

IN THE MATTER OF * BEFORE THE
PROFESSIONAL ARTS PHARMACY * STATE BOARD OF
Respondent * PHARMACY
*

PERMIT NO: P01022 * CASE NO: PI-16-175

* * * * *

CONSENT ORDER

On March 15, 2017, the Maryland State Board of Pharmacy (the “Board”) charged **Professional Arts Pharmacy, permit number P01022** (“the Respondent-Pharmacy”), under the Maryland Pharmacy Act (the “Act”), Md. Code Ann., Health Occ. II (“Health Occ. II”), §§ 12-101 *et seq.* (2014 Repl. Vol. and 2016 Supp.) and the Code of Maryland Regulations (“COMAR”).

The Board charged the Respondent-Pharmacy with violating the following provisions of the Act:

§ 12-403. Required standards.

...
(c) *In general.* – Except as otherwise provided in this section, a pharmacy for which a pharmacy permit has been issued under this title:

- (1) Shall be operated in compliance with the law and with the rules and regulations of the Board;
- (2) Shall be located and equipped so that the pharmacy may be operated without endangering the public health or safety;
- ...
(11) (i) Shall maintain at all times the minimum professional and technical equipment and sanitary appliances that are necessary in a pharmacy:

- 1. To prepare and dispense prescriptions properly; and
- 2. To otherwise operate a pharmacy; and

(ii) Shall:

1. Be equipped with the minimum equipment and appliances specified by the Board under this section; and
2. Be kept in a clean and orderly manner;

...

(12) Shall store all prescriptions or nonprescription drugs or devices properly and safely subject to the rules and regulations adopted by the Board

The Board also charged the Respondent-Pharmacy with violating the following COMAR provisions:

10.34.19. Sterile Pharmaceutical Compounding.

09. Minimum Facility Requirements.

...

B. Controlled Environment - Clean Room. The permit holder shall ensure that the clean room in the controlled environment:

- (1) Meets USP 797 Standards for design and USP 797 performance criteria quality standards for clean rooms.

10. Minimum Requirements for Equipment.

A. The permit holder shall provide at least the following equipment that is maintained in working order:

...

- (4) Laminar air flow workstation or compounding aseptic isolator that meets USP 797 Standards, dedicated for products other than antineoplastics;

...

- (6) Appropriate filters and filtration equipment.

B. If used, the permit holder shall provide the following that is maintained in working order, calibrated, or certified where appropriate: (1) Autoclave; (2) Automated compounding devices ... ; ... (5) Thermometers or other temperature device; and (6) Incubator.

12. Minimum Requirements for Policies and Procedures.

A. The permit holder shall ensure that the pharmacist or the pharmacist's designee shall maintain a policy and procedure manual, reviewed annually, that sets forth

in detail the permit holder's standard operating procedures with regard to compounding sterile preparations.

B. The permit holder shall insure that the policy and procedure manual that sets forth the standard operating procedures with regard to compounding sterile preparations is implemented and adhered to.

C. The policy and procedure manual shall include policies and procedures governing the following:

...

- (3) Equipment including, but not limited to: (a) Procedures for use;
- (4) Sanitation standards and procedures including monitoring for bacterial microorganisms to demonstrate effectiveness of cleaning activities.

13. Attire.

A. When compounding sterile preparations, individuals shall comply with the following standards:

...

- (1) Sequencing of garbing that complies with USP 797 Standards;
- (2) Thorough hand-washing before gowning;
- (3) Wearing clean room garb inside the designated area at all times, which consists of: (a) A non-shedding coverall or gown; (b) Head and facial hair covers; (c) A face mask; and (d) Shoe covers;
- (4) Clean room garb, with the exception of sterile gloves, shall be donned and removed outside the designated clean room area; . . .
- (6) Sterile gloves are required

14. Training of Staff, Patient, and Caregiver.

...

B. The permit holder shall ensure that pharmacy personnel engaging in compounding sterile preparations are trained and demonstrate competence in the safe handling and compounding of compounded sterile preparations and parenteral solutions, including cytotoxic agents if applicable.

C. The permit holder shall maintain records of training and demonstrated competence for individual employees for 5 years.

15. Quality Assurance.

The permit holder shall ensure that the compounded sterile preparation retains its potency and sterility throughout the assigned “beyond use” dating period through a written quality assurance program that includes:

A. A reasonable effort by the pharmacist to assure that compounded sterile preparations shall be kept under appropriate controlled conditions before dispensing, during transport, and at the location of use by providing adequate labeling and verbal or written instructions regarding proper storage and administration, as set forth by the product manufacturer and established standards and literature, with each compounded sterile preparation dispensed;

B. The phases of compounded sterile preparation, distribution, storage, administration, and directions for use for each type of preparation dispensed.

C. Environmental sampling for microbial organisms in laminar air flow workstations and clean rooms is performed according to methods and schedules specified by USP 797 Standards and if microbial contamination is suspected, for example, in the event of positive media fill verification results;

D. Laminar air flow workstations, biological safety cabinets, and compounding aseptic isolators certified by a trained and qualified operator;

E. Clean room and anteroom certification by a trained and qualified operator according to USP 797 Standards;

F. The proper disposal in accordance with accepted professional standards and applicable State and federal laws of unused drugs and materials used in the preparation of compounded sterile preparations, including antineoplastic agents and hazardous materials;

G. A formal written review process to report and evaluate compliance with this chapter; and

H. A process that complies with applicable USP 797 Standards for performing sterility checks or pyrogen testing, or both, for applicable compounded sterile preparations.

On May 3, 2017, the Respondent-Pharmacy attended a Case Resolution Conference ("CRC") in an effort to resolve the pending charges in lieu of an evidentiary hearing. As a result of the CRC, the Respondent-Pharmacy agreed to enter into this Consent Order consisting of Findings of Fact, Conclusions of Law, and Order.

I. FINDINGS OF FACT

The Board finds that:

1. At all times relevant to these charges, the Respondent-Pharmacy was located in Baltimore, Maryland, 21244.
2. The Respondent-Pharmacy was issued pharmacy Permit No. P01022 to operate a resident pharmacy in the State of Maryland on April 22, 1991.
3. The Respondent-Pharmacy last renewed its permit on March 31, 2016.
4. On or about April 13, 2016, the Board became aware that the U.S. Food and Drug Administration (FDA) had issued a Form 483 regarding the Respondent-Pharmacy. The redacted Form 483 can be found on the FDA's website at <https://www.fda.gov/downloads/AboutFDA/CentersOffices/OfficeofGlobalRegulatoryOperationsandPolicy/ORA/ORAElectronicReadingRoom/UCM497121.pdf>.
5. The FDA's Form 483 noted the following observations with the Respondent-Pharmacy's sterile compounding practice, which were observed by FDA inspectors between March 2, 2016 and March 23, 2016:

a. Aseptic processing areas are deficient regarding air supply that is filtered through high-efficiency particulate air filters under positive pressure.

- i. HEPA filters are located in the "Clean Room"¹ (ISO 6²) in the ceiling

¹ "Clean room" means a room with an International Standards Organization (ISO) Class 5 environment or an ISO Class 7 environment that meets USP 797 Standards, inside which compounding occurs within an ISO Class 5 engineering control device such as a laminar airflow workstation or a biological safety cabinet. COMAR 10.34.19.03(6).

² "ISO" means International Organization for Standardization. COMAR 11.14.07.02(7). ISO develops and publishes International Standards, <http://www.iso.org/iso/home.htm>. The relevant ISO standard in this case is ISO 14644-1, Cleanrooms and associated controlled environment – Part 1: Classification of air cleanliness by particle concentration. http://www.iso.org/iso/catalogue_detail?csnumber=53394. ISO 14644-1 provides 10 cleanroom classifications rated according to how much particulate of specific sizes exist per cubic meter; for example, ISO 6 means Class 6. <https://www.terrauniversal.com/cleanrooms/iso-classification-cleanroom-standards.php>.

above the laminar flow hoods. There are no HEPA filters in the "Gowning Room" (ISO 6). The Respondent-Pharmacy does not do environmental monitoring of the air supply.

b. Clothing of personnel engaged in the processing of drug products is not appropriate for the duties they perform.

- i. On March 3, 2016, a technician was observed gowning up prior to entering and cleaning the floors in the "Clean Room" which includes laminar flow hoods (ISO 5) used to produce sterile drug preparations, the adjacent "Gowning Room", and the adjacent "Entry Room" (nonclassified). The "Entry Room" contains materials used for sterile preparations. The technician wore only non-sterile gloves and non-sterile shoe covers, and a non-sterile face mask prior to entering and cleaning the floors in the "Clean Room" and "Gowning Room". The same shoe covers and gloves worn in the "Entry Room" were also worn in the "Gowning Room" and "Clean Room." The technician's arms, face, neck, and hair were exposed within the "Clean" and "Gowning" rooms. Direct contact of the technician's arms/skin was observed with the plastic curtains used to provide physical separation between the "Clean Room" and "Gowning Room," and between the "Gowning Room" and the "Entry Room." The technician put on a non-sterile hairnet and a non-sterile gown using the same pair of non-sterile gloves that were worn to clean the floors in the "Clean," "Gowning," and "Entry" rooms. The same pair of non-sterile gloves was used after cleaning and before donning the hairnet and gown.
- ii. On March 8, 2016, a technician was observed wearing a non-sterile gown,

hairnet, face mask, and shoe covers in the "Clean Room." The technician's face/skin above the mask was exposed. The technician went into the "Gowning Room" and removed the sterile gloves followed by the gown, hairnet, and face mask. The gloves and face mask were discarded, but the gown and hairnet were kept in the "Gowning Room" for reuse. The technician was wearing street clothes with arms exposed. The technician went from the "Gowning Room" to the "Entry Room" by passing front facing through the plastic curtains which came into contact with the technician's exposed arms and street clothes. The technician re-entered the "Gowning Room" front facing and donned a new nonsterile face mask followed by the previously worn hairnet and gown prior to re-entering the "Clean Room" front facing through the plastic curtain.

c. Procedures designed to prevent microbiological contamination of drug products purporting to be sterile are not established and followed.

- i. The Respondent-Pharmacy does not monitor the differential pressures between the classified and unclassified areas ("Clean Room," "Gowning Room," and "Entry Room").
- ii. Smoke studies are not performed under dynamic conditions.
- iii. The Respondent-Pharmacy does not perform environmental monitoring of the plastic curtains used to separate the classified and unclassified rooms ("Clean Room," "Gowning Room," and "Entry Room").
- iv. The Respondent-Pharmacy uses non-sterile equipment and non-

depyrogenated³ equipment to produce sterile drug products.

- v. The Respondent-Pharmacy does not have adequate standardized procedures. On February 25, 2016, a failure occurred for Prednisolone 50mg/ml injectable (Batch No. AS699). A pharmacist stated that the sterilization failed and that they repeated the sterilization. There is no written record of any investigation.
- vi. There is no qualification, no calibration or preventive maintenance of the sterile compounding equipment used by the Respondent-Pharmacy.

d. Aseptic processing areas are deficient regarding the system for cleaning and disinfecting the room to produce aseptic conditions.

- i. On March 3, 2016, a technician was observed cleaning the laminar flow hood. The technician alternated between cleaning of the interior and exterior surfaces of the hood using the same non-sterile wipe. By the completion of the cleaning, the surfaces did not appear to be wetted. The working surface of the laminar flow hood is the last surface to be cleaned. The equipment was not moved to wipe the counter underneath. The top of the horizontal shield of the hood was not cleaned. The Respondent-Pharmacy has not established contact times for the cleaning and disinfecting of surfaces. The Respondent-Pharmacy uses non-sterile wipes to clean the laminar flow hoods. The work area of the laminar flow hoods are constructed of formica.

³ “Depyrogenation” is a process used to destroy or remove pyrogens (e.g., endotoxin).¶ 310,821 Current Good Manufacturing Practice Interim Guidance for Human Drug Compounding Outsourcing Facilities under Section 503B of the FD&C ACTFT, Food Drug Cosm. L. Rep. P 310821.

ii. A white residue and a yellow residue were observed on the stainless steel back of the laminar flow hood. What appeared to be rust was observed along the left hand side of laminar flow hood.

e. Test procedures relative to appropriate laboratory testing for sterility are not written and followed.

i. The owner stated they started doing sterility testing in December 2015. As per the Respondent-Pharmacy's sterility testing log, they have sent out samples from sterile product prescriptions.

ii. The Respondent-Pharmacy produces sterile drugs. At the time of dispensing a label is added indicating: "*only good for ____ days in refrigerator and 45 days in the freezer.*"

f. Component testing is deficient in that each component is not tested for conformity with all appropriate written specifications for purity, strength, and quality.

i. The Respondent-Pharmacy used a non-pharmaceutical grade product for the preparation of prescribed sterile eyes drops. Batch records indicated that the concentration was not adjusted to conform to specifications.

6. The Respondent-Pharmacy's owner provided a written response to the FDA inspection and observations. Among other things, the response letter from the Respondent-Pharmacy included the following:

a. The Respondent-Pharmacy ceased engaging in sterile compounding on April 12, 2016 and began using a third-party company to manage the recall of questionable drugs that the Respondent-Pharmacy had compounded.

b. The Respondent-Pharmacy indicated that they had made numerous remedial

changes following the FDA's inspection.

- c. The Respondent-Pharmacy noted that the Pharmacy "compounds small batches of its formulations; the 'batch' of Prednisolone addressed by FDA in this Observation consisted of two (2) vials of Prednisolone. Generally, the vast majority of sterile compounding (called 'batches') at the Pharmacy consists of only two or three vials of product."
7. Upon review of the Form 483, the Board initiated an investigation and requested that a sterile compounding expert review the documents and provide an opinion based upon his review.
 8. The expert noted the following:
 - a. There is adequate evidence that the Respondent-Pharmacy does not meet the standards required in the Board's regulations or in the USP General Chapter 797.
 - b. While the response from the Respondent-Pharmacy indicated changes in procedure, the changes do not appear to go far enough to meeting the requirements of the regulations and USP General Chapter 797 because: a full assessment of the air exchange and handling requirements for a clean room does not exist; procedures are not in place to ensure that the air handling equipment is run for 24 hours a day or that testing is conducted to see if existing procedures meet standards; training has not been adequately addressed nor has an appropriate Policy and Procedure Manual for the facility been provided; the Respondent-Pharmacy fails to regularly observe staff or document regular cleaning and independent testing of the cleaning procedures; the Respondent-Pharmacy compounds large numbers of products without adequate end product testing; and the Respondent-Pharmacy fails to apply Beyond Use Dating based on actual

testing.

- c. In addition, the expert noted that “[b]ased on feedback from the FDA the pharmacy discontinued production of the specific product cited in the report. The fact that the facility produced products without adequate review of the potential risks for using non-pharmaceutical grade components leads to the conclusion that there should be a review of all preparations to determine if this is part of an ongoing pattern.”
- d. The expert noted that “of particular concern are the frequently observed failure to gown and garb properly and the use of non-sterile gloves and equipment while setting up or performing procedures.”
- e. More critical was the Respondent-Pharmacy’s failure to conduct a thorough analysis of any discrepancies or product failures. The expert noted that “there is a direct correlation between the quantity of a product that is compounded and the quality of that product. Producing small volume products in small quantities may result in a higher risk of error from any procedural deficiencies, including measurement errors. The fact that the compounding facility produces two or three vials in a production run should not lead to the conclusion that any testing procedures could be minimized or eliminated. . . . [Although] [i]t may not be feasible or cost effective to test batches of product to fully ensure that the resultant product meets standards for sterility and equally importantly, standards for stability, . . . this action is essential for any compounding facility to perform.”
- f. The expert also questioned whether it might be feasible to bring the facility into compliance with USP 797 clean room requirements, noting that based on the information in the Form 483, “it appears as if the facility may have been placed in

an existing space without a full assessment of the air exchange and handling requirements for a clean room. . . . The changes required to bring the facility into compliance may not be feasible in the existing space without significant structural changes and the addition of new air handling devices.”

9. On April 22, 2016, the Board’s Compliance Officer, Board Inspector and the sterile compounding expert conducted an inspection of the Respondent-Pharmacy.

10. The inspection noted the following findings:

- a. There is a HEPA filter in the Gowning Room, which looks different than that in the Clean Room; however, a pharmacist indicated the HEPA filter was installed at the same time as the Clean Room HEPA filters. This is contradictory to what was noted on the FDA report.
- b. The inspectors observed the word "leak" written on a ceiling grid at the HEPA Filter in Clean Room. Pharmacist A stated the leak had been scheduled to be fixed the following week but the appointment was canceled due to the closure of the sterile compounding area of the pharmacy.
- c. The ceiling tiles were not compliant with USP 797 as they were not sealed.
- d. The hoods were not operating during the Board visit.
- e. The Entry Room to the Gowning Room and from the Gowning Room to the Clean Room were separated by plastic strip curtain.
- f. The Respondent-Pharmacy indicated that it had returned all of the previous gowns, gloves and attire that the FDA mentioned in the Form 483 report. Present in the Gowning Room were sterile gloves, mask and shoe covers, and hair nets.
- g. Pharmacist A stated that sterile compounding staff wore masks all the time and that shoe covers were put on and hand washing was conducted before entering the

Gowning Room. Staff placed another set of shoe covers on in the gowning room in addition to the required gowning attire.

- h. No policy and procedure for gowning and training or retraining documents for employees on gowning was available. Pharmacist A stated that a pharmacist and a technician received certification from PCCA in 2012 on gowning, but no additional training or monitoring had been conducted since then.
- i. The review of documentation of the Clean Room Cleaning Competencies was available for April 2016 only.
- j. Per Pharmacist A, powders are weighed in the Entry Room. Products must go through the Gowning Room before entering Clean Room. There are no pass through windows in the sterile compounding facility. Sterile compounded drugs would have to leave the same way the ingredients came in, that is going through the plastic curtains.
- k. There was no evidence that Magnehelic gauges⁴ were installed.
- l. The owner reported that a smoke study had been scheduled but was cancelled because the Respondent-Pharmacy had voluntarily ceased sterile compounding.
- m. The owner has ceased operations for sterile compounding although the plastic curtains remained in place.
- n. The inspectors were shown that glass beakers and spatulas were autoclaved and wrapped in aluminum foil and then in a non-sterile plastic tote.
- o. The pharmacy does not have procedures for placement of the chemical indicators within the Autoclave. Pharmacist B verbally reported the procedures on using

⁴ “A Magnehelic gauge is an a measuring instrument that measures the static pressure in a heating, venting and cooling or HVAC system.” <https://www.reference.com/home-garden/magnehelic-gauge-work-c789652e1c1d0eb0>

steam and dry heat sterilization procedures, but no documentation of these procedures was provided.

- p. There was no evidence of daily calibration of the autoclave, dry heat oven, and incubator maintained until April 2016.
- q. An empty bottle was still present on top of the hood although this had been cited by the FDA a month prior to the Board's inspection.
- r. The laminar flow hoods in the Clean Room had been replaced with stainless steel counters. There is also a stainless steel counter bench in the Gowning room (a little pitted), and Formica was only seen on the counter of the entry room.
- s. Per Pharmacist B, the Respondent-Pharmacy does not have a consistent process to determine the frequency of sterility testing. Sterility testing was completed on 12/23/15, 03/04/16, and 03/26/16. Potency testing was conducted as follows: 2014 (4 times?); 2015 (12 of them); and 2016 (6 of them starting on March 4, 2016). Some of this testing was not completed until months after the products were first compounded. Endotoxin testing were done on 02/02/2016 and 03/09/2016.
- t. All products compounded are considered high risk and thus must be kept at -20C to maintain sterility. Pharmacist A described the procedure in which products were released to the testing facility and indicated that no extra doses were prepared for dispensing for sterility testing. Pharmacist A stated that testing is done randomly and results are not received until months after the products have already been dispensed.

11. On or about April 25, 2016, the Respondent-Pharmacy recalled over 1,618 prescriptions,

which included such drug products as cyclosporine⁵, apomorphine⁶, Glutathione⁷, methylcobal⁸, tacrolimus⁹, and PZI¹⁰.

12. Subsequently, the Respondent-Pharmacy voluntarily agreed to cease all sterile operations and recall all sterile products remaining within expiry.

13. After the Board's inspection, the Board's sterile compounding expert further remarked that:

- a. The sterile compounding program is managed in a manner that is not focused on the specifications required for sterile compounding. For example, the Respondent-Pharmacy is equipped with curtains instead of doors, an unsuitable space for the

⁵ Various doses of cyclosporine were recalled including cyclosporine 0.2% oph sol, cyclosporine 1% oph 10cc, cyclosporine 2% oph 10cc, and cyclosporine 2% oph soln. Cyclosporine Ophthalmic Solution is a sterile eye solution containing cyclosporine which helps to treat keratoconjunctivitis sicca (KCS or dry eye) in dogs. 1800petmeds.com, <http://www.1800petmeds.com/Cyclosporine+Ophthalmic+Solution+Compounded-prod90027.html> (last visited March 3, 2017).

⁶ Various doses of apomorphine were recalled including apomorphine 3mg/ml inj. Apomorphine is used for treating loss of control of body movements such as muscle stiffness, slow movements, or trouble moving associated with advanced Parkinson disease. Apomorphine is a dopamine agonist. It works by stimulating dopamine receptors, which helps improve motor function. Drugs.com, <https://www.drugs.com/cdi/apomorphine.html> (last visited March 3, 2017).

⁷ Various doses of Glutathione were recalled including Glutathione 200mg/ml inj. Glutathione is a substance produced naturally by the liver. Glutathione is used to treat cataracts and glaucoma, preventing aging, treating or preventing alcoholism, asthma, cancer, heart disease (atherosclerosis and high cholesterol), hepatitis, liver disease, diseases that weaken the body's defense system (including AIDS and chronic fatigue syndrome), memory loss, Alzheimer's disease, osteoarthritis, and Parkinson's disease. Glutathione is also used for maintaining the body's defense system (immune system) and fighting metal and drug poisoning. WebMD, <http://www.webmd.com/vitamins-supplements/ingredientmono-717-glutathione.aspx?activeingredientid=717> (last visited March 3, 2017).

⁸ Various doses of methylcobal were recalled including methylcobal 25mg/ml inj. Methylcobalamin, or vitamin B12, is a B-vitamin. Methylcobalamin is used to treat pernicious anemia and vitamin B12 deficiency. Empower Pharmacy, <https://empower.pharmacy/drugs/methylcobalamin-vitamin-b12-injection.html> (last visited March 3, 2017).

⁹ Various doses of tacrolimus were recalled including tacrolimus 0.03% ophsol and tacrolimus 0.02% oph sol. Tacrolimus modifies the immune response and is used as an ophthalmic preparation in the eye for the treatment of keratoconjunctivitis sicca and chronic superficial keratitis in dogs. Peteducation.com, <http://www.peteducation.com/article.cfm?c=26+1303&aid=3570> (last visited March 3, 2017).

¹⁰ Various doses of PZI were recalled including PZI 40U/ml insulin and PZI U100 insulin. Protamine Zinc Insulin ("PZI") is a type of insulin combined with zinc and protamine to slow the release of the insulin into bodily tissue. PZI is used to treat feline diabetes. Pet Health: PZI, <http://www.felinediabetes.com/pzi.htm> (last visited March 3, 2017).

preparation area, and an undersized, poorly organized cleanroom area.

- b. The documentation of training was inadequate and did not demonstrate a focus on continued observation of the staff by a manager who has the specialized training and ongoing continuing education required to provide sterile compounds.
- c. Each prescription was issued a prescription number assigned by the pharmacy computer, and that number was used to track the identity of component drugs and expiration dating on a manual log sheet. Lot numbers were not assigned. Refills were not consistently assigned a new prescription number so that each compound was readily identifiable.
- d. The process for end product testing is the greatest concern. In an effort to ensure that there is appropriate expiration dating, the Respondent-Pharmacy treats all compounds as being in the USP 797 high risk category. The Respondent-Pharmacy provided the page directly from USP 797 regulations indicating the Beyond Use Dating (BUD) for high risk compounding of three (3) days under refrigeration, after compounding. The concern here is that this designation does not differentiate between products that have different stabilities due to drug diluent-compatibility and solubility issues. Many of the preparations described in the prescription documents are complex, multi-component admixtures that could well be beyond the scope of most large volume facilities.
- e. A review of the compounding protocols indicated that some of the products must be produced in an ISO Class 5 room. The room, however, is an ISO 6 space, and therefore there should be additional limits on which products the facility should compound.
- f. The review of the testing results from a third-party testing company provides the

most critical concern for the operation of the sterile compounding program at the Respondent-Pharmacy. There did not appear to be an understanding of the need to link testing to production so as to ensure that there is a statistical comparison. This linkage would ensure that adequate end product testing is being conducted. The important issue is that a facility that produces high risk compounds should have a well-developed, thoroughly documented, high volume analysis program. In addition, there should be an understanding of the comparative risk of each type of compound that would drive laboratory testing. Neither issue seems to be the focus of the managers of the facility.

- g. The recall was limited to products that were not expired as instructed by the FDA. This limitation results in the majority of the products that had been compounded not being subject to the recall and therefore the recipients not being notified.
- h. The degree of autonomy and the improper use of equipment at the Respondent-Pharmacy is a real concern. Technicians were observed compounding nonsterile products. A technician was observed independently mixing a powder into a large beaker of liquid and immersed the handheld, battery operated mixer into the liquid all the way up to the air intake of the motor. Another technician appeared to prepare capsules by manually filling a capsule tray without weighing the capsules or any receiving direct oversight by the pharmacist.

14. After the Board issued charges in this case, on or about April 3, 2017, the Board became aware that the FDA had issued a Warning Letter regarding the Respondent-Pharmacy. The Warning Letter can be found on the FDA's website at <https://www.fda.gov/ICECI/EnforcementActions/WarningLetters/2017/ucm550802.htm>. The Respondent-Pharmacy timely responded to the FDA's Warning Letter confirming

that it had ceased sterile compounding and does not intend to resume sterile compounding.

15. On March 10, 2017, the Board conducted an annual inspection of the Respondent-Pharmacy, which revealed no deficiencies.

II. CONCLUSIONS OF LAW

Based on the foregoing Findings of Fact, the Board concludes as a matter of law that the Respondent-Pharmacy violated the following provisions of the Act:

§ 12-403. Required standards.

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(c) *In general.* – Except as otherwise provided in this section, a pharmacy for which a pharmacy permit has been issued under this title:

(1) Shall be operated in compliance with the law and with the rules and regulations of the Board;

(2) Shall be located and equipped so that the pharmacy may be operated without endangering the public health or safety;

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1. To prepare and dispense prescriptions properly; and

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1. Be equipped with the minimum equipment and appliances specified by the Board under this section; and

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A. The permit holder shall provide at least the following equipment that is maintained in working order:

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- (4) Laminar air flow workstation or compounding aseptic isolator that meets USP 797 Standards, dedicated for products other than antineoplastics;

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- (6) Appropriate filters and filtration equipment.

B. If used, the permit holder shall provide the following that is maintained in working order, calibrated, or certified where appropriate: (1) Autoclave; (2) Automated compounding devices ... ; ... (5) Thermometers or other temperature device; and (6) Incubator.

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A. The permit holder shall ensure that the pharmacist or the pharmacist's designee shall maintain a policy and procedure manual, reviewed annually, that sets forth in detail the permit holder's standard operating procedures with regard to compounding sterile preparations.

B. The permit holder shall insure that the policy and procedure manual that sets forth the standard operating procedures with regard to compounding sterile preparations is implemented and adhered to.

C. The policy and procedure manual shall include policies and procedures governing the following:

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- (3) Equipment including, but not limited to: (a) Procedures for use;
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13. Attire.

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- (2) Thorough hand-washing before gowning;
- (3) Wearing clean room garb inside the designated area at all times, which consists of: (a) A non-shedding coverall or gown; (b) Head and facial hair covers; (c) A face mask; and (d) Shoe covers;
- (4) Clean room garb, with the exception of sterile gloves, shall be donned and removed outside the designated clean room area; . . .
- (6) Sterile gloves are required

14. Training of Staff, Patient, and Caregiver.

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B. The permit holder shall ensure that pharmacy personnel engaging in compounding sterile preparations are trained and demonstrate competence in the safe handling and compounding of compounded sterile preparations and parenteral solutions, including cytotoxic agents if applicable.

C. The permit holder shall maintain records of training and demonstrated competence for individual employees for 5 years.

15. Quality Assurance.

The permit holder shall ensure that the compounded sterile preparation retains its potency and sterility throughout the assigned “beyond use” dating period through a written quality assurance program that includes:

A. A reasonable effort by the pharmacist to assure that compounded sterile preparations shall be kept under appropriate controlled conditions before dispensing, during transport, and at the location of use by providing adequate labeling and verbal or written instructions regarding proper storage and administration, as set forth by the product manufacturer and established standards and literature, with each compounded sterile preparation dispensed;

B. The phases of compounded sterile preparation, distribution, storage, administration, and directions for use for each type of preparation dispensed.

C. Environmental sampling for microbial organisms in laminar air flow workstations and clean rooms is performed according to methods and schedules specified by USP 797 Standards and if microbial contamination is suspected, for example, in the event of positive media fill verification results;

D. Laminar air flow workstations, biological safety cabinets, and compounding aseptic isolators certified by a trained and qualified operator;

E. Clean room and anteroom certification by a trained and qualified operator according to USP 797 Standards;

F. The proper disposal in accordance with accepted professional standards and applicable State and federal laws of unused drugs and materials used in the preparation of compounded sterile preparations, including antineoplastic agents and hazardous materials;

G. A formal written review process to report and evaluate compliance with this chapter; and

H. A process that complies with applicable USP 797 Standards for performing sterility checks or pyrogen testing, or both, for applicable compounded sterile preparations.

III. ORDER

Based upon the foregoing Findings of Fact and Conclusions of Law, it is this 1st day of June, 2017, by the affirmative vote of a majority of the members of the Board:

ORDERED that the Respondent-Pharmacy's permit to operate as a pharmacy in the State of Maryland is hereby **REPRIMANDED**; and it is further

ORDERED that within thirty (30) days from the date the Board executes this Consent Order, the Respondent-Pharmacy shall pay a civil fine in the amount of **EIGHT THOUSAND (\$8,000.00) DOLLARS**, payable by certified check or money order to The Maryland State Board of Pharmacy; and it is further

ORDERED that the Respondent-Pharmacy's permit shall be placed on **PROBATION** for a period of thirty (30) days; and it is further

ORDERED that the Respondent-Pharmacy shall **CEASE AND DESIST** from sterile compounding in Maryland and shall not resume sterile compounding in Maryland unless and until the Respondent-Pharmacy receives approval by the FDA and an inspection by the Board, or its designee, that demonstrates that the Respondent-Pharmacy is in compliance with all Federal

and State laws, as well as properly equipped for sterile compounding, including having proper protocols and procedures in place for sterile compounding and adequate training for staff; and it is further

ORDERED that if the Respondent-Pharmacy resumes sterile compounding in Maryland, it shall operate according to the Maryland Pharmacy Act and in accordance with all applicable laws, statutes and regulations pertaining to its operation as a pharmacy; and it is further

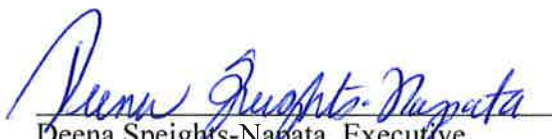
ORDERED that the Respondent-Pharmacy shall operate in accordance with the laws and regulations governing the operation of a pharmacy in Maryland; and be it further

ORDERED that if the Respondent violates any of the terms or conditions of this Consent Order, the Board, in its discretion, after notice and an opportunity for a show cause hearing, may impose any other disciplinary sanctions the Board may have imposed under § 12-409 of the Act, including a suspension, revocation and/or a monetary fine, said violation being proven by a preponderance of the evidence; and it is further

ORDERED that the Respondent-Pharmacy shall bear the cost(s) of complying with the Consent Order; and it is further

ORDERED that this Consent Order is considered a **PUBLIC DOCUMENT** pursuant to Md. Code Ann., Gen. Prov. §§ 4-101 *et seq.* (2014 Repl. Vol. and 2016 Supp.).

6-1-17
Date


Deena Speights-Napata, Executive
Director, for
MitraGavani, Pharm.D., President
State Board of Pharmacy

CONSENT

I, Simeon Georgiou, owner of Professional Arts Pharmacy, acknowledge that I have had the opportunity to consult with legal counsel before signing this document. By this Consent, I accept, on behalf of Professional Arts Pharmacy, to be bound by this Consent Order and its conditions and restrictions. On its behalf, I waive any rights Professional Arts Pharmacy may have had to contest the Findings of Fact and Conclusions of Law.

I acknowledge the validity of this Consent Order as if entered into after the conclusion of a formal evidentiary hearing in which Professional Arts Pharmacy would have had the right to counsel, to confront witnesses, to give testimony, to call witnesses on its behalf and to all other substantive and procedural protections as provided by law.

I acknowledge the legal authority and the jurisdiction of the Board to initiate these proceedings and to issue and enforce this Consent Order. I also affirm that I am waiving Professional Arts Pharmacy's right to appeal any adverse ruling of the Board that might have followed any such hearing.

I sign this Consent Order without reservation, and I fully understand and comprehend the language, meaning and terms of this Consent Order. I voluntarily sign this Order on behalf of Professional Arts Pharmacy and understand its meaning and effect.



Date



Simeon Georgiou, Owner
Professional Arts Pharmacy


NOTARY

STATE OF Maryland
COUNTY/CITY OF : Baltimore

I hereby certify that on this day of , 2017, before me, a Notary Public of the State of Baltimore and County/City aforesaid, personally appeared **Simeon Georgiou**, and made an oath in due form that the foregoing Consent was his voluntary act and deed.

AS WITNESSETH my hand and notarial seal.

TARA PATEL
NOTARY PUBLIC
BALTIMORE COUNTY
MARYLAND
My Commission Expires August 21 2020



Notary Public

My Commission Expires: 8-21-2020