RECEIVED
Dec 27 2023
S.C. SUPREME COURT

Attachment A

AFFIDAVIT OF DR. MICHAELA ALMGREN

I. Background and Qualifications

1. My name is Michaela Almgren, Pharm.D., M.S. I am over the age of eighteen and competent to testify to the truth of the matters contained herein. The factual statements I make here are true and correct to the best of my knowledge.

2. I am a Clinical Associate Professor in the Department of Clinical Pharmacy and Outcomes Sciences at the University of South Carolina College of Pharmacy. I teach principles of sterile compounding per United States Pharmacopeia ("USP")[1] Chapters 797 and 800, aseptic technique and pharmacy regulations applicable in sterile compounding environment[2] under 503a guidance and section 503b of the Drug Quality and Security Act of 2013, as well as pharmacokinetics, pharmacotherapy, pharmacy law, and biopharmaceutics courses. I specialize in sterile compounding, medication safety, and pharmacy laws and regulations that relate to pharmacy compounding practices. I also provide continuing education courses for pharmacists in those topics. I received my Doctor of Pharmacy degree from the University of South Carolina College of Pharmacy in 2010. Additionally, I have a Master's Degree in Pharmaceutical Chemistry from the University of Florida.

3. In conjunction with my academic appointment, I currently maintain a practice site at a 503b[3] outsourcing pharmacy where I perform duties of an outsourcing pharmacist, clinical advisor, and pharmacy student preceptor. Previously, I worked in pharmacy operations at a large local teaching hospital as a pharmacist. I have over ten years of experience in sterile

---

[1] USP sets standards for the identity, strength, quality, and purity of medicines, food ingredients, and dietary supplements in the United States. The USP publishes the United States Pharmacopeia-National Formulary (USP-NF), which contains a compendium of quality standards and specifications for a wide range of pharmaceuticals and related products. USP Chapters 797 and 800 are part of the USP-NF compendium.

[2] Aseptic technique in drug compounding refers to specific practices to avoid physical and microbial contamination when preparing sterile medications that are to be used for parenteral applications, such as IV infusion, injection, etc.

[3] 503b Outsourcing Pharmacy is a compounding pharmacy that produces large batches of sterile products and distributes them directly to health systems pharmacies to address drug shortages, as specified in Section 503B of the FD&C Act.

compounding and aseptic technique. Prior to joining the faculty at the University of South Carolina I worked for several years in pharmaceutical manufacturing where I was involved in drug formulation, quality assurance, quality control, and analytical method development and validation. My professional qualifications are Doctor of Pharmacy and Master of Science in Pharmacy with focus on Pharmaceutical Chemistry. A copy of my CV is attached as Exhibit A.

4. I have been asked by attorneys who represent the death-sentenced inmates in *Owens v. Stirling*, No. 2022-001280, to submit an expert pharmaceutical and scientific opinion based on the information and documentation provided to me about whether there is a risk of harm and unnecessary suffering that can be caused by the use of pentobarbital of unknown origin in lethal injection.

II. Pentobarbital injection may come from various sources that need to be examined and verified to assure the drug potency and ability to function as anticipated. The drugs are typically acquired directly from a manufacturer, or compounded in accordance with 503a regulations, as outlined in USP Chapter 797.

5. Major manufacturers of pentobarbital, including companies like Fresenius Kabi, Hospira, and Baxter, currently refuse to sell the drug for execution purposes. There is also major concern surrounding another significant manufacturer of pentobarbital injection, Akorn Pharmaceuticals. The company has recently filed for Chapter 7 bankruptcy, resulting in the closure of all U.S. operations. Akorn Pharmaceuticals had received numerous FDA Warning letters, indicating significant concerns about the quality of their drugs. With the company's closure, a comprehensive drug recall covering all their medications, including pentobarbital injection, a potential substance for lethal injections, has been implemented.

6. This raises concerns that the drug intended for use in South Carolina may be subject to recall, posing risks of insufficient potency, contamination, or being an entirely different substance than indicated on the label. The utilization of this specific drug product may lead to a failed execution.

7. The restricted availability of commercially manufactured pentobarbital injection—which, as indicated by Akorn, is not itself necessarily a guarantee of efficacy—indicates that the preparation for administering capital punishment in South Carolina could only be obtained in contravention of the manufacturer's prohibition against such use or is subject to a recall with quality concerns. This raises the prospect that the pentobarbital injection will be of compounded origin, which poses some quality concerns and thus risks.

III. The lack of compounding information regarding the preparation of the pentobarbital injection raises concerns due to the chemical and physical properties of pentobarbital sodium and the complexity of the compounding procedure of pentobarbital Injection.

8. The SC Shield Law eliminates oversight from the SC Board of Pharmacy or FDA concerning the licensure and qualifications of the pharmacist who may undertake the compounding of pentobarbital. Additionally, there is no scrutiny of the quality records of the facility where the compounding might occur, or the origins of the active pharmaceutical ingredient (API) used in the preparation of the lethal injection drug. All these factors raise significant concerns, given that the compounding of pentobarbital is an intricate process that demands specialized skills, equipment, and compounding facilities. A pharmacy preparing this type of compound should have extensive injectable drug compounding experience to be able to prepare this drug correctly. There are several recipes for pentobarbital sodium injection.

9. The first step in compounding pentobarbital requires proper dissolution of the active pharmaceutical ingredients (API) of the drug (the key ingredients that produce the desired effect). Pentobarbital sodium powder API[4] is not soluble in water alone. According to a formulation recipe listed in literature, the API must be dissolved in water that has been alkalinized using sodium hydroxide pellets to bring the pH to 12. If this sensitive process is not

[4] API stands for Active Pharmaceutical Ingredient. It is the biologically active component in a pharmaceutical drug, responsible for its therapeutic effects. The API is the specific substance or mixture of substances that produces the intended pharmacological activity in the patient. In simple terms, it is the key ingredient in a drug that produces the desired therapeutic effect.

performed correctly or the recipe is not followed exactly, the drug will produce a suspension which is not a homogenous (or evenly dissolved) solution, but a heterogeneous mixture, in which some of the particles will disperse while others may settle at the bottom. Such a suspension is not suitable for intravenous injection because it contains undissolved solids, so it cannot be safely injected. Intravenous injection of a drug with an undissolved particulate suspension can cause extreme pain and suffering.

10. After the API has been properly dissolved, in the next step of the compounding procedure, hydrochloric acid solution is then added to the compound to bring the pH back down to around 9.8 (until pentobarbital just barely stays in solution). Next, propylene glycol is added (40% v/v), followed by alcohol. The drug is then filtered using a 0.22 micron filter to achieve sterility. A quality control procedure must be performed on the filter afterwards to demonstrate that the filter integrity was maintained. Even small changes in pH can cause the pentobarbital to precipitate out of the solution—meaning that the previously dissolved substances will combine to form a solid—which will change in the potency of the drug. This preparation recipe closely mimics the commercial formulation of pentobarbital injection.

11. As the formulation recipe described above illustrates, the preparation of this compounded sterile product involves numerous ingredients, sequential steps, and chemical adjustments, and necessitates a certain level of expertise on the part of the compounder. Deviations from the appropriate procedure can significantly impact the efficacy and safety of pentobarbital injection. For example, if there is a shift in concentration of one of the ingredients, this can lead to the formation of precipitant and oxidation of the product, which will also impact the potency of the drug and its pharmacological effects. Insufficient potency of the drug will lead to inadequate pharmacological effect and prolonged suffering of the inmate. A change in pH of the drug due to improper storage, or incorrect addition order of the

formulation components, can lead to extreme pain during the injection stage of the execution and suffering of the prisoner.

12. In general, compounding logs must be maintained by the compounding pharmacy and all the details listed above must be recorded to assure the traceability and quality of the compounded product. Such logs must typically include the criteria used to determine the beyond use date (BUD), a master formulation worksheet containing storage requirements and documentation of performance of quality control procedures. Due to the SC Shield law, none of the logs will be reviewed or verified. Without access to these logs, it is not possible to verify that the pentobarbital injection was properly prepared and is safe to be used without causing unnecessary suffering to the prisoner. Reviewing compounding records in the pharmacy is a fundamental aspect of ensuring the safety, accuracy, and quality of compounded medications, complying with regulatory requirements, and maintaining accountability throughout the compounding process.

IV. Concerns about the lack of information about the source of the active pharmaceutical ingredient (API) to be used in the compounding of the pentobarbital injection.

13. The quality, purity, and regulatory compliance of the APIs used in compounding sterile drugs significantly impact the safety and efficacy of the final compounded product. According to public data on the FDA's website, 72 percent of API manufacturing sites are located outside of the United States. This fact is concerning, as the manufacturers with overseas locations often do not have good quality records. For example, in one overseas API facility, an FDA investigator observed vermin—including birds and insects—near the equipment used for drug manufacturing. In another instance, incorrect information was provided on the Certificate of Analysis of a drug product available for sale in the United States.

14. Additionally, due to COVID-19, there has been reduction in foreign manufacturing site inspections. leading to potentially less oversight by the FDA's Center for

Drug Evaluation and Research (CDER) and Division of Pharmaceutical Quality Operations to monitor foreign API manufacturers and to enforce US quality standards for API manufacturing. This can lead to lower quality, purity and potency of the API.

15. Even if the API is purchased from a domestic pharmacy supplier, the chemicals may still be contaminated. Professional Compounding Centers of America ("PCCA") is the leading supplier of pharmacy chemicals, well known across the compounding pharmacies in the United States. However, on January 27, 2021, PCCA received a Warning Letter from FDA due to its distribution of adulterated drugs and use of unverified API suppliers and suppliers who had received Warning Letters from the FDA. Some of the PCCA's products were deemed adulterated and labelled incorrectly. This causes a significant concern about the quality of the API used to prepare pentobarbital injection.

16. Healthcare professionals and compounding pharmacies must source APIs from trustworthy and FDA-registered suppliers. They should also perform due diligence in verifying the quality and regulatory compliance of the APIs. Additionally, adherence to good compounding practices and appropriate quality control testing can further ensure the safety and effectiveness of compounded sterile drugs.

V. Pentobarbital injection expiry/BUD status and storage conditions are unknown.

17. "Drug expiry" or the "drug expiration date" is the date until which a pharmaceutical product (commercially manufactured, not compounded) is expected to remain stable, effective, and safe to use. This date is determined through stability testing conducted by the drug manufacturer. It is important to adhere to the expiration date and not use the drug beyond that point, as expired medications may lose their potency or, in some cases, become unsafe to use.

18. Beyond Use Dating ("BUD") is an important concept in pharmaceutical compounding. BUD refers to the date after which a compounded medication should not be

used, as it may no longer maintain its intended quality, safety, and effectiveness. The purpose of establishing BUD is to ensure that compounded drugs remain stable and maintain their therapeutic properties over a specified period. Deviating from BUD guidelines can have negative consequences potentially leading to poor quality and questionable potency of the compounded medication. Unlike the expiration date, which is determined by the drug manufacturer for commercially produced medications, the BUD is assigned by the pharmacist or compounding practitioner for medications prepared in a pharmacy setting as specified in USP Chapter 797.

19. According to the SC Pharmacy Practice Act and USP Chapter 797, the set of regulations which provides guidelines for sterile compounding, sterile medications that are prepared from initially non-sterile components, such as APIs, or using a methodology that causes the preparation potentially to lose sterility, are considered "high risk" compounds. The preparations must be terminally sterilized if they are to be used for parenteral[5] application. The storage conditions for all medication, and especially for compounded medications, are crucial to maintaining drug quality, stability, and safety. Compounded medications can be more susceptible to degradation and changes over time compared to commercially manufactured drugs. But proper storage of all injectable medications is essential to ensure their intended properties. It is essential to adhere to the recommended storage conditions to ensure the medications do not degrade and lose potency due to environmental exposure. Failure to follow appropriate storage conditions (specified in the USP Chapter 659) can result in a loss of potency, changes in the chemical composition, or contamination of compounded medications, which can impact their safety and efficacy. Due to the SC Shield Law, there are no records

[5] "Parenteral" refers to a route of administration for medications or substances that bypasses the gastrointestinal tract. In other words, it involves the introduction of a substance directly into the body, typically through methods such as injection (intravenous, intramuscular, or subcutaneous), or infusion.

provided to document and verify whether the lethal injection preparations are stored under correct conditions.

VI. Conclusion

21. Without information regarding the manner in which drugs used for execution purposes are prepared and stored, there is a substantial risk that the drugs that are intended to be use in execution will not be of the appropriate quality and potency to cause death without significant suffering. The potency and pH of a drug is contingent on a number of factors, including the quality of the active pharmaceutical ingredient, pharmacy practices, compounding pharmacist training, records of the compounding pharmacy, and conditions and manner of storage and handling. Here, knowledge gaps and potential improper pharmacy practices create the risk that these drugs will not be sufficiently stable, potent, and effective. It has the potential to trigger highly violent reactions, such as choking, spasms, groaning, and gasping. If the drug falls out of solution, the resulting solids, or precipitates, would cause intense pain upon injection. If the potency of the drug is insufficient, the injection could result in a prisoner regaining consciousness, perhaps with organ or brain damage from the oxygen deprivation due to respiratory depression suffered during the attempt at execution.

I declare under penalty of perjury under the laws of the United States of America that the foregoing is true and correct.

Executed on this 27th day of December 2023.

Michaela M. Almgren

Dr. Michaela M. Almgren

Sworn to and subscribed before me
This 27th day of December, 2023

Charlene Matthews

Notary Public for the State of South Carolina
My commission expires: Feb. 16, 2033

CHARLENE MATTHEWS
Notary Public
State of South Carolina
My Commission Expires Feb 16, 2033

Exhibit A

Michaela M. Almgren, PharmD, MS

161 Wilmont Drive
Lexington, SC 29072
almgren@cop.sc.edu
(803) 622-5231

EDUCATION

Doctor of Pharmacy, 2010 *Magna Cum Laude*
South Carolina College of Pharmacy, University of South Carolina, Columbia, SC

Master of Science in Pharmacy, 2010 *Magna Cum Laude*
Pharmaceutical Chemistry (Industrial Pharmacy focus)
University of Florida, Gainesville, FL

Bachelor of Science, 1997 *Magna Cum Laude, Graduated with Honors*
Major: Biology, Chemistry
Columbia College of South Carolina, Columbia, SC

EMPLOYMENT HISTORY AND EXPERIENCE

Clinical Associate Professor
University of South Carolina, College of Pharmacy, Columbia, SC
August 2013 – present

- Teach pharmacokinetics and biopharmaceutics lectures.
- Teach pharmacy law and ethics lectures and moderate in-class discussions, including ethics debates .
- Lectures at USC School of Medicine on natural medicine, pain management pharmacology, opioid and non-opioid as well as multimodal analgesia.
- Teach in USC School of Medicine PA program lectures on women's health.
- As a former Institutional Lab Course coordinator taught basic and advanced institutional pharmacy practice focused laboratory courses with focus on sterile compounding and aseptic technique to students in the second year of pharmacy education. Typical class size is 110 students.
- Developed, completely designed and implemented training course content for basic sterile compounding training with focus on USP chapters 797 and 800, and introduction to current institutional pharmacy practice.
- Developed and implemented 6-hour module for student training in 503A versus 503B environment regulations to emphasize critical differences in cGMP (per 21 CFR 210 and 211) versus USP standard requirements.
- Implemented practical assessment criteria for student competency of performing basic sterile compounding procedures according to USP 797 and 800 guidelines to demonstrate and document preparedness for IPPEs and APPEs.

- Revised course content and objectives for the laboratories to meet the ASHP-ACPE Task Force guidelines for entry-level competencies needed for pharmacy practice in hospital and health-systems.
- Enhanced and updated the content of advanced sterile compounding course PHMY 791, including TPN compounding, neonatal TPN formulation and compounding, chemotherapy and hazardous drug compounding, and IV access line introduction and maintenance.
- Introduced hazardous drug handling guidelines and USP 800, with emphasis on student training in utilization of all closed system transfer devices currently available in the U.S.
- Provided competency testing and certification for students to be able to participate in institutional pharmacy practice site sterile compounding activities (media fill testing, fingertip testing).
- Consulting pharmacist, performing duties of a permit holder (Non-dispensing pharmacy permit # 4956) and fully responsible for maintaining the facility, inventory control and daily operations.
- Mentor students in research offering variety of independent study projects.
- Clinical seminar evaluator and student advisor.
- Developed and implemented ACPE accredited course titled *Basic Aseptic Technique* for Kennedy Pharmacy Innovation Center, offering pharmacists and pharmacy technicians 23.5 hours of continuing education credit composed of two-day live hands-on course as well as home study.

Outsourcing Pharmacist and Clinical Specialist
Preceptor for University of South Carolina College of Pharmacy APPE Program
Nephron Pharmaceuticals Company, West Columbia SC
September 2018 - present

- Lead number of innovative and research-oriented projects (Yaskawa, Straubli, SteraMist) for manufacturing and outsourcing facility.
- Oversee formulation and filling operations for 503B outsourcing pharmacy.
- Perform product development including scale-ups for product development for outsourcing pharmacy.
- Troubleshoot quality events to develop safe solutions and set clinical limits for quality excursions.
- Develop new standard operating procedures and train staff as needed.
- Provide research information about new products, develop support materials for marketing purposes.
- Answer clinical questions when customers reah out for product guidance.
- Developed and maintain APPE site for 4th year pharmacy students, precepting record numbers of students yearly.
- ACTO app (training platform for sales force) management—review of content, provide training information about products.
- Assist with FDA quality inquiry investigations and management.
- Provide information for product development and production planning.
- Provide important information on labeling guidance for new products.
- Provide DocMatter clinician Q and A website support.
- Training of sales force via live lectures, seminars and pre-recorded lectures.

Hospital Staff Pharmacist
Palmetto Health Richland Hospital Pharmacy, Columbia SC
August 2013 – September 2018

- Performed duties of staff pharmacist—review orders, medication utilization review, order entry.
- Preparation and checking of sterile and non-sterile medication compounds.
- Medication history pharmacist—collect medication history via patient interviews, perform medication reconciliation, clinical consultations, patient education, medication use evaluation, and medication history consults.
- Maintained USC College of Pharmacy practice site.

Assistant Professor of Clinical and Pharmaceutical Sciences
South University School of Pharmacy, Columbia, SC
May 2010 -- August 2013

- Taught lectures in large number of courses in pharmaceutical sciences as well as pharmacy practice in distance education setting, managing two classrooms and collaborating with faculty members located in Savannah, GA. Typical class size was 80 students in the Columbia campus classroom, with 90 additional students at the distant site in Savannah.
- Completely redesigned Pharmaceutical Calculations course structure to flipped classroom model in order to increase effectiveness of teaching, significantly reducing the number of students needing remediation and improving overall test scores in the capstone course.
- Applied several active learning teaching techniques and team-based learning to traditionally taught courses to enhance student learning.
- Developed laboratory exercises to increase student understanding by applying learned material to practice using hands-on experiments.
- Developed and delivered elective course on animal envenomation pharmacology, medicinal chemistry and drug management.
- Taught majority of hospital-related lab coursework including TPN compounding, IV and chemotherapy preparation, and USP<797> training.
- Provided competency testing and certification for students to be able to participate in institutional pharmacy practice site sterile compounding activities (media fill testing, fingertip testing).
- Evaluated student performance of Objectively Structured Clinical Examination (OSCEs).
- Provided APhA certified immunization training for pharmacy students.
- Initiated student chapter of Student Society of Health Systems Pharmacists and guided students to the ASHP national recognition of the chapter.
- Served as faculty advisor for Rho Chi chapter.
- Academic advisor to 30 students per year.
- Faculty advisor to Student Society of Health Systems Pharmacists chapter.
- Research interests: use of complementary medicine in treatment of chronic disease states, smoking cessation and electronic cigarette utilization, new and engaging teaching methods in pharmacy education.
- Precepted Advanced Pharmacy Practice Experience students in elective academia setting.

Adjunct Faculty, University of Florida Graduate Distance Programs
University of Florida, School of Pharmacy
January 2011-- May 2014

- Supported distance education learning for UF Masters and Doctorate degree programs.
- Met with students on-line in small group setting as well as large discussion groups.
- Led chat sessions, communicate via email.
- Graded assignments, tests and presentations.

Consulting/Dispensing Pharmacist PRN
United Healthcare, Lexington, SC
August 2010 - August 2012

- Performed patient medical chart reviews, clinical monitoring, and managed appropriate drug therapy in accordance with federal and state regulations.
- Evaluated physician medication orders regarding dosage, appropriateness of drug, potential interactions, stability and route of administration.
- Analyzed, retrospectively and prospectively, drug utilization for the institutional drug formulary maintenance.
- Reviewed and checked technician prepared orders for delivery and dispensing.
- Consulted with advanced practitioners, healthcare professionals and managers of pharmaceutical services to develop and implement best working practices.

Hospital Pharmacy Student Intern
Lexington Medical Center, West Columbia, SC
June 2008 - May 2010

- Prepared IV compounded medications, interpreted and prepared orders per medications orders in CPOE.
- Ensured proper control and dispensing of narcotics.
- Interacted with clinical pharmacists, physicians, and nurses regarding drug therapy.
- Compounded a wide variety of specialty preparations including chemotherapy and TPN.

Retail Pharmacy Student Intern
Rite Aid Pharmacy, Columbia, SC
September 2006 – May 2010

- Accurately interpreted, processed, and filled prescriptions.
- Effectively communicated with physicians' offices and insurance companies regarding patients' pharmacy needs.
- Counseled and answered patients' questions concerning their prescriptions, OTC medications, nutritional supplements, and herbal products.
- Assisted with appropriate recordkeeping to assure compliance with federal and state laws.
- Maintained pharmacy inventory and supplies.
- Provided excellent customer support and follow up.

Senior Pharmaceutical Formulation Scientist
Pfizer Inc., December 2004 – August 2006

- Worked with formulation team in determining of yields (actual and theoretical), performed batch production record verification, ingredient review, and conditional quality releases, all per company's SOPs (standard operating procedures) and following guidance of cGMPs.
- Performed OOS (Out-Of-Specifications) investigations and reported process deviations on products not meeting all quality criteria set by QC department (for example, content uniformity, particle size and other quality issues.)
- Collaborated with drug formulation research team in development of new products and their test methods, with focus on natural products, supplements, and vitamins.
- Assisted with development of new medication delivery system of liquid drug products (Licaps), assisting with taking the products through ANDA process.

- Developed and validated methods for analytical testing of raw materials and finished products for QC department to test for identity, purity and strength to meet quality standards set by FDA and USP.
- Assisted with improvements in stability studies, including utilizing USP 71 guidance in new products.
- Supported all activities involving new product transfers, compliance, testing and various manufacturing process validations.
- Authored, updated and edited SOPs for training of new employees, changes in process control as well as laboratory manuals, then trained personnel to assure proper understanding of the methodology and troubleshooting.
- Comfortable with regulatory environment as set by cGMPs per 21CFR 210 and 211, USP, BP, EP, ISO, ICH and FDA regulations.
- Assisted with management of five laboratory technician team.
- Certified emergency responder.

OTHER PROFESSIONAL ACTIVITIES

Sterile Compounding Committee Volunteer Expert
SC Board of Pharmacy, Columbia SC
August 2019-present

- Provide expertise on sterile compounding practices to the Board of Pharmacy members to help with updating of the assessment forms for inspections of pharmacy facilities.
- Consult members of state legislature on options in regulatory areas of pharmacy practice, specifically in the area of compounding.

Expert Witness

- Area of expertise includes sterile compounding, compounding, pharmacy, pharmacokinetics, USP 797, drug preparation.
- Provide medicolegal consulting for state and federal court cases.
- Analyze evidence provided and consult the legal team with options for further actions.
- Prepare testimony statements, depositions, testify in court.

Lexington School District 1 Health Sciences Advisory Committee Member

- Provide guidance and recommendations on development of health and science related courses in the district's curriculum for high school students.

Lexington School District 2 Health Sciences Advisory Committee Member

- Provide guidance and recommendations on how to initiate and develop health and science related courses in the district's curriculum for high school students.

Member of South Carolina Pharmacy Practice Act (SC PPA) Revision taskforce

- Chair of the committee on compounding section revision: lead a group of professionals to update SC PPA section of steile and non-sterile compounding
- Memmber of the group aligning the SC PPA with NABP's Model pharmacy act
- Member of the taskforce working on pharmacy practice expansion

FACULTY APPOINTMENTS AND TEACHING EXPERIENCE

DIDACTIC TEACHING EXPERIENCE

Clinical Assistant Professor in Department of Clinical Pharmacy and Outcomes Sciences, University of South Carolina, Columbia SC
August 2013 to present

- PHMY 885: Pharmacy Law and Ethics (3 credit hours, course coordinator)
- PHMY 790: Pharmacy Skills Laboratory III: Introduction to Health-Systems Pharmacy I (1 credit laboratory course, course coordinator)
- PHMY 791: Pharmacy Skills Laboratory IV: Advanced Health System Pharmacy Practice (1 credit laboratory course, course coordinator)
- PHAR 401: Introduction to Pharmacy as a Profession
- PHMY 710: Biopharmaceutics, Pharmaceutics and Pharmacokinetics (3 credit hours)
- PHMY 999: Clinical Seminar
- PHMY 757: Independent Study

KPIC Master instructor, University of South Carolina, Columbia SC
August 2014 to March 2015

- Basic Aseptic Technique course, 23.5 hours of CE, Master instructor
- Advanced Aseptic Technique course 16 live hours of CE, Master instructor

Assistant Professor of Pharmacy
South University School of Pharmacy, Columbia SC,
May 2010 to August 2013

- PHA 4367 Integrated Sequence IV Autonomic Nervous System (Pharmacology and Pharmacotherapy lectures), 8 credit hours
- PHA 3159 Introduction to Integrated Sequence: Basic Pharmacology Modules, Medicinal Chemistry, 6 credit hours
- PHA 3107 Pharmaceutical Calculations (use of pre-recorded lectures and in-class hands-on exercises), 3 credit hours (course coordinator)
- PHA 3113 Pathophysiology I (topics include geriatrics, inflammation, cancer, HIV, immune response), 4 credit hours (course coordinator)
- PHA 3114 Pathophysiology II (topics include autonomic nervous system, wound healing, gout, RA), 4 credit hours
- PHA 3109 Microbiology and Immunology (lectures in immunology, virology), 5 credit hours
- PHA 5335 Animal Venoms and Poisons (developed and implemented this elective), 3 credit hours (course coordinator)
- PHA 5332 Applied Pharmaceutical Care II (topics including, OA, RA, BPH, ED), 4 credit hours
- PHA 4265 Integrated Sequence III Inflammation (Pharmacology and Pharmacotherapy of osteoarthritis, rheumatoid arthritis, gout, would healing, lupus), 6 credit hours
- PHA 3162 Integrated Sequence I: Introductory Pharmacology and Medicinal Chemistry, 5 credit hours
- PHA 4212 Pharmacokinetics I (Implemented team-based learning), 4 credit hours

- PHA 4228 Pharmacokinetics II (Implemented team-based learning), 4 credit hours
- PHA 3135 Integrated Pharmacy Skills Lab I, 3 credit hours
- PHA 3136 Integrated Pharmacy Skills Lab II, 3 credit hours
- PHA 3137 Integrated Pharmacy Skills Lab III, 3 credit hours
- PHA 4238 Integrated Pharmacy Skills Lab IV, 3 credit hours
- Longitudinal Pharmacy Practice Experiences I – V: PHA 3135, 3163, 4266, 4369, 5330, 1 credit hour, course coordinator

Adjunct Faculty, UFL Graduate Distance Programs
University of Florida, School of Pharmacy, January 2012—April 2016
- Medicinal Chemistry I
- Fundamentals of Medicinal Chemistry, course coordinator
- Herbal and Dietary Supplements

EXPERIENTIALTEACHING EXPERIENCE
Advanced Pharmacy Practice Experience (APPE) Elective INDUSTRY—University of South Carolina College of Pharmacy, Preceptor for PharmD students**.**

Advanced Pharmacy Practice Experience (APPE) Academic Rotation—South Carolina College of Pharmacy, Preceptor for PharmD students.

Advanced Pharmacy Practice Experience (APPE) Academic Rotation—South University School of Pharmacy, Preceptor for PharmD students.

COLLEGE OF PHARMACY COMITTEES
- South University SOP Curriculum Committee, member, chair 2013
- South University SOP Curriculum Subcommittee for Pharmaceutical Calculations course advisory member, 2010-2012
- South University SOP Committee for Professional Outreach, member 2011-2013
- South University SOP Technology Committee, member 2010-2013
- South University SOP ACPE Self-Study and Assessment Committee, member 2012-2013
- South University SOP Admissions Committee, member 2012-2013
- University of South Carolina COP Continuing Education Committee, member 2013-2016
- University of South Carolina COP Search Committee for Lab assistant, chair, 2014-2016
- University of South Carolina COP Curriculum Committee, member 2017-2019
- University of South Carolina COP Admissions Committee, member 2019-present

AWARDS
2018: SC College of Pharmacy CPOS Department Service Award
2020: SC College of Pharmacy CPOS Department Service Award
2022: University of South Carolina Clinical Teaching Award

INVITED LECTURES AND PRESENTATIONS

Almgren M. Mitigation Strategies of COVID-19 in the Workplace. Palmetto Business Forum. Presented Webinar September 13, 2021.

Almgren M. CDB: Exploring Regulations, Trends and a Potential role in Opioid Epidemic. Annual Continuing Education Conference. Presented live April 21st, 2021.

Emelia Beam PharmD, Michaela Almgren, PharmD, MS. Update on COVID19 Vaccines. Nephron Pharmaceuticals, May 3, 2021.

Almgren, M., COVID-19 Prevention Myth vs. Fact: Assessment of Complementary Therapies as Preventative Measures for Safety and Efficacy. SCSHP Fall 2020 Meeting, Columbia, SC, October 2020.

2020 Immunization Update. 1.0 ACPE accredited CE presentation at Nephron Pharmaceuticals, October 2020.

COVID 19 Prevention: Myth versus Fact. 1.0 credit hour ACPE accredited presentation at Nephron Pharmaceuticals Inc., West Columbia, SC June 8th, 2020.

Update on COVID19 Vaccines. 1.0 credit hour ACPE accredited presentation at Nephron Pharmaceuticals Inc., West Columbia SC, May 3rd, 2021.

M. Almgren. My Path to Pharmacy. CAPPS USC student chapter speaker, February 4th, 2021.

USP Updates in Sterile Compounding. 1.0 credit hour ACPE accredited presentation at Nephron Pharmaceuticals Inc., West Columbia, SC, April 13th and 15th, 2020.

Multimodal Analgesia Basics. 1.0 credit hour ACPE accredited presentation at Nephron Pharmaceuticals Inc., West Columbia SC, April 1st and April 3rd, 2020.

COVID19—Separating Facts from Fiction. SC Palmetto Business Forum Quarterly Meeting in Columbia SC, March 9th, 2020.

New Approaches to Pain Management: Multimodal Opioid Free Analgesia. 1.0 credit hour ACPE accredited presentation at UofSC COP CE Conference, February 1st, 2020.

Medication Safety of Hazardous Drugs: Can We All Be Safe? 1.0 credit hour ACPE accredited CE presentation at SCSHP Fall Meeting in Columbia SC, October 17th 2018.

Review of Sterile Compounding per USP 797. 1.0 credit hour ACPE accredited CE presentation at SCSHP Fall Meeting in Columbia SC, October 17th 2018.

M. Almgren. Current Status and Future Trends in Sterile Compounding as Defined by USP Chapters 797 and 800. 1.0 ACPE Live CE accreditation awarded. SCSHP Annual Meeting March 11-13, 2018, Hilton Head Island, SC.

M. Almgren. Who wants to be a pharmacist? CAPPS USC student chapter speaker, April 11th, 2018.

M. Almgren. Importance of unification of performance protocols for CSTD testing per NIOSH. November 7, 2016, Cincinnati, OH. NIOSH Public Comment meeting, invited speaker.

M. Almgren. Important role of CSTD utilization in compounding of hazardous materials to enhance protection of the compounder. 2016 ASHP Midyear, Las Vegas. Hazardous Drug Task Force speaker for USP 800 implementation.

M. Almgren. Sterile Compounding and Implementation of USP Chapter 797: Where we came from, where we are and where we might be headed. 1.0 ACPE Live CE accreditation awarded. SCSHP Annual Meeting, March 2015, Hilton Head Island, SC.

M. Almgren. Pharmacy school pathways. CAPPS USC student chapter speaker, April 2015.

PEER-REVIEWED PUBLICATIONS

Almgren M., Cooper C., Maxwell W., Baker J. Instruction on compounded sterile preparations at U.S. schools of pharmacy—a ten year follow up study. American Journal of Health-System Pharmacy, Volume 75, Issue 12, 15 June 2018 Pages 845-847, https://doi.org/10.2146/ajhp170641

Textbook chapter: Khazan M., Phillips C., **Almgren M**. "Pharmaceutical Calculations" In: Sutton S. Scott. McGraw Hill's NAPLEX Review Guide. 3rd Edition, McGraw Hill 2018

Textbook chapter: **Almgren M**. "Sterile Compounding Regulations" In: Sutton S. Scott. *McGraw Hill's NAPLEX Review Guide*. 3rd Edition.

Karyn I. Cotta, Samit Shah, PhD, RPh, MBA, **Michaela M. Almgren**, PharmD, MS, Lilia Z. Macías-Moriarity, PhD, MPH, Vicky Mody. Effectiveness of flipped classroom instructional model in teaching pharmaceutical calculations. *Currents in Pharmacy Teaching and Learning*. 2016. Volume 8, Issue 5, Pages 646–653. https://doi.org/10.1016/j.cptl.2016.06.011

Braga S, **Almgren M**. Complementary Therapies in Cystic Fibrosis: nutritional supplements and herbal products. *Journal of Pharmacy Practice*. 2013 Feb;26(1):14-7.

Wynn W, **Almgren M**, Stroman R, Clark K. Pharmacist's Toolbox for Smoking Cessation. *Journal of Pharmacy Practice.* 2012 Dec;25(6):591-9.

POSTERS WITH ABSTRACTS

Rachel Lehn, BS, PharmD Candidate; Kayla Hutto, BS, PharmD Candidate; Nikki Chen, PharmD Candidate; Lauren Caines, PharmD Candidate; **Michaela Almgren, PharmD, MS**. Comparison of Impact of Facial Coverings Mandate as Mitigation Strategy on Positivity Rates of COVID-19 in a Workplace versus Community Rates Prior to Vaccine Availability. December 2021 ASHP Midyear Virtual Clinical Meeting.

Kara Taylor, PharmD Candidate; Lauren Caines, PharmD Candidate; Cole Colemander, PharmD Candidate; Zach Altenberg, PharmD Candidate; **Michela Almgren, PharmD, MS**.

Safety Evaluation of a New Container Closure System Design of a Blow Fill Seal Type of IV Bottles. December 2021 ASHP Midyear Virtual Clinical Meeting.

Lauren Caines, PharmD Candidate; Kara Taylor, PharmD Candidate; **Michaela Almgren, PharmD, MS**. Impact of Implementation of Mandatory Facial Coverings as Mitigation Strategy on Rates of Positive Cases of COVID19 in a Workplace Prior to Vaccine Availability. December 2021 ASHP Midyear Virtual Clinical Meeting.

Petscavage Katie, PharmD Candidate; **Almgren Michaela, PharmD, MS**. Assessment of complementary therapies as preventive measures for COVID-19 for safety and efficacy. December 2020 ASHP Midyear Virtual Clinical Meeting. Poster #SP-243.

Aya Ahmed PharmD Candidate; **Michaela Almgren PharmD, MS**; Ryan McCormick PharmD Candidate; Carolyn McNamara PharmD Candidate; Robert Singleton PhD. Establishing a Coronavirus (COVID-19) Testing Lab in 40 Days. December 2020 ASHP Midyear Virtual Clinical Meeting.

Ryan McCormick PharmD Candidate; **Michaela Almgren, PharmD, MS**; Sarah Arnold PharmD Candidate, Madeline Dean PharmD Candidate, Marianna Vinson, PharmD Candidate. Process improvements and validation of a syringe-filling robot though collaboration between pharmacy and engineering student teams. December 2020 ASHP Midyear Virtual Clinical Meeting.

Alexis Caronis, PharmD Candidate 2021; **Michaela Almgren, PharmD, MS**; Samantha Lindeman, PharmD Candidate 2021; Kristen Kilby, PharmD Candidate 2021. Evaluation of medication safety effectiveness training in a workplace environment. 2020 APHA Annual Meeting, Baltimore MD, March 2020.

Caroline Hansen PharmD Candidate; **Michaela Almgren PharmD, MS**; Kristen Kilby PharmD Candidate; Alexis Caronis PharmD Candidate; Ryan McCormick PharmD Candidate; Benjamin Tabor PharmD Candidate. College of Pharmacy and School of Engineering Student Teams' collaboration to design pharmacy compounding system using robotic arm to perform aseptic syringe filling. 2020 SCSHP Annual Meeting, Charleston SC, March 2020.

Alexis Caronis, PharmD Candidate 2021; **Michaela Almgren, PharmD, MS**; Kristen Kilby, PharmD Candidate 2021; Caroline Hansen, PharmD Candidate 2021; Benjamin Tabor, PharmD Candidate 2021; Ryan McCormick, PharmD Candidate 2022. Development of the Masterflex L/S peristaltic pump process validation in a 503B outsourcing pharmacy. 2019 ASHP Midyear Clinical Meeting, Las Vegas, December 2019. Poster #3-445.

Ashton Holley, PharmD Candidate**; Michaela Almgren, PharmD, M.S**.; Normando Sandoval, PharmD Candidate; Priya Patel, PharmD Candidate; Xiaoxia Wang, PharmD Candidate; Lauren Moran, PharmD Candidate. Evaluation of cleaning effectiveness of 7.8% ionized hydrogen peroxide mist versus 7.8% hydrogen peroxide mist in a cleanroom environment. 2019 ASHP Midyear Clinical Meeting, Las Vegas, December 2019. Poster #3-449.

Caroline Hansen PharmD Candidate; **Michaela Almgren PharmD, MS**; Kristen Kilby PharmD Candidate; Alexis Caronis PharmD Candidate; Ryan McCormick PharmD Candidate; Benjamin Tabor PharmD Candidate. College of Pharmacy and School of Engineering Student Teams' collaboration to design pharmacy compounding system using robotic arm to perform aseptic

syringe filling. 2019 ASHP Midyear Clinical Meeting, Las Vegas, December 2019. Poster #3-432.

Kristen Kilby PharmD Candidate**; Michaela Almgren PharmD, MS**; Alexis Caronis PharmD Candidate; Caroline Hansen PharmD Candidate; Ryan McCormick PharmD Candidate, Benjamin Tabor PharmD Candidate, Noah Smith MBA, PharmD Candidate**.** Performance comparison of the Baxter repeater pump and the Masterflex peristaltic pump using high flow tubing set L/S 24. 2019 ASHP Midyear Clinical Meeting, Las Vegas, December 2019. Poster #3-446.

Samantha Lindeman, PharmD Candidate 2021; **Michaela Almgren, PharmD, MS**; Alexis Caronis, PharmD Candidate 2021; Kristen Kilby, PharmD Candidate 2021; Noah Smith, Pharm D Candidate 2020; Caroline Hansen, PharmD Candidate 2021; Ashton Holley, PharmD Candidate 2021; Priya Patel, PharmD Candidate 2021. Evaluation of naloxone safety effectiveness training in a workplace environment. 2019 ASHP Midyear Clinical Meeting, Las Vegas, December 2019. Poster #3-440.

Tristan Gore, PharmD Candidate 2022. Noah Smith, PharmD Candidate 2020. Dana Nelson, PharmD Candidate 2020. **Michaela Almgren, PharmD, MS**. Incidence and clinical impact of particulate matter in injectable drug products. 2019 ASHP Midyear Clinical Meeting, Las Vegas, December 2019. Poster #3-422.

Almgren M, Maxwell W, Grant A, Hembree H, Shah A. Disability and Accommodations in Pharmacy Practice and Education. 2019 AACP Annual Meeting, Chicago 2019. Abstract #53.

Cooper C., **Almgren M.**, Maxwell W., Baker J. Instruction on compounded sterile preparations at US pharmacy schools. 2018 SCSHP Annual Meeting poster session, Hilton Head Island, SC.

Cooper C., **Almgren M**. Maxwell W., Baker J. Instruction on compounded sterile preparations at US pharmacy schools. Poster presentation at 2017 ASHP Midyear in Orlando, FL, poster # 368.

Parth Parikh, PharmD. Candidate; Paul Philavong, PharmD Candidate, Sam McCallum, PharmD Candidate, Nhung Nguyen, PharmD Candidate; **Michaela Almgren, PharmD, MS**. Assessing Microbial Growth Rates of Sterile Versus Non-Sterile Gloves Used During Sterile Compounding. 2017 SCSHP Annual Meeting Hilton Head, SC, poster session.

Cotta K**, Almgren M**. "Effectiveness of Blended Teaching Method for Pharmaceutical Calculations." Poster presentation at 2012 AACP Annual meeting in Kissimmee FL.

Almgren M., Clark K. "Laboratory Exercise to Enhance Integration and Application of Basic Sciences to Pharmacy Practice in Students." Poster presentation at 2012 AACP Annual meeting in Kissimmee FL**.**

Peer Review/Editorial Boards/Editorships for Journals

Reviewer for AJPE
Reviewed: Prerequisite Courses: Barriers to Pharmacy Admission or the Keys to Student Success?

Reviewer for Currents in Pharmacy Teaching and Learning.

Reviewed: Book review of the Handbook on Injectable Drugs

Reviewer for AJHP
Reviewed: Commentary: Impact of revised USP 797 guidance and how we might mitigate risk: A real-world example

Reviewer for AJHP
Reviewed: Third Consensus Development Conference on the Safety of Intravenous Drug Delivery Systems – 2018

Peer Reviewer for The Joint Commission Journal on Quality and Patient Safety
Reviewer and member of editorial board of Alternative Medicine Studies Journal
Reviewer for Journal of Dietary Supplements
Reviewer for Natural Standard Research Collaboration
Reviewer for Currents in Pharmacy Teaching and Learning
Reviewer for AACP Annual Meeting Research/Education Abstracts for Poster Session

PROFESSIONAL AFFILIATIONS

American Pharmacist Association (APhA), 2006-2018

American Society of Consultant Pharmacists (ASCP), 2008-2013

American Society of Health-System Pharmacists (ASHP), 2008-present
- Pain management SIG 2011-2013

SC Pharmacist Association (SCPhA), member 2006-2018
- Professional Affairs committee 2010-2011, 2017-2018
- Legislative Affairs Committee 2011-2012

SC Society of Health Systems Pharmacists member (SCSHP) 2008-present
- Education Committee 2014-2016
- Professional Affairs Committee 2015-2016
- Legislative Committee 2017-2018

American Association of College of Pharmacy (AACP), member 2010-present
- AACP Pharmacy Practice Strategic Plan, Bylaws, and Resolutions Committee member 2018-2020
- Member of the Scholarship Committee of the Curriculum SIG for AACP 2018-2020
- AACP Audit Committee member 2018-present
- House of Delegates representative for USC College of Pharmacy 2017-2018
- AACP Pharmacy Practice Strategic Plan, Bylaws, and Resolutions Committee member 2018-2019
- Lyman Award Committee Member 2012-2013

Parenteral Drug Association Member (PDA) 2019-2022