Before the New Hampshire
Board of Pharmacy
Concord, NH 03301

In the Matter of: Docket No: 2017-01

Wells Pharmacy, NR0198

(Show Cause Hearing for renewal of NRMO Pharmacy Application)

ORDER OF DENIAL

A show cause hearing commenced on April 19, 2017 to determine whether the Board properly denied the Renewal Application of Wells Pharmacy ("Wells") NR 0198, of Ocala, Florida. For the following reasons, the Board has voted to DENY Wells' application.

Background

Wells filed an application for renewal for a Non-Resident Pharmacy Permit which was accepted for filing on December 13, 2016. On or about February 15th , 2017, the Board issued an Order denying Wells' application but giving Wells the opportunity to request a hearing on the denial and show cause why it should be licensed. The Board's reason for the denial was twofold. First, the Board found that Wells' application packet documented recent disciplinary action taken by at least four different states. On that basis, the Board denied Wells' application pursuant to Ph 905.01(a)(6). Additionally, the Board stated that through Wells' application, the Board first became aware that Wells engages in the process of lyophilization and the process of producing pellets; the Board stated that if Wells wishes to continue doing so it must obtain a manufacturing or 503-B permit from the Board.

On or about March 15th, 2017, Wells requested a hearing on its denial, and on April 19, 2017, the Board held a show cause hearing on Wells' application. Kristopher Fishman, Senior Vice President of Operations, appeared on behalf of Wells.

Mr. Fishman explained why the other states had disciplined Wells. According to Mr. Fishman, in February 2016 Wells staff tested one of Wells' compounding rooms for contamination and the room tested positive for airborne mold. Wells sent the sample to a lab and determined it was pennicilium. Wells disinfected and cleaned the facility, and a few weeks later there was no sign of the mold. Then, in late March 2016, the compounding room again tested positive for airborne mold. When Wells sent this sample for testing, they learned that there was both pennicilium and a different type of fungal growth present. Wells staff again disinfected and cleaned the facility. At some point in the future, Wells staff again determined there was an airborne mold in the compounding room, and Wells then shut that specific compounding room down.

Mr. Fishman explained that the company had already scheduled to demo the room to get it fully up to 797 standards and convert it to an 800 room. After the demo was started, Wells employees discovered the source of the mold — a small leak around a pipe that ran from the ceiling to about twenty feet above the ceiling tiles to the room. Mr. Fishman explained that no one had found that leak because no one had thought to pop the ceiling tiles.

Mr. Fishman explained that the room was completely remodeled to higher standards before being put back into use. He further explained that Wells worked with the Florida Board of Pharmacy and the FDA to recall their products, notifying the approximately 25,000 patients that were affected. He stated that throughout the recall process, there were zero adverse effects reported. Mr. Fishman further explained that Wells took all its products from its store room and sent them out for testing; there were zero concerns with sterility. He explained that Wells now tests the air continuously and tests for viables during batch time, which is every day.

Mr. Fishman explained that after the remodel, the National Association of Boards of Pharmacy ("NABP") inspected the facilities. Mr. Fishman explained that Wells passed the NABP inspection. Shortly thereafter, NABP called the Texas Board of Pharmacy, and that board lifted the restrictions it had put on Wells' license. Shortly thereafter, the boards in both South Carolina and Arizona lifted the restrictions from Wells' license, as well.

With regard to lyophilization and pellets, Mr. Fishman stated that he is not a pharmacist so is not an expert, but told the Board that Wells uses the lyophilization process in order to keep the correct potency of the drugs. He stated that he understands that lyophilization can be difficult, particularly if a pharmacist does not have the correct equipment. Mr. Fishman stated that Wells will not lyophilize more than 250-500 vials at a time. Mr. Fishman explained that Wells does not produce pellets on site; the pellets are transferred from a 503(b) facility.

In response to Board questioning, Mr. Fishman admitted that once the mold was discovered, Wells failed to re-test frequently enough. Mr. Fishman stated that the individual who was responsible for overseeing quality at Wells is no longer with the company due to the unacceptable response to this incident.

Commissioner Stout stated that the standard operating procedures that Wells had provided in its packet to the Board were satisfactory. However, Commissioner Stout stated that the 2012 USP 797s, Compounding Standards, had wonderful guidance for operating procedures, and he asked why Wells failed to implement those. For instance, Commissioner Stout stated Wells had documented training deficiencies and cleaning deficiencies, and used to allow technicians to verify products for the final visual check. Commissioner Stout thus asked Mr. Fishman why the Board should be confident that Wells would comply with the satisfactory standard operating procedures it provided last week when it did not have sufficient procedures in

place for so long. Mr. Fishman explained that the business changed hands in 2011, and he was not hired until 2014. Mr. Fishman stated that once he started at the company, he began establishing standard operating procedures, hitting the 797 standards or higher. Mr. Fishman explained that Wells had been working to improve its policies.

Commissioner Stout then asked about a citation in the NABP report concerning Wells shipping products for office use. Mr. Fishman explained that that citation was for veterinary products, and he stated that there was no regulation with this restriction for veterinary products. The Board clarified that here in New Hampshire, there is such a regulation, and stated that Wells is thus out of compliance with various Board statutes and rules.

Commissioner Rochefort asked Mr. Fishman about how Wells' pharmacists are trained on lyophilization, as it is not traditionally taught in schools. Mr. Fishman explained that Wells' head pharmacist had been Wells' pharmacist for 15 years, and he learned to lyophilize on the job. Mr. Fishman stated that after the lyophilized products are made, they are tested and verified. Commissioner Rochefort asked if this pharmacist had trained any others; Mr. Fishman answered that in the last three years the pharmacist has only trained two others.

Relevant Law

RSA 318:1

III-a. "Compounding" means the preparation, mixing, assembling, packaging or labeling of a drug or device as a result of a practitioner's prescription drug order or initiative based on the pharmacist-patient-prescriber relationship in the course of professional practice or, for the purpose of, or as an incident, to research, teaching, or chemical analysis, but not selling or dispensing. "Compounding" also includes the preparation of drugs or devices in anticipation of prescription drug orders based on routine, regularly observed prescribing patterns. "Compounding" shall not include the reconstitution of powdered formulations before dispensing or the addition of flavoring.

318:14-a Compounding.

I. Products that are not commercially available may be compounded for hospital or office use

but shall not be resold or dispensed. Nonprescription items may be compounded upon order by a practitioner for sale as long as the labeling complies with RSA 318:47-a and the product is not a copy of, or similar to, prescription or nonprescription products. All compounding shall be done in compliance with the United States Pharmacopeia as defined by board of pharmacy rules.

II. The compound drug product shall bear the label of the pharmacy responsible for compounding and dispensing the product directly to the patient for administration, and the prescription shall be filed at that pharmacy. Compounded prescription labels shall include the phrase "compounded per subscriber request" or a similar statement on the prescription label or through the use of an auxiliary label attached to the prescription container.

III. A pharmacist shall offer a compounded drug product to a practitioner for administration to an individual patient, in limited quantities. The compounded drug products are for practitioner administration only and shall not be re-dispensed. The pharmacist shall maintain records to indicate what compounded drug products were provided to the medical office or practice. Compounding pharmacies may advertise or otherwise promote the fact that they provide prescription compounding services, in accordance with state law and rules of the board, as well as applicable federal laws.

IV. Where a commercial drug shortage exists because a manufacturer is the only entity currently manufacturing a drug product of a specific strength, dosage form, or route of administration for sale in the United States, and the manufacturer cannot supply the drug product to the public or to practitioners for use, a pharmacist may compound a limited quantity using the active pharmaceutical ingredient and sell to a patient with a valid prescription from a valid prescriber. When the compounded drug product is sold to a medical office or practice it is for the practitioner to administer to patients, and shall not be for resale.

V. The board shall adopt rules under RSA 541-A concerning the regulation of compounding.

VI. Labeling requirements pursuant to paragraph II shall not apply when medication is dispensed to institutionalized patients as provided under RSA 318:47-b.

Ph 905.01 Effect of Revocation and Denial.

(a) The board shall refuse to issue a registration or shall revoke a registration whenever the board determines that a mail-order pharmacy, its pharmacist-in-charge, owner(s) or corporate officer(s) has, after notice and opportunity for a hearing, except pursuant to (c) below, committed an act such as but not limited to:

. . .

(4) Failed to comply with RSA 318:37, II, the provisions of Ph 900, or both;

. . .

(6) Been found guilty of any violation of federal, state or local drug law or have entered into any agreement to resolve violations of such.

. . .

(c) Notwithstanding the above the board shall issue a registration or not revoke if:
(1) No harm resulted from the actions of the applicant or registrant;
(2) There was no intent to violate any provisions of RSA 318;
(3) Corrective action has been taken by the registrant;
(4) Remunerations have been made to the affected party(s); and
(5) The board determines the action is unlikely to occur again.

Ph 404.04(b) and (c) Regulatory Requirements for Sterile Compounding

(b) When a compounder prepares more than 50 dosage units for non-patient specific preparations the compounder shall be registered as a drug manufacturer or 503B with the FDA.

(c) Compounders supplying limited quantities, less than 50 dosage units, to providers for administration use shall have an MOU with the provider for each compounded product they supply to the provider. When a compounder provides a practitioner a non-patient specific preparation, the compounder shall provide the practitioner a copy of the test result for each lot provided to the practitioner.

Ph 404.02(u) Definitions

(u) "Limited quantities" means a batch with 50 or less dosage units provided to a hospital or practitioner to administer to their own patient.

Findings of Facts and Rulings of Law

In arriving at the decision below, the Board considered the original application packet from Wells, the documents Wells provided in anticipation of the hearing, and the testimony of Mr. Fishman.

Recent Disciplinary Action

The Board first considered, in light of the Board denying Wells' application due in part to the recent disciplinary actions of other states under Ph 905.01(a), whether all five mitigating factors if Ph 905.01(c) had been met.

The Board first finds that under Ph 905.01(c)(1), no harm resulted from the Wells' actions. Mr. Fishman testified that Wells took action to recall any affected drugs and notify the approximately 25,000 patients that were affected. Mr. Fishman testified that there were zero major adverse effects reported. When asked to clarify whether there were any adverse effects reported, Mr. Fishman stated that there were no adverse effects reported at all. On the basis of

Mr. Fishman's testimony, then, the Board determines that the mitigating factor in Ph 905.01(c)(1) has been met.

The Board questions whether, under Ph 905.01(c)(2), there was no intent to violate any provisions of RSA 318. The Board does find that Wells did not intend to violate RSA 318 with its past contamination problems, as the Board is satisfied that the airborne mold was caused by a leaky pipe that remained undiscovered. However, as the Board noted at the hearing, Wells' practice of distributing directly to veterinary practices is not in compliance with RSA 318:14-a, III and Ph 404.02. The Board understands from Mr. Fishman's testimony that Wells was unaware of this regulation in New Hampshire, but the Board notes that it is the responsibility all licensees and registrants to comply with the relevant laws.

The Board next finds that under Ph 905.01(c)(3), Wells has taken corrective action. Mr. Fishman testified that Wells has since demolished the contaminated compounding room, fixed the leak, and rebuilt the room to 800 standards. In addition, Wells recalled all the affected products and it now does daily testing for viables. The Board does note that Wells did not test frequently enough after first discovering the contamination. Mr. Fishman, however, admitted this and stated the individual responsible for overseeing quality during that time was no longer with the company due to the unacceptable response to this incident.

The Board finds that under Ph 905.01(c)(4), Wells made remunerations to the affected parties. As stated above, Wells recalled all affected products and no adverse effects were reported.

The Board finds, however, that under Ph 905.01(c)(5), it does not have confidence yet that the action is unlikely to occur again. The Board is concerned that Wells in the past failed to follow the guidance of the 2012 USP 797 Compounding Standards. The Board specifically notes

that Wells has documented training deficiencies and cleaning deficiencies, and it further allowed technicians to verify products for the final visual check. The Board does note that Wells produced satisfactory standard operating procedures that Mr. Fishman stated employees will now be following. However, given Wells' failure to have sufficient procedures in place for so long and its failure to adopt the 797s, the Board is not confident yet that Wells will adequately comply with these standard operating procedures. The Board also has concerns that Wells just learned at the hearing of New Hampshire's restriction on distributing directly to veterinary practices.

For the reasons stated above, the Board finds that the five mitigating factors in Ph 905.01(c) have not all been met. Based on Wells' history of having insufficient procedures in place, the Board does not yet have confidence that the action is unlikely to occur again. The Board is also concerned that Wells was distributing directly to veterinary practices, in violation of RSA 318:14-a, III and Ph 404.02. Wells' application for renewal is therefore denied.

Lyophilization

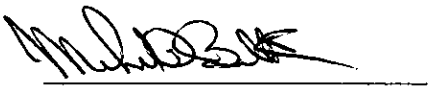
The Board next considers whether, by engaging in lyophilization, Wells was engaged in the practice of manufacturing, thus necessitating a 503B permit. Mr. Fishman stated that Wells lyophilizes in order to keep the correct drug potency. He further stated Wells' average batch size when lyophilizing is 250–500 vials. Ph 404.04(b) specifically states that "[w]hen a compounder prepares more than 50 dosage units for non-patient specific preparations, the compounder shall be registered as a drug manufacturer or 503B with the FDA." Therefore, if Wells wishes to continue lyophilizing, when it re-applies it must apply for and obtain as a 503B permit.

Conclusion

For the reasons stated above, the renewal application of Wells Pharmacy, Ocala Florida is DENIED.

BY ORDER OF THE BOARD_*/

Dated: July 18th, 2017



Michael D. Bullek, BSP, R.Ph.
Authorized Representative of the
New Hampshire Board of Pharmacy

_*/ Board Member recused