of the licensed premises, on a
form prescribed by the Board. The pharmacy
did not submit an application for their USP
800 room. The USP 800 room is a modular
room that was inserted in the pharmacy |

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permitted area. The addition of the 800 lab was implemented by the former owners of the pharmacy in 2017.”

5. The Board’s Investigation Member has determined that there is probable cause to believe that Respondent Registration could be disciplined pursuant to K.S.A. 65-1627(e)(1) and (e)(4).

6. Respondent hereby waives any further proof in this or any other proceeding before or initiated by the Board with respect to this matter, and upon motion duly made, seconded, and passed, the Board finds the following:

A. Respondent reported discipline by the New Jersey Board of Pharmacy arising from deficiencies and violations found during a September 26, 2019 inspection.

B. The deficiencies and resulting discipline violate the conditions of Respondent’s May 3, 2019 Summary Order and Probation.

7. Upon motion duly made, seconded, and passed, the Board finds and concludes that the events described in paragraph 6 above constitute the operation of a nonresident pharmacy in a manner that violates the Act and the Regulations of the Board and disciplinary action against Respondent by the New Jersey Pharmacy Board and are therefore grounds for disciplinary action against the Respondent’s Kansas Registration pursuant to K.S.A. 65-1627(e)(1) and (e)(4).

8. The Board finds, concludes, and orders that the following disposition is just and appropriate under the circumstances:

A. PROBATION. Respondent’s Probation is hereby extended for a period of five (5) years. As a condition of Probation, Respondent must submit a new inspection report that meets the requirements of K.A.R. 68-7-12a(a)(3) showing that the deficiencies have been corrected and no further deficiencies that could result in patient harm exist. Respondent must

also notify the Board within seven (7) days of any disciplinary action by any state or federal government. Further, violation of Respondent's conditions of Probation will result in revocation of Respondent's Kansas registration.

B. ADMINISTRATIVE FINE. Respondent shall pay to the Board the previously suspended administrative fine in the amount of Three Thousand Dollars (\$3,000.00) within ten (10) days of the Board approving this Stipulation and Consent Order. The Respondent is notified that any future violation of the terms of their probation will result in a minimum administrative fine of \$5,000.00.

C. NABP INSPECTION. Respondent shall obtain a NABP inspection within twenty-four (24) months of this Stipulation and Consent Order. Respondent shall report to the Board the results of the NABP inspection within ten (10) days of receipt of the inspection report. If the FDA performs an inspection during the term of Respondent's Probationary period, Respondent shall provide an unredacted copy of the FDA inspection report to the Board within ten (10) days of receipt.

D. OTHER REQUIREMENTS. Respondent acknowledges and agrees that as a condition of this Stipulation and Consent Order it must, and the Board further orders the Respondent to:

- i. Comply fully with this Stipulation and Consent Order; and
- ii. In all applicable respects, comply fully with the Kansas Pharmacy Act, the Board's rules and regulations and all state and federal laws relating to pharmacies.

9. Respondent agrees that all information in the possession of the Board's Investigation Member, its staff, its investigators and or its attorney regarding the investigation which lead to this disciplinary action and all information discovered during the pendency of the

disciplinary action may be disclosed to and considered by the Board as part of the presentation and consideration of the proposal of settlement in the form of this Stipulation and Consent Order and the Final Order provided for herein, with or without the presence of the Respondent or its attorney. In the event that this Stipulation and Consent Order and the Final Order provided for herein are not accepted and approved by the Board, the Respondent further waives any objection to the Board members' consideration of this Stipulation and Consent Order or the information mentioned in the preceding sentence and further agrees to waive any claim of due process violation or the right to seek the disqualification of any Board member as a result of the Board member's consideration of said document and information.

10. The stipulations contained herein shall not become binding until this Stipulation and Consent Order is approved by the Board and the Consent Order provided for herein is entered by the Board. If the Board fails to approve this Stipulation and Consent Order, it shall be of no force or effect to either the Board or the Respondent. The Respondent acknowledges that the approval of the Board's Investigation Member or its attorney shall not constitute the approval of the Board or bind the Board to approve this Stipulation and Consent Order.

11. The Respondent agrees that this Stipulation and Consent Order is in conformance with Kansas and federal law and the Board has jurisdiction to enter into it and enter the Final Order provided for herein. The Respondent further agrees, for purposes of this matter, that the Kansas Pharmacy Act, K.S.A. 65-1626 *et seq.* is constitutional on its face and as applied in this case.

12. This Stipulation constitutes the entire agreement of the parties and may only be modified by a subsequent writing signed by them. The agreement shall be interpreted in accordance with the laws of the State of Kansas.

13. The Respondent acknowledges that it has the following rights:
- A. To have formal notice of charges served upon it;
 - B. To file a response to the charges;
 - C. To have notice of and participate in a formal adjudicative hearing with the Board or its designee making specific findings of facts and conclusions of law based only upon evidence admitted at such hearing; and
 - D. To take advantage of all applicable provisions of the Kansas Administrative Procedure Act, K.S.A. 77-501 *et seq.* and the Kansas Judicial Review Act, K.S.A. 77-601 *et seq.*

The Respondent freely waives these rights and acknowledges that said waiver is made voluntarily and in consideration of the Board's limiting the disciplinary action taken against it to those provided for herein. The Respondent further waives the right to seek reconsideration or appeal or otherwise contest this Stipulation and Consent Order provided for herein.

14. The Respondent acknowledges that it enters into this Stipulation and Consent Order freely and voluntarily after consultation with counsel of its choosing. The Respondent further acknowledges that it has read this Stipulation and Consent Agency order in its entirety, that it understands its legal consequences and that it agrees that none of its terms are unconscionable, arbitrary or capricious.

15. Time is of the essence to this Stipulation and Consent Order. Respondent acknowledges and agrees that any violation of this Stipulation and Consent Order shall constitute a willful violation of a lawful Board order and grounds for further disciplinary action against it. The pendency of any disciplinary action arising out of an alleged violation of this Stipulation and

Consent Order shall not affect the obligation of Respondent to comply with all terms and conditions of this Stipulation and Consent Order.

16. This Stipulation and Consent Order constitutes the entire and final agreement of the parties. In the event any provision of this Stipulation and Consent Order is deemed invalid or unenforceable by a court of competent jurisdiction, it shall be severed and the remaining provisions of this Stipulation and Consent Order shall be given full force and effect.

17. Upon approval and entry of the Final Order by the Board, this Stipulation and Consent Order shall be a public record in the custody of the Board.

18. This Stipulation and Consent Order shall become effective on the day it is approved, accepted, and made an order of the Board by way of signature of the Board's authorized representative.

19. The Respondent acknowledges that it has been advised by the Board that it would have the right within 15 days after service of the Final Order provided for herein to file a petition for reconsideration with the Board and the right within 30 days after service of the Final Order provided for herein to file a petition for judicial review in the District Court of Shawnee County, Kansas in accordance with the Kansas Judicial Review Act, K.S.A. 77-601 *et seq.* and to serve such a petition for judicial review on the Kansas Board of Pharmacy by serving Alexandra Blasi, JD, MBA, its Executive Secretary at 800 SW Jackson St., Suite 1414, Topeka, KS 66612. The Respondent hereby waives those rights.

ENTERED AND EFFECTIVE this 7th day of December, 2021.

KANSAS BOARD OF PHARMACY

By:



DR. JONATHAN BRUNSWIG, President

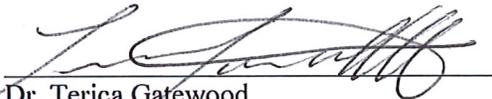
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AGREED AND APPROVED BY:

Hopewell Pharmacy
1 West Broad St.
Hopewell, NJ 08525

By: 

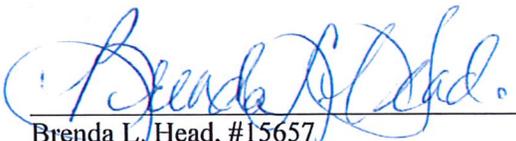
11/17/21
Date


Dr. Terica Gatewood
Investigation Member

12/2/21
Date


Bradley W. Howard, Esq.
BROWN & FORTUNATO, PC
905 S. Fillmore, Suite 400
Amarillo, TX 79101
(806) 345-6310
Attorney for Hopewell Pharmacy

11/17/2021
Date


Brenda L. Head, #15657
FRIEDEN & FORBES, LLP
1414 SW Ashworth Place, Suite 201
Topeka, KS 66604
(785) 354-1100
Attorney for Kansas Pharmacy Board

11-18-2021
Date

CERTIFICATE OF SERVICE

The undersigned hereby certifies that a copy of the foregoing STIPULATION AND CONSENT ORDER was served by depositing same in the United States mail, postage prepaid, this 7th day of December, 2021 addressed to:

Brenda L. Head
FRIEDEN & FORBES, LLP
1414 SW Ashworth Place, Suite 201
Topeka, KS 66604

Hopewell Pharmacy
1 West Broad St.
Hopewell, NJ 08525



Representative of the
KANSAS BOARD OF PHARMACY