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BOARD OF PHARMACY

STATE OF NEW JERSEY
DEPARTMENT OF LAW & PUBLIC SAFETY
DIVISION OF CONSUMER AFFAIRS
STATE BOARD OF PHARMACY

IN THE MATTERS OF THE SUSPENSION OR REVOCATION OF THE LICENSE OF DANIEL ALBIZATI, R.Ph. LICENSE NO.: 28RI0140200 TO PRACTICE PHARMACY IN THE STATE OF NEW JERSEY AND THE SUSPENSION OR REVOCATION OF THE PERMIT OF BURGESS CHEMIST NO. 2 PERMIT NO.: 28RS00400000 TO OPERATE AS A PHARMACY PRACTICE SITE IN THE STATE OF NEW JERSEY	Administrative Action CONSENT ORDER

These matters were opened to the New Jersey State Board of Pharmacy ("Board") by Robert Lougy, Acting Attorney General of New Jersey, Christopher Salloum, Deputy Attorney General, appearing, upon receipt of information evidencing that Daniel Albizati, R.Ph., ("Respondent Albizati") and Apteka Inc., doing business as Burgess Chemist No. 2 ("Respondent Burgess"), whose address is 559 Franklin

Avenue, Nutley, New Jersey, committed myriad violations of the laws, rules, and regulations governing the practice of pharmacy in the State of New Jersey. Respondents contest several of these allegations.

By way of background, Respondent Albizati is presently the owner and the pharmacist-in-charge of Respondent Burgess, and, at all times relevant hereto, Respondent Albizati was also an owner of Alblez, Inc., whose address is 25 West Main Street, Rockaway, New Jersey 07866, also known as Rockaway Pharmacy & Compounding ("Rockaway Pharmacy"). It is the Board's position that Respondent Burgess and Rockaway Pharmacy never requested, and never obtained, written approval from the Board to engage in sterile compounding as required by N.J.A.C. 13:39-11.3 and its predecessors, and, accordingly, that neither Respondent Burgess nor Rockaway Pharmacy was authorized to compound and/or dispense sterile preparations in this State. Respondent Burgess contests this allegation.

Despite allegedly never having received approval to engage in sterile compounding, it is the Board's position that Respondent Burgess, by and through Respondent Albizati, nonetheless compounded and dispensed sterile preparations. This first came to the Board's attention in June 2013, when the Board was informed that a recent New Jersey Department of Health survey of Renaissance Surgery Center in Saddle Brook, New Jersey, discovered two bags of Lidocaine 2GM in D5W 250 ml compounded by Respondent Burgess that

were labeled with a beyond-use date of one year and without assigned lot numbers.

On July 23, 2013, the Board conducted an inspection of Respondent Burgess to examine Respondent Burgess's sterile compounding practice. That inspection revealed numerous violations of the Board's regulations regarding sterile compounding, including regulations concerning training, environment, cleaning and disinfection, and compounding procedures, to wit N.J.A.C. 13:39-4(d), -14(b)(1), -11.14(a)(3)(ii), -11.14(a)(5), -11.15, -11.16(b), -11.17, 11.19(1), -11.20(a), -11.20(b), -11.21, 11.22(a)(1), and -11.12(6)(vi). The Respondents contest the applicability of these regulations.

In an attempt to address the serious compliance and public safety concerns raised by the Board's July 2013 inspection, by Interim Consent Order dated October 8, 2013, the Board ordered, and Respondent Burgess agreed, that Respondent Burgess immediately cease and desist from all sterile compounding operations ("2013 Order").

On March 7, 2014, the Board conducted a second inspection of Respondent Burgess, which revealed that Respondent Burgess continued to engage in the compounding and dispensation of sterile preparations and also violated the Board's regulation concerning centralized prescription handling codified at N.J.A.C. 13:39-4.19(b). Specifically, the March 2014 inspection discovered on the

premises of Respondent Burgess a sealed multi-dose vial that was labeled as follows:

Rockaway Pharmacy & Compounding
Renacidin Irrigation Solution 50ml
(citric acid, glucolactone, magnesium carbonate)
Date of prep: 2/4/14
Exp. Date: 8/4/14

On March 17, 2014, the Board conducted a separate inspection of Rockaway Pharmacy. That inspection discovered, among other things, a vial of Renacidin containing the same label described above, and a vial of a compounded sterile preparation Tri-Mix injection with a label indicating that it had been prepared on October 30, 2013. When the Board questioned Gregory DePaolo, the pharmacist-in-charge of Rockaway Pharmacy, regarding the origin of said vials of Renacidin and Tri-Mix injection, Mr. DePaolo explained that the Renacidin and Tri-Mix had been compounded by Respondent Burgess and delivered to Rockaway Pharmacy for dispensation. This arrangement, and each and every other instance, if any, in which Rockaway Pharmacy and Respondent Burgess "share[d] responsibility for performing the four component functions of handling a prescription," N.J.A.C. 13:39-1.19(b), constitutes centralized prescription handling. Because Rockaway Pharmacy and Respondent Burgess did not obtain Board approval to engage in centralized prescription handling as required by Board regulation, Respondent Burgess's participation in an unauthorized centralized

prescription handling arrangement violated N.J.A.C. 13:39-4.19(d)(2).

In April 2014, the Board subpoenaed documentation from Respondents Burgess and Albizati that allegedly revealed that Respondent Burgess, by and through Respondent Albizati, engaged in even more sterile compounding operations subsequent to the entry of the 2013 Order, and also allegedly violated several additional Board regulations. For instance, it is the Board's position that Respondent Burgess compounded and dispensed dozens of vials, without limitation, of the sterile preparations Doxycycline, C-Pilocarpine 0.25% ophthalmic solution, Hydroxyprogesterone Caproate Injection, and Bi-Mix Injection. In addition, such documentation allegedly revealed that Respondent Burgess had compounded and dispensed non-sterile preparation domperidone, which is a drug not approved for human use by the Food and Drug Administration, in violation of the Federal Food, Drug, and Cosmetic Act ("FDCA"), 21 U.S.C. 301 et seq., and in deviation from the general standards of the professional practice of pharmacy.

On August 6, 2014, Respondent Albizati appeared and provided sworn testimony before a committee of the Board regarding this matter. It is the Board's position that Respondent Albizati's testimony was not consistent with his pharmacy records. Respondent Albizati's records indicated, for example, that certain sterile preparations were compounded subsequent to the filing of the 2013

Order. But Respondent Albizati testified that he had compounded those sterile preparations prior to the execution of the October 2013 Consent Order, and then dispensed them as consumers needed them. If Respondent Albizati's testimony were to be believed, then those sterile preparations may have been dispensed beyond their use-by date. Accordingly, Mr. Albizati either willfully lied to the Board, or, by his own admission, dispensed compounded sterile preparations with inaccurate use-by dates.

Pursuant to N.J.S.A. 45:14-69(e), Respondent Albizati, as the owner and pharmacist-in-charge of Respondent Burgess and an owner of Rockaway Pharmacy, is responsible for the above-mentioned violations of the laws, rules, and regulations governing the practice of pharmacy, if proven.

The Board finds that the Respondents' conduct, as described above, provides grounds for disciplinary action against Respondent Albizati pursuant to N.J.S.A. 45:1-21(b), (e), and (h), and against Respondent Burgess pursuant to N.J.S.A. 45:14-75(b)(1) & (10) and N.J.S.A. 45:14-69.

The Respondents, on the advice of counsel, agreeing to the terms of this Consent Order, and the Board, finding the within disposition adequately protective of the public health, safety, and welfare, and good cause having been shown,

IT IS, THEREFORE, ON THIS 5th day of May 2016

ORDERED and AGREED that:

1. Effective ninety (90) days from the date that this Order is filed ("Effective Suspension Date"), Respondent Albizati's license to practice pharmacy in this State shall be suspended for sixty (60) months, of which at least thirty-six (36) months shall be served as a period of active suspension, and the remainder shall be served as a period of probation. Respondent Albizati's license shall be placed on probation no earlier than thirty-six (36) months from the Effective Suspension Date, provided, however, that all civil penalties, costs, and attorneys' fees assessed herein, including any amount that has been stayed, are paid in full.

2. On the Effective Suspension Date, Respondent Albizati shall cease and desist from engaging in the practice of pharmacy in this State. This provision shall include, without limitation, the following restrictions:

a. Respondent shall not handle, order, inventory, compound, count, fill, refill, or dispense any drug;

b. Respondent shall not handle anything requiring a prescription, including devices and medications;

c. Respondent shall not handle prescriptions;

d. Respondent shall not advise or consult with patients;

e. Respondent shall not be present within any area of any pharmacy in this State that is not open to the general public,

including, without limitation, the prescription filling area of a pharmacy.

3. On the Effective Suspension Date, Respondent Burgess shall designate Maureen Paonessa, R.Ph., as pharmacist-in-charge. So long as Respondent Albizati maintains an ownership interest in Respondent Burgess and is actively suspended from the practice of pharmacy in this State, Ms. Paonessa shall remain pharmacist-in-charge pending further order of the Board. As evidenced by her signature below, Ms. Paonessa agrees to assume the duties and responsibilities of pharmacist-in-charge, and further agrees, consistent with her obligations as a Board licensee and her obligations as pharmacist-in-charge, to report to the Board any violations of this Order committed by Respondent Albizati. Ms. Paonessa agrees that her failure to do so shall constitute professional misconduct and shall provide a basis for discipline against her license to practice pharmacy in this State pursuant to N.J.S.A. 45:1-21(e).

4. On the Effective Suspension Date, and throughout the duration of the active suspension of his pharmacy license, Respondent Albizati shall be barred from the premises of Respondent Burgess with the following exception: Respondent Albizati shall be permitted to be present on the premises of Respondent Burgess for the sole and singular purpose of showing the premises to

prospective purchasers of Respondent Burgess, provided, however, that Ms. Paonessa is present and monitors the visit.

5. Respondent Albizati shall be, and hereby is, permanently barred from compounding sterile preparations in this State.

6. Respondent Burgess shall be, and hereby is, permanently barred from compounding sterile preparations in this State so long as Respondent Albizati maintains an ownership interest in Respondent Burgess.

7. Respondents Albizati and Burgess shall be, and hereby are, assessed a civil penalty in the amount of Twenty Thousand and 00/100 Dollars ($20,000).

8. Respondents Albizati and Burgess shall be, and hereby are, assessed costs in the amount of Twelve Thousand Seven Hundred Fifty-Nine and 26/100 Dollars ($12,759.26).

9. Respondents Albizati and Burgess shall be, and hereby are, assessed attorneys' fees in the amount of Twenty-Eight Thousand and 00/100 Dollars ($28,000), of which Ten Thousand and 00/100 Dollars ($10,000) shall be stayed provided that the Respondents comply with the terms of this Consent Order. Failure to comply with the terms of this Consent Order shall automatically activate the stayed attorneys' fees, which shall then be immediately due and owing.

10. The Respondents shall be jointly and severally liable for the timely payment of all penalties and costs assessed herein.

11. The Respondents shall pay all civil penalties, costs, and attorneys' fees assessed herein as follows:

a. Respondents shall pay Twelve Thousand and 00/100 Dollars ($12,000) simultaneously upon the execution of this Consent Order.

b. Respondents shall pay Thirty-Eight Thousand Seven Hundred Fifty-Nine and 26/100 ($38,759.26) in two payments of Nineteen Thousand Three Hundred Seventy-Nine and 63/100 Dollars ($19,379.63) no later than December 30, 2016.

12. Any and all payments required to be made by this Consent Order shall be made by wire transfer or by bank check, money order, or certified check made payable to the State of New Jersey and sent to Anthony Rubinaccio, R.Ph., Executive Director, New Jersey Board of Pharmacy, P.O. Box 45013, Newark, New Jersey 07101. Any payment in a form other than those noted herein shall be rejected and returned. Failure to make timely payment shall result in the filing of a Certificate of Debt pursuant to N.J.S.A. 45:1-24 for the total amount due and owing. Subsequent violations of Board statutes, regulations, or orders, including this Consent Order, will subject the Respondents to enhanced penalties pursuant to N.J.S.A. 45:1-25.

13. The entry of this Consent Order shall be without prejudice to further investigation and/or action by this Board, the Attorney General, the Director of the Division of Consumer Affairs,

or any other government entities resulting from Respondents' conduct not addressed by the terms of this Order.

NEW JERSEY STATE BOARD OF PHARMACY

By: Thomas F.X. Bender, Jr., RPh
Thomas F.X. Bender, R.Ph.
President

I have read the within Order and understand it. I agree to be bound by its terms and hereby consent to it being entered by the New Jersey Board of Pharmacy.

Daniel Albizati RPh
Daniel Albizati, R.Ph.

I am the owner and pharmacist-in-charge of Respondent Burgess. Burgess agrees to be bound by the terms of this Order, and hereby consents to the entry of this Order by the Board.

Burgess Chemist No. 2

By: Daniel Albizati RP
Daniel Albizati, R.Ph.
Owner and Pharmacist-in-Charge

Consent as to form and entry:

Angelo Cifalci, Esq.
Attorney for Respondents

I have read the within Order in its entirety, and agree to be bound by its terms insofar as they pertain to me. I agree to report any and all violations of this Order committed by Burgess and/or Daniel Albizati to the Board.

Maureen Paonessa, RPh.
Maureen Paonessa, R.Ph.