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BEFORE THE
BOARD OF PHARMACY
DEPARTMENT OF CONSUMER AFFAIRS
STATE OF CALIFORNIA

In the Matter of the Accusation Against: **BARTON HEALTHCARE SYSTEM, DBA BARTON MEMORIAL HOSPITAL PHARMACY** **2170 South Avenue** **So. Lake Tahoe, CA 95731** **Original Permit Number No. HSP 21312** **Original Sterile Compounding Permit No. LSC 100403,** **and** **TERRIANN HUGHES CHERRY** **PO Box 551425** **So. Lake Tahoe, CA 96155** **Original Pharmacist License No. RPH 33004** Respondent.	Case No. 5541 **A C C U S A T I O N**

Complainant alleges:

PARTIES

1. Virginia Herold (Complainant) brings this Accusation solely in her official capacity as the Executive Officer of the Board of Pharmacy, Department of Consumer Affairs.

2. On or about May 12, 1980, the Board of Pharmacy issued Original Permit Number Number HSP 21312 to Barton Healthcare System, dba Barton Memorial Hospital Pharmacy

(Respondent BMHP). The Original Permit Number was in full force and effect at all times relevant to the charges brought herein and will expire on February 1, 2016, unless renewed.

3. On or about June 30, 2014, the Board of Pharmacy issued Original Sterile Compounding Permit Number LSC 100403 to Respondent BMHP. The Original Sterile Compounding Permit will expire on February 1, 2016, unless renewed.

4. On or about August 14, 1979, the Board of Pharmacy issued Original Pharmacist License Number RPH 33004 to Terriann Hughes Cherry (Respondent Cherry). The Original Pharmacist License will expire on October 31, 2016, unless renewed.

JURISDICTION

5. This Accusation is brought before the Board of Pharmacy (Board), Department of Consumer Affairs, under the authority of the following laws. All section references are to the Business and Professions Code unless otherwise indicated.

6. Section 4300.1 of the Code states:

> "The expiration, cancellation, forfeiture, or suspension of a board-issued license by operation of law or by order or decision of the board or a court of law, the placement of a license on a retired status, or the voluntary surrender of a license by a licensee shall not deprive the board of jurisdiction to commence or proceed with any investigation of, or action or disciplinary proceeding against, the licensee or to render a decision suspending or revoking the license."

7. Section 4301 of the Code states, in pertinent part:

> "The board shall take action against any holder of a license who is guilty of unprofessional conduct ... Unprofessional conduct shall include, but is not limited to, any of the following:
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> ...
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> (j) The violation of any of the statutes of this state, or any other state, or of the United States regulating controlled substances and dangerous drugs.
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> ...
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> (o) Violating or attempting to violate, directly or indirectly, or assisting in or abetting the violation of or conspiring to violate any provision or term of this chapter or of the applicable federal and state laws and regulations governing pharmacy, including regulations established by the board or by any other state or federal regulatory agency.
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> ..."

STATUTORY REFERENCES

8. Code section 4059 states, in pertinent part:

"(b) This section does not apply to the furnishing of any dangerous drug or dangerous device by a manufacturer, wholesaler, or pharmacy to each other or to a physician, dentist, podiatrist, optometrist, veterinarian, or naturopathic doctor pursuant to Section 3640.7, or to a laboratory under sales and purchase records that correctly give the date, the names and addresses of the supplier and the buyer, the drug or device, and its quantity. This section does not apply to the furnishing of any dangerous device by a manufacturer, wholesaler, or pharmacy to a physical therapist acting within the scope of his or her license under sales and purchase records that correctly provide the date the device is provided, the names and addresses of the supplier and the buyer, a description of the device, and the quantity supplied."

9. Code section 4059.5 states, in pertinent part:

"(e) A dangerous drug or dangerous device shall not be transferred, sold, or delivered to a person outside this state, whether foreign or domestic, unless the transferor, seller, or deliverer does so in compliance with the laws of this state and of the United States and of the state or country to which the dangerous drugs or dangerous devices are to be transferred, sold, or delivered. Compliance with the laws of this state and the United States and of the state or country to which the dangerous drugs or dangerous devices are to be delivered shall include, but not be limited to, determining that the recipient of the dangerous drugs or dangerous devices is authorized by law to receive the dangerous drugs or dangerous devices."

10. Code section 4113 states, in pertinent part:

"(a) Every pharmacy shall designate a pharmacist-in-charge and, within 30 days thereof, shall notify the board in writing of the identity and license number of that pharmacist and the date he or she was designated.

...

(c) The pharmacist-in-charge shall be responsible for a pharmacy's compliance with all state and federal laws and regulations pertaining to the practice of pharmacy."

11. Code section 4169 states, in pertinent part:

"(a) A person or entity shall not do any of the following:

(1) Purchase, trade, sell, warehouse, distribute, or transfer dangerous drugs or dangerous devices at wholesale with a person or entity that is not licensed with the board as a wholesaler, third-party logistics provider, or pharmacy."

FEDERAL REGULATION

12. Section 1305.03 of title 21 of the Code of Federal Regulations states, in pertinent part: "Either a DEA Form 222 or its electronic equivalent … is required for each distribution of a Schedule I or II controlled substance…"

CALIFORNIA REGULATIONS

13. Section 1735.2 of title 16 of the California Code of Regulations (16 CCR 1735.2) states, in pertinent part:

"(d) A drug product shall not be compounded until the pharmacy has first prepared a written master formula record that includes at least the following elements:
(1) Active ingredients to be used.
(2) Equipment to be used.
(3) Expiration dating requirements.
(4) Inactive ingredients to be used.
(5) Process and/or procedure used to prepare the drug.
(6) Quality reviews required at each step in preparation of the drug.
(7) Post-compounding process or procedures required, if any."

14. 16 CCR 1735.3 states, in pertinent part:

"(a) For each compounded drug product, the pharmacy records shall include:
(1) The master formula record.
(2) The date the drug product was compounded.
(3) The identity of the pharmacy personnel who compounded the drug product.
(4) The identity of the pharmacist reviewing the final drug product.
(5) The quantity of each component used in compounding the drug product.
(6) The manufacturer, expiration date and lot number of each component. If the manufacturer name is demonstrably unavailable, the name of the supplier may be substituted. Exempt from the requirements in this paragraph are sterile products compounded on a one-time basis for administration within seventy-two (72) hours and stored in accordance with standards for "Redispensed CSPS" found in Chapter 797 of the United States Pharmacopeia - National Formulary (USP-NF) (35th Revision, Effective May 1, 2012), hereby incorporated by reference, to an inpatient in a health care facility licensed under section 1250 of the Health and Safety Code.
(7) A pharmacy assigned reference or lot number for the compounded drug product.
(8) The expiration date of the final compounded drug product.
(9) The quantity or amount of drug product compounded."

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15. 16 CCR 1735.8 states, in pertinent part:

"(c) The quality assurance plan shall include written standards for qualitative and quantitative integrity, potency, quality, and labeled strength analysis of compounded drug products. All qualitative and quantitative analysis reports for compounded drug products shall be retained by the pharmacy and collated with the compounding record and master formula."

16. 16 CCR 1751 states, in pertinent part:

"(b) The pharmacist-in-charge shall be responsible to ensure all pharmacy personnel engaging in compounding sterile injectable drug products shall have training and demonstrated competence in the safe handling and compounding of sterile injectable products, including cytotoxic agents if the pharmacy compounds products with cytotoxic agents."

17. 16 CCR 1751.3 states, in pertinent part:

"(b) The ingredients and the compounding process for each preparation must be determined in writing before compounding begins and must be reviewed by a pharmacist."

18. 16 CCR 1751.4 states, in pertinent part:

"(b) During the preparation of sterile injectable products, access to the designated area or cleanroom must be limited to those individuals who are properly attired.

...

(d) Exterior workbench surfaces and other hard surfaces in the designated area, such as walls, floors, ceilings, shelves, tables, and stools, must be disinfected weekly and after any unanticipated event that could increase the risk of contamination."

19. 16 CCR 1751.6 states, in pertinent part:

"(b) The pharmacist-in-charge shall be responsible to ensure all pharmacy personnel engaging in compounding sterile injectable drug products shall have training and demonstrated competence in the safe handling and compounding of sterile injectable products, including cytotoxic agents if the pharmacy compounds products with cytotoxic agents."

20. 16 CCR 1751.7 states, in pertinent part:

"(a) Any pharmacy engaged in compounding sterile injectable drug products shall maintain, as part of its written policies and procedures, a written quality assurance plan

including, in addition to the elements required by section 1735.8, a documented, ongoing quality assurance program that monitors personnel performance, equipment, and facilities. The end product shall be examined on a periodic sampling basis as determined by the pharmacist-in-charge to assure that it meets required specifications. The Quality Assurance Program shall include at least the following:

(1) Cleaning and sanitization of the parenteral medication preparation area.

(2) The storage of compounded sterile injectable products in the pharmacy and periodic documentation of refrigerator temperature.

(3) Actions to be taken in the event of a drug recall.

(4) Written justification of the chosen expiration dates for compounded sterile injectable products.

...

(d) Batch-produced sterile to sterile transfers shall be subject to periodic testing through process validation for sterility as determined by the pharmacist-in-charge and described in the written policies and procedures."

21. 24 CCR 1250.4 (California Building Code) states, in pertinent part:

"Compounding area for parenteral solutions. The pharmacy shall have a designated area for the preparation of sterile products for dispensing which shall:

...

2. Have nonporous and cleanable surfaces, ceilings and ceiling tiles, walls, floors and floor coverings."

COST RECOVERY

22. Section 125.3 of the Code states, in pertinent part, that the Board may request the administrative law judge to direct a licentiate found to have committed a violation or violations of the licensing act to pay a sum not to exceed the reasonable costs of the investigation and enforcement of the case.

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CAUSES FOR DISCIPLINE

Barton Memorial Hospital Pharmacy (BMHP)

FIRST CAUSE FOR DISCIPLINE

(Failure to follow proper garbing procedures)

23. Respondent BMHP is subject to disciplinary action under title 16 of the California Code of Regulations, section 1751.4, subdivision (b), (16 CCR 1751.4(b)), by and through Code section 4301(o), in that they failed to follow proper garbing procedures. The circumstances are as follows:

24. On or about May 12, 2014, until on or about January 9, 2015, Respondent BMHP had staff don personal protective equipment in an unsafe manner and inconsistent with their stated standards, including donning booties and hair covers while standing on carpet outside of the ante room, donning sterile gowns prior to sanitizing hands, donning face masks after sanitizing hands, and using non-sterile gloves.

SECOND CAUSE FOR DISCIPLINE

(Failure to train staff who compound sterile products)

25. Respondent BMHP is subject to disciplinary action under 16 CCR 1751.6(b), by and through Code section 4301(o), in that they failed to train staff that compound sterile products. The circumstances are as follows:

26. On or about May 12, 2014, until on or about January 9, 2015, Respondent BMHP did not administer didactic training and test staff who prepared compounded sterile products, in accordance with their policies and procedures. Additionally, there were no competency tests on file for Pharmacist-in-Charge Terriann Cherry. And there were no training records on file for environmental services staff who cleaned the clean room documenting their training to perform this service.

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THIRD CAUSE FOR DISCIPLINE

(Noncompliant Cleanable Surfaces)

27. Respondent BMHP is subject to disciplinary action under 16 CCR 1751(b) as it relates to 24 CCR 1250.4(2), by and through Code section 4301(o), in that they allowed porous and uncleanable surfaces in a clean room. The circumstances are as follows:

28. On or about May 12, 2014, until on or about January 9, 2015, Respondent BMHP had exposed particle board on the underside of countertops in the buffer area, a wood entry door, voids in walls and a compact disc player with compact discs, which were either not cleanable or were porous surfaces.

FOURTH CAUSE FOR DISCIPLINE

(Noncompliant Quality Assurance Plan for Qualitative and Quantitative Testing)

29. Respondent BMHP is subject to disciplinary action under 16 CCR 1735.8(c), by and through Code section 4301(o), in that they failed to conduct qualitative and quantitative testing of compounded sterile products. The circumstances are as follows:

30. On or about May 12, 2014, until on or about January 9, 2015, Respondent BMHP did not have a quality assurance plan to test batch produced compounded sterile products for integrity, potency, quality, or labeled strength.

FIFTH CAUSE FOR DISCIPLINE

(Failure to Conduct Quality Assurance Tests)

31. Respondent BMHP is subject to disciplinary action under 16 CCR 1751.7(a) and (d), by and through Code section 4301(o), in that they did not conduct quality assurance tests for end product testing and for sterility testing of batch produced compounded sterile products. The circumstances are as follows:

32. On or about May 12, 2014, until on or about January 9, 2015, Respondent BMHP did not conduct any end product testing for labeled potency or for sterility of batch compounded sterile preparations.

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SIXTH CAUSE FOR DISCIPLINE

(Failure to Maintain Master Formulas)

33. Respondent BMHP is subject to disciplinary action under 16 CCR 1735.2(d), by and through Code section 4301(o), in that they did not create a master formula for every product compounded prior to making the compounded product. The circumstances are as follows:

34. On or about May 12, 2014, until on or about January 9, 2015, Respondent BMHP had no master formulas for any of the compounded sterile products routinely prepared.

SEVENTH CAUSE FOR DISCIPLINE

(Failure to have Pharmacists Review Preparations Prior to Compounding)

35. Respondent BMHP is subject to disciplinary action under 16 CCR 1751.3(b), by and through Code section 4301(o), in that they failed to have a pharmacist review preparations prior to compounding. The circumstances are as follows:

36. On or about May 12, 2014, until on or about January 9, 2015, Respondent BMHP did not have a pharmacist review the ingredients and written compounding process for each preparation prior to compounding.

EIGHTH CAUSE FOR DISCIPLINE

(Failure to Maintain Records of Compounded Products)

37. Respondent BMHP is subject to disciplinary action under 16 CCR 1735.3(a), by and through Code section 4301(o), in that no record was made for compounded drug products. The circumstances are as follows:

38. On or about May 12, 2014, until on or about January 9, 2015, Respondent BMHP made no record documenting:

a. the manufacturer and lot number of each component,

b. the date the drug product was compounded,

c. the identity of the pharmacy personnel who compounded the drug product,

d. the identity of the pharmacist reviewing the final drug product, and

e. the quantity of each component used in compounding the drug product.

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NINTH CAUSE FOR DISCIPLINE

(Failure to follow standards for frequency of cleaning)

39. Respondent BMHP is subject to disciplinary action under 16 CCR 1751.4(d), by and through Code section 4301(o), in that they failed to follow proper frequency for cleaning. The circumstances are as follows:

40. On or about May 12, 2014, until on or about January 9, 2015, Respondent BMHP sanitized the walls, ceilings, shelves, tables, and stools monthly when it was required to be done weekly.

TENTH CAUSE FOR DISCIPLINE

(Furnishing to an Unlicensed Facility)

41. Respondent BMHP is subject to disciplinary action under Code sections 4169(a)(1), 4059(b), and 4059.5(e), by and through Code section 4301(j), in that they furnished dangerous drugs and controlled substances to an unlicensed entity. The circumstances are as follows:

42. On or about October 1, 2014, until on or about January 10, 2015, Respondent BMHP furnished to Lake Tahoe Surgical Center (LTSC), in Zephyr Cove, Nevada, a surgical center without a California license:

a. 421 doses of 7 different schedule II controlled substances in various strengths and sizes,

b. 168 doses of 3 schedule III-IV controlled substances in various strengths and sizes, and

c. 1269 doses of 57 different dangerous drugs in various strengths and sizes.

ELEVENTH CAUSE FOR DISCIPLINE

(Furnishing Schedule II Controlled Substances Without Required Order Form)

43. Respondent BMHP is subject to disciplinary action under section 1305.03 of title 21 of the Code of Federal Regulations, by and through Code section 4301(o), in that they furnished to LTSC schedule II controlled substances without the required DEA 222 order forms. The circumstances are as follows:

44. On twelve separate dates, October 7, 24, 28, and 29, 2014, November 4, 11, and 18, 2014, December 8, 9, 10, and 22, 2014, and January 8, 2015, Respondent BMHP furnished to LTSC 27 line items of schedule II controlled substances in various strengths and sizes, totaling 421 doses of 7 controlled substances to LTSC without executing a DEA 222 order form for each transaction.

Terriann Hughes Cherry

45. Respondent Terriann Hughes Cherry has been the designated Pharmacist-In-Charge for Barton Memorial Hospital Pharmacy under Code section 4113(a) since March 1, 2013. As pharmacist-in-charge for BMHP, Respondent Cherry was responsible for BMHP's compliance with all state and federal laws and regulations pertaining to the practice of pharmacy under Code section 4113(c).

TWELFTH CAUSE FOR DISCIPLINE

(Failure to follow proper garbing procedures)

46. Respondent Cherry is subject to disciplinary action under title 16 of the California Code of Regulations, section 1751.4, subdivision (b), (16 CCR 1751.4(b)), by and through Code section 4301(o), in that she, as pharmacist-in-charge for BMHP, failed to follow proper garbing procedures. The circumstances are set forth in paragraph 24 above.

THIRTEENTH CAUSE FOR DISCIPLINE

(Failure to train staff who compound sterile products)

47. Respondent Cherry is subject to disciplinary action under 16 CCR 1751.6(b), by and through Code section 4301(o), in that she, as pharmacist-in-charge for BMHP, failed to train staff that compound sterile products. The circumstances are set forth in paragraph 26 above.

FOURTEENTH CAUSE FOR DISCIPLINE

(Noncompliant Cleanable Surfaces)

48. Respondent Cherry is subject to disciplinary action under 16 CCR 1751(b) as it relates to 24 CCR 1250.4(2), by and through Code section 4301(o), in that she, as pharmacist-in-

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charge for BMHP, allowed porous and uncleanable surfaces in a clean room. The circumstances are set forth in paragraph 28 above.

FIFTEENTH CAUSE FOR DISCIPLINE

(Noncompliant Quality Assurance Plan for Qualitative and Quantitative Testing)

49. Respondent Cherry is subject to disciplinary action under 16 CCR 1735.8(c), by and through Code section 4301(o), in that she, as pharmacist-in-charge for BMHP, failed to conduct qualitative and quantitative testing of compounded sterile products. The circumstances are set forth in paragraph 30 above.

SIXTEENTH CAUSE FOR DISCIPLINE

(Failure to Conduct Quality Assurance Tests)

50. Respondent Cherry is subject to disciplinary action under 16 CCR 1751.7(a) and (d), by and through Code section 4301(o), in that she, as pharmacist-in-charge for BMHP, did not conduct quality assurance tests for end product testing and for sterility testing of batch produced compounded sterile products. The circumstances are set forth in paragraph 32 above.

SEVENTEENTH CAUSE FOR DISCIPLINE

(Failure to Maintain Master Formulas)

51. Respondent Cherry is subject to disciplinary action under 16 CCR 1735.2(d), by and through Code section 4301(o), in that she, as pharmacist-in-charge for BMHP, did not create a master formula for every product compounded prior to making the compounded product. The circumstances are set forth in paragraph 34 above.

EIGHTEENTH CAUSE FOR DISCIPLINE

(Failure to have Pharmacists Review Preparations Prior to Compounding)

52. Respondent Cherry is subject to disciplinary action under 16 CCR 1751.3(b), by and through Code section 4301(o), in that she, as pharmacist-in-charge for BMHP, failed to have a pharmacist review preparations prior to compounding. The circumstances are set forth in paragraph 36 above.

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NINETEENTH CAUSE FOR DISCIPLINE

(Failure to Maintain Records of Compounded Products)

53. Respondent Cherry is subject to disciplinary action under 16 CCR 1735.3(a), by and through Code section 4301(o), as pharmacist-in-charge for BMHP, in that no record was made for compounded drug products. The circumstances are set forth in paragraph 38 and its subparts above.

TWENTIETH CAUSE FOR DISCIPLINE

(Failure to follow standards for frequency of cleaning)

54. Respondent Cherry is subject to disciplinary action under 16 CCR 1751.4(d), by and through Code section 4301(o), in that she, as pharmacist-in-charge for BMHP, failed to follow proper frequency for cleaning. The circumstances are set forth in paragraph 40 above.

TWENTY-FIRST CAUSE FOR DISCIPLINE

(Furnishing to an Unlicensed Facility)

55. Respondent Cherry is subject to disciplinary action under Code sections 4169(a)(1), 4059(b), and 4059.5(e), by and through Code section 4301(j), in that she, as pharmacist-in-charge for BMHP, furnished dangerous drugs and controlled substances to an unlicensed entity. The circumstances are set forth in paragraph 42 and its subparts above.

TWENTY-SECOND CAUSE FOR DISCIPLINE

(Furnishing Schedule II Controlled Substances Without Required Order Form)

56. Respondent Cherry is subject to disciplinary action under section 1305.03 of title 21 of the Code of Federal Regulations, by and through Code section 4301(j), in that she, as pharmacist-in-charge for BMHP, furnished schedule II controlled substances to LTSC without the required DEA 222 order forms. The circumstances are set forth in paragraph 44 above.

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PRAYER

WHEREFORE, Complainant requests that a hearing be held on the matters herein alleged, and that following the hearing, the Board of Pharmacy issue a decision:

1. Revoking or suspending Original Permit Number Number HSP 21312, issued to Barton Healthcare System, dba Barton Memorial Hospital Pharmacy

2. Revoking or suspending Original Sterile Compounding Permit Number LSC 100403, issued to Barton Healthcare System, dba Barton Memorial Hospital Pharmacy;

3. Revoking or suspending Original Pharmacist License Number RPH 33004, issued to Terriann Hughes Cherry

4. Ordering Barton Healthcare System, dba Barton Memorial Hospital Pharmacy, and Terriann Hughes Cherry to pay the Board of Pharmacy the reasonable costs of the investigation and enforcement of this case, pursuant to Business and Professions Code section 125.3;

5. Taking such other and further action as deemed necessary and proper.

DATED: 2/5/16

Virginia Herold

VIRGINIA HEROLD
Executive Officer
Board of Pharmacy
Department of Consumer Affairs
State of California
Complainant

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