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8	BEFORE THE	
9	BOARD OF PHARMACY DEPARTMENT OF CONSUMER AFFAIRS	
10	STATE OF CALIFORNIA	
11	In the Matter of the Accusation Against:	Case No. 4929
12	GRANDPA'S COMPOUNDING	
13	PHARMACY 7563 Green Valley Road	ACCUSATION
14	Placerville, CA 95667	
15	Pharmacy License No. PHY 45878 Sterile Compounding License No. LSC	
16	99109	
17	Respondents.	·
18	Complainant alleges:	
19	<u>PARTIES</u>	
20	1. Virginia Herold (Complainant) brings this Accusation solely in her official capacity as	
21	the Executive Officer of the Board of Pharmacy, Department of Consumer Affairs.	
22	2. On or about May 30, 2002, the Board of Pharmacy issued Pharmacy License Number	
23	PHY 45878 to Grandpa's Compounding Pharmacy (Respondent). The Pharmacy License was in	
24	full force and effect at all times relevant to the charges brought herein and will expire on May 1,	
25	2014, unless renewed.	
26	3. On or about July 14, 2003, the Board of Pharmacy issued Sterile Compounding	
27	License Number LSC 99109 to Grandpa's Compounding Pharmacy (Respondent). The Sterile	
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	1 Accusation	
	1	Accusation

Compounding License was in full force and effect at all times relevant to the charges brought herein and will expire on May 1, 2014, unless renewed.

JURISDICTION

- 4. 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.
- 5. Section 4005 of the Code provides that the Board may adopt rules and regulations to enforce this chapter. Those rules and regulations are found in the California Code of Regulations (CCR), title 16, division 17. All references to CCR sections are to title 16, division 17, unless otherwise indicated.
 - 6. Section 4300 of the Code states in pertinent part:
 - "(a) Every license issued may be suspended or revoked.
- "(b) The board shall discipline the holder of any license issued by the board, whose default has been entered or whose case has been heard by the board and found guilty, by any of the following methods:
 - "(1) Suspending judgment.
 - "(2) Placing him or her upon probation.
 - "(3) Suspending his or her right to practice for a period not exceeding one year.
 - "(4) Revoking his or her license.
- "(5) Taking any other action in relation to disciplining him or her as the board in its discretion may deem proper."
 - 7. 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."

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STATUTORY PROVISIONS

3. 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 or whose license has been procured by fraud or misrepresentation or issued by mistake.

Unprofessional conduct shall include, but is not limited to, any of the following:

- "(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."
- 9. Section 4123 of the Code provides in pertinent part that a pharmacy shall compound sterile injectable products from one or more nonsterile ingredients in one of the following environments: (a) An ISO class 5 laminar airflow hood within an ISO class 7 cleanroom. The cleanroom must have a positive air pressure differential relative to adjacent areas.
- 10. Section 4127.7 of the Code provides: "Any pharmacy that contracts to compound a drug for parenteral therapy, pursuant to a prescription, for delivery to another pharmacy shall report that contractual arrangement to the board. That information shall be reported by the pharmacy performing the compounding services within 30 days of commencing that compounding"
- 11. Section 4329 of the Code provides: "Any nonpharmacist who takes charge of or acts as supervisor, manager, or pharmacist-in-charge of any pharmacy, or who compounds or dispenses a prescription or furnishes dangerous drugs except as otherwise provided in this chapter, is guilty of a misdemeanor."

REGULATIONS

- 12. CCR section 1735.5 states in pertinent part:
- "(a) Any pharmacy engaged in compounding shall maintain a written policy and procedure manual for compounding that establishes procurement procedures, methodologies for the formulation and compounding of drugs, facilities and equipment cleaning, maintenance, operation, and other standard operating procedures related to compounding.
- "(b) The policy and procedure manual shall be reviewed on an annual basis by the pharmacist-in-charge and shall be updated whenever changes in processes are implemented.

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COST RECOVERY

19. Section 125.3 of the Code provides, 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, with failure of the licentiate to comply subjecting the license to not being renewed or reinstated. If a case settles, recovery of investigation and enforcement costs may be included in a stipulated settlement.

BACKGROUND INFORMATION

20. On or about April 18, 2013, a Board of Pharmacy Inspector began a regular annual inspection at Respondent's facilities. Pursuant to Code section 4127.1, subdivision (c), every pharmacy that is a licensed sterile compounding (LSC) pharmacy must be inspected annually prior to renewal. On April 18, 2013, the Board Inspector found violations of Pharmacy Law.

Therefore, on May 2, 2013, a Board Inspector returned to Respondent's facility to obtain further information in regards to applicable compounding practices. Violations of Pharmacy Law were observed and a Cease and Desist Order was issued. On May 29, 2013, a Board Inspector continued the inspection of Respondent's facility. On or about June 11, 2013, a Board Inspector documented further violations of Pharmacy Law. On or about September 6, 2013, a Board Inspector documented further violations of Pharmacy Law and a second Cease and Desist Order was issued.

FIRST CAUSE FOR DISCIPLINE

(Failure to Document Sterility and Endotoxin Testing and Cleaning of Preparation Areas)

21. Respondent Grandpa's Compounding Pharmacy is subject to disciplinary action for unprofessional conduct under code section 4301, subdivision (o), for violating CCR sections 1751.7, subdivisions (a) and (c), 1735.8, subdivisions (a), (b), and (c), and 1751.4, subdivision (a) in that Respondent did not maintain or follow a quality assurance program that included documented sterility and endotoxin testing, and cleaning of compounding preparation areas. The circumstances are that Respondent was unable to or failed to provide accurate logs documenting sterility or endotoxin testing or cleaning of the areas used to prepare compounding materials.

Respondent therefore compounded sterile injectable drugs in an environment failing to meet the criteria for safe compounding of sterile injectable drugs.

SECOND CAUSE FOR DISCIPLINE

(Failure to Train or Document Training of Staff in Compounding)

22. Respondent Grandpa's Compounding Pharmacy is subject to disciplinary action for unprofessional conduct under code section 4301, subdivision (o) for violating CCR section 1751.6, subdivisions (b)-(e), in that Respondent failed to ensure that all pharmacy personnel engaged in compounding sterile injectable drug products had training and demonstrated competence. Respondent further failed to document or retain documentation of any training provided. Respondent was unable to or failed to provide training records or proof of competency for any pharmacists employed at the facility.

THIRD CAUSE FOR DISCIPLINE

(Failure to Utilize Appropriate Sterile Garb)

- 23. Respondent Grandpa's Compounding Pharmacy is subject to disciplinary action for unprofessional conduct under code section 4301, subdivision (o), for violating CCR section 1751.4, subdivision (a), and 1751.5, subdivision (b), in that Respondent compounded sterile injectable drugs but failed to provide an appropriate sterile injectable compounding environment by failing to provide appropriate clean room garb to its employees. The circumstances are as follows:
- 24. Respondent does not possess or provide appropriate low-shedding garb to its employees. Specifically, Respondent is required to provide a low-shedding coverall, head cover, face mask, and shoe covers. Respondent failed to provide low-shedding coveralls, head covers, or face masks to its employees for purposes of compounding.

FOURTH CAUSE FOR DISCIPLINE

(Failure to Correctly Don Compounding Garb)

25. Respondent Grandpa's Compounding Pharmacy is subject to disciplinary action for unprofessional conduct under code section 4301, subdivision (o), for violating CCR section 1751.4, subdivision (a), in that Respondent compounded sterile injectable drugs but failed to provide an appropriate sterile injectable compounding environment by failing to follow its written

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standard operating procedure (SOP) number 3.3.52. Respondent failed to train and ensure that its employees follow the SOP to apply and utilize the compounding garb correctly. The circumstances are as follows:

26. A pharmacy technician employed by Respondent failed to follow SOP number 3.3.52, which requires compounding garb to be applied in the following order: 1) shoe cover, 2) hair cover, 3) mask, 4) wash hands pursuant to procedure for hand washing for sterile phase, 5) gown, 6) gloves, 7) enter cleanroom. Respondent's employee donned the gown (step 5), prior to washing hands (step 4), and therefore splashed non-sterile water onto the gown. Respondent's employee further entered the cleanroom (step 7), prior to donning gloves (step 6).

FIFTH CAUSE FOR DISCIPLINE

(Failure to Rotate Disinfectants)

- 27. Respondent Grandpa's Compounding Pharmacy is subject to disciplinary action for unprofessional conduct under code section 4301, subdivision (o), for violating CCR section 1751.3, subdivision (d), paragraph (3), subparagraph (G), and 1751.4, subdivision (a), in that Respondent compounded sterile injectable drugs but failed to provide an appropriate sterile injectable compounding environment by failing to comply with its SOP number 3.2.20 and provide a regular cleaning schedule including alternation of disinfectants on a quarterly basis. The circumstances are as follows:
- 28. SOP number 3.2.20 requires disinfectants from four different chemical classes (alcohol, quarternary ammonium compound, phenolic, and oxidizing agent) to be rotated on a quarterly basis for purposes of cleaning cleanroom surfaces and equipment. The use of these disinfectants is to be logged, and all records kept for three (3) years. The logs showed that from January 1, 2013, through September 5, 2013, the same two cleaning agents were used; alcohol and a commercial product named "Purinse." No quarterly rotation was done, and no other products or classes of disinfectants were used for this nine (9) month span.

SIXTH CAUSE FOR DISCIPLINE

(Inappropriate Depyrogenation Chamber, Failure to Document Use)

- 29. Respondent Grandpa's Compounding Pharmacy is subject to disciplinary action for unprofessional conduct under code section 4301, subdivision (o), for violating CCR section 1735.5, subdivision (c), paragraph (3), 1751.3, subdivision (a), and 1751.4, subdivision (a) in that Respondent compounded sterile injectable drugs but failed to provide an appropriate sterile injectable compounding environment by failing to have or comply with a written SOP containing the procedures for maintaining, storing, calibrating, cleaning, and disinfecting equipment used in compounding, and for failing to train staff in these procedures as part of the staff training and competency evaluation process. Further, Respondent failed to follow SOP number 5.6.23. The circumstances are as follows:
- 30. SOP number 5.6.23 states depyrogenation¹ is usually conducted at temperatures over 250 degrees centigrade, and that the item, temperature, and time must be logged. Respondent was unable to or failed to provide any logs of items, temperature, or time. Further, Respondent's depyrogenation oven is unable to heat above 148.9 degrees centigrade².

SEVENTH CAUSE FOR DISCIPLINE

(Failure to Report Manufacturing Activities to Board)

31. Respondent Grandpa's Compounding Pharmacy is subject to disciplinary action for unprofessional conduct under code section 4301, subdivision (o), for violating Code section 4127.7 in that Respondent compounded sterile injectable compounding drugs for another pharmacy and not for a specific patient pursuant to a valid prescription for four (4) consecutive months without notifying the Board of the arrangement.

¹ Deyprogenation is a sterilization process for removing pyrogens from a substance or surface. A pyrogen is any substance, usually bacteria, that can cause a fever. Although there are several methods of depyrogenation, the only one at issue in this matter is utilization of high heat in a depyrogenation chamber.

² Respondent's depyrogenation oven is a DeLonghi brand, Alfredo model, household counter-style toaster oven that has been modified by an unknown individual drilling a hole in the top of the oven and inserting a thermometer.

EIGHTH CAUSE FOR DISCIPLINE

(Release of Drugs Prior to Sterility Testing)

- 32. Respondent Grandpa's Compounding Pharmacy is subject to disciplinary action for unprofessional conduct under code section 4301, subdivision (o), for violating CCR section 1751.4, subdivision (a), and 1751.7, subdivision (c), in that Respondent compounded sterile injectable drugs but failed to provide an appropriate sterile injectable compounding environment by failing to follow its SOP number 9.1.30 by appropriately testing batch-produced sterile injectable drugs, and failing to quarantine such batch-produced drugs for the full 14 day time period required to determine whether the end product is sterile. The circumstances are as follows:
- 33. Respondent's SOP number 9.1.30 in effect at the April 18, 2013, inspection requires a pharmacist to read sterility test results after a 72 hour incubation period. If found sterile, the batch may then be released. The medium used to test sterility continues to be incubated for a total of 14 days after which a pharmacist will examine the medium to ensure it remains sterile. Respondent's logs showed that on Mondays, Respondent had been releasing batch-produced sterile injectable drugs that had been compounded on the previous Friday. This could result in an incubation period of less than 72 hours depending on the time of compounding on Friday and the time of release on Monday. The times of compounding and release of the drugs was not logged. Respondent also failed to continue incubating the testing medium for 14 days.

NINTH CAUSE FOR DISCIPLINE

(Failure to Annually Review Policies and Procedures)

34. Respondent Grandpa's Compounding Pharmacy is subject to disciplinary action for unprofessional conduct under code section 4301, subdivision (o), by violating CCR section 1735.5, subdivision (b), in that Respondent failed to have the Pharmacist-in-Charge review the policies and procedures manual on an annual basis. The circumstances are that at the time of the inspection, the SOP manual had not been reviewed by the Pharmacist-In-Charge for the previous three (3) years.

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TENTH CAUSE FOR DISCIPLINE

(Failure to Log Cleaning, Calibration or Use of Incubator)

35. Respondent Grandpa's Compounding Pharmacy is subject to disciplinary action for unprofessional conduct under code section 4301, subdivision (o), by violating CCR section 1735.5, subdivision (a), and 1751.4, subdivision (a) in that compounded sterile injectable drugs but failed to provide an appropriate sterile injectable compounding environment by failing to follow its SOP number 3.3.34, Incubator Use. The circumstances are that SOP number 3.3.34 requires documentation of all tests done using the incubator and a monthly cleaning schedule using rotating disinfectants. Respondent was unable to or failed to provide documentation of use of the incubator, nor did Respondent have a monthly cleaning schedule using rotating disinfectants.

ELEVENTH CAUSE FOR DISCIPLINE

(Failure to Log Cleaning, Calibration or Use of Autoclave)

36. Respondent Grandpa's Compounding Pharmacy is subject to disciplinary action for unprofessional conduct under code section 4301, subdivision (o), by violating CCR section 1735.5, subdivision (a) and 1751.4, subdivision (a), in that Respondent compounded sterile injectable drugs but failed to provide an appropriate sterile injectable compounding environment by failing to follow its SOP number 5.6.30, Procedure for Steam Sterilization By Autoclave. The circumstances are that SOP number 5.6.30 requires documentation of time, load, temperature, and pressure during use of the autoclave. Respondent was unable to or failed to provide documentation of time, load, temperature, or pressure for use of the autoclave.

TWELFTH CAUSE FOR DISCIPLINE

(Improperly Testing Drug Sterility)

37. Respondent Grandpa's Compounding Pharmacy is subject to disciplinary action for unprofessional conduct under code section 4301, subdivision (o), by violating CCR section 1751.4, subdivision (a), and 1751.7, subdivision (c), in that Respondent compounded sterile injectable drugs but failed to provide an appropriate sterile injectable compounding environment by failing to properly test batch-produced sterile injectable drugs. The circumstances are that Respondent failed to follow the manufacturer's specifications for the use of two commercial

testing products, TuffTest and PyroTest. Therefore, the test results obtained using these two methods are not reliable.

THIRTEENTH CAUSE FOR DISCIPLINE

(Non-Pharmacist Manager of Pharmacy)

38. Respondent Grandpa's Compounding Pharmacy is subject to disciplinary action for unprofessional conduct under code section 4301, subdivision (o), by violating code section 4329 in that a non-pharmacist, Daniel Wills, managed the pharmacy. The circumstances are that from approximately February 13, 2013, until September 6, 2013, Daniel Wills, who is not a licensed pharmacist, was running and managing the pharmacy.

FOURTEENTH CAUSE FOR DISCIPLINE

(Failure to Maintain Positive Air Pressure in Cleanroom)

- 39. Respondent Grandpa's Compounding Pharmacy is subject to disciplinary action for unprofessional conduct under code section 4301, subdivision (o), by violating code section 4123, and CCR section 1751.4, subdivision (a), in that Respondent compounded sterile injectable drugs but failed to provide an appropriate sterile injectable compounding environment by failing to follow its SOP number 3.3.10 and also failing to keep or log positive air pressure in the cleanroom used for compounding sterile injectable drugs. The circumstances are as follows:
- 40. Respondent's SOP number 3.3.10 requires that positive pressure in the cleanroom will be documented with each use of the sterile room, and that positive pressure is obtained when "the plastic cover is pushed out at floor level." Code section 4123 provides that the cleanroom must have a positive air pressure differential relative to adjacent areas. Respondent's SOP number 3.3.10 does not ensure that positive pressure is obtained. Respondent was unable to or failed to provide the required documentation.

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:

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