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

In the Matter of the Accusation Against: **GRANDPA'S COMPOUNDING PHARMACY** 7563 Green Valley Road Placerville, CA 95667 Pharmacy License No. PHY 45878 Sterile Compounding License No. LSC 99109 Respondent.	Case No. 4929

DECISION AND ORDER

The attached Stipulated Settlement and Disciplinary Order is hereby adopted by the Board of Pharmacy, Department of Consumer Affairs, as its Decision in this matter.

This decision shall become effective on July 28, 2014.

It is so ORDERED on July 23, 2014.

BOARD OF PHARMACY
DEPARTMENT OF CONSUMER AFFAIRS
STATE OF CALIFORNIA

By _____
STAN C. WEISSER
Board President

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

In the Matter of the Accusation Against: **GRANDPA'S COMPOUNDING PHARMACY** **7563 Green Valley Road** **Placerville, CA 95667** **Pharmacy License No. PHY 45878** **Sterile Compounding License No. LSC 99109** Respondent.	Case No. 4929 **STIPULATED SURRENDER OF LICENSE AND ORDER**

IT IS HEREBY STIPULATED AND AGREED by and between the parties to the above-entitled proceedings that the following matters are true:

PARTIES

1. Virginia Herold (Complainant) is the Executive Officer of the Board of Pharmacy. She brought this action solely in her official capacity and is represented in this matter by Kamala D. Harris, Attorney General of the State of California, by Kristina T. Jansen, Deputy Attorney General.

2. Grandpa's Compounding Pharmacy (Respondent) is representing itself in this proceeding and has chosen not to exercise its right to be represented by counsel.

3. On or about May 30, 2002, the Board of Pharmacy issued Pharmacy License No. PHY 45878 to Grandpa's Compounding Pharmacy (Respondent). The Pharmacy License was in

full force and effect at all times relevant to the charges brought in Accusation No. 4929 and will expire on May 1, 2014, unless renewed.

4. On or about July 14, 2003, the Board of Pharmacy issued Sterile Compounding License No. LSC 99109 to Grandpa's Compounding Pharmacy (Respondent). The Sterile Compounding License was in full force and effect at all times relevant to the charges brought in Accusation No. 4929 and will expire on May 1, 2014, unless renewed.

JURISDICTION

5. Accusation No. 4929 was filed before the Board of Pharmacy (Board), Department of Consumer Affairs, and is currently pending against Respondent. The Accusation and all other statutorily required documents were properly served on Respondent on January 13, 2014. Respondent timely filed its Notice of Defense contesting the Accusation. A copy of Accusation No. 4929 is attached as Exhibit A and incorporated by reference.

ADVISEMENT AND WAIVERS

6. Respondent has carefully read, and understands the charges and allegations in Accusation No. 4929. Respondent also has carefully read, and understands the effects of this Stipulated Surrender of License and Order.

7. Respondent is fully aware of its legal rights in this matter, including the right to a hearing on the charges and allegations in the Accusation; the right to be represented by counsel, at its own expense; the right to confront and cross-examine the witnesses against them; the right to present evidence and to testify on its own behalf; the right to the issuance of subpoenas to compel the attendance of witnesses and the production of documents; the right to reconsideration and court review of an adverse decision; and all other rights accorded by the California Administrative Procedure Act and other applicable laws.

8. Respondent voluntarily, knowingly, and intelligently waives and gives up each and every right set forth above.

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CULPABILITY

1. Respondent understands and agrees that the charges and allegations in Accusation No. 4929, if proven at a hearing, constitute cause for imposing discipline upon its Sterile Compounding License.

2. For the purpose of resolving the Accusation without the expense and uncertainty of further proceedings, Respondent agrees that, at a hearing, Complainant could establish a factual basis for the charges in the Accusation, and that Respondent hereby gives up its right to contest those charges.

9. Respondent understands that by signing this stipulation Entity enables the Board to issue an order accepting the surrender of their Sterile Compounding License without further process.

CONTINGENCY

10. This stipulation shall be subject to approval by the Board of Pharmacy. Respondent understands and agrees that counsel for Complainant and the staff of the Board of Pharmacy may communicate directly with the Board regarding this stipulation and surrender, without notice to or participation by Respondent. By signing the stipulation, Respondent understands and agrees that they may not withdraw its agreement or seek to rescind the stipulation prior to the time the Board considers and acts upon it. If the Board fails to adopt this stipulation as its Decision and Order, the Stipulated Surrender and Disciplinary Order shall be of no force or effect, except for this paragraph, it shall be inadmissible in any legal action between the parties, and the Board shall not be disqualified from further action by having considered this matter.

11. The parties understand and agree that Portable Document Format (PDF) and facsimile copies of this Stipulated Surrender of License and Order, including Portable Document Format (PDF) and facsimile signatures thereto, shall have the same force and effect as the originals.

12. This Stipulated Surrender of License and Order is intended by the parties to be an integrated writing representing the complete, final, and exclusive embodiment of their agreement. It supersedes any and all prior or contemporaneous agreements, understandings, discussions, negotiations, and commitments (written or oral). This Stipulated Surrender of License and Order

may not be altered, amended, modified, supplemented, or otherwise changed except by a writing executed by an authorized representative of each of the parties.

13. In consideration of the foregoing admissions and stipulations, the parties agree that the Board may, without further notice or formal proceeding, issue and enter the following Order:

ORDER

IT IS HEREBY ORDERED that Sterile Compounding License No. LSC 99109 issued to Respondent Grandpa's Compounding Pharmacy, is surrendered and accepted by the Board of Pharmacy.

1. Respondent shall lose all rights and privileges as a Sterile Compounding Pharmacy in California as of the effective date of the Board's Decision and Order.

2. Respondent shall pay to the Board costs associated with its investigation and enforcement pursuant to Business and Professions Code section 125.3 in the amount of $7,000.00. Such costs shall be paid to the Board prior to issuance of any new or reinstated license to the current principals of Respondent, William Ray Wills (RPH 27496) and Daniel R. Wills (TCH 36985).

3. It is understood by all Parties that Respondent has previously caused to be delivered to the Board its pocket license and, if one was issued, its wall certificate. However, should Respondent retain either a pocket license or a wall certificate, Respondent will cause said license or certificate to be delivered to the Board on or before the effective date of the Decision and Order.

4. If Respondent ever files an application for licensure or a petition for reinstatement in the State of California, the Board shall treat it as a new application for licensure. Respondent must comply with all the laws, regulations and procedures for licensure, and all of the charges and allegations contained in Accusation No. 4929 shall be deemed to be true, correct and admitted by Respondent when the Board determines whether to grant or deny the application.

5. Respondent may not apply for licensure until three (3) years after the effective date of this Decision and Order.

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6. If Respondent should ever apply or reapply for a new license or certification, or petition for reinstatement of a license, by any other health care licensing agency in the State of California, all of the charges and allegations contained in Accusation, No. 4929 shall be deemed to be true, correct, and admitted by Respondent for the purpose of any Statement of Issues or any other proceeding seeking to deny or restrict licensure.

ACCEPTANCE

I have carefully read the Stipulated Surrender of License and Order. I understand the stipulation and the effect it will have. I enter into this Stipulated Surrender of License and Order voluntarily, knowingly, and intelligently, and agree to be bound by the Decision and Order of the Board of Pharmacy.

GRANDPA'S COMPOUNDING PHARMACY
PHY 45878, Respondent

DATED: 9 May 2014 — William R Wills
WILLIAM RAY WILLS RPH 27496

DATED: 23 May 2014 — Daniel R Wills
DANIEL R. WILLS TCH 36985

ENDORSEMENT

The foregoing Stipulated Surrender of License and Order is hereby respectfully submitted for consideration by the Board of Pharmacy of the Department of Consumer Affairs.

Dated: May 28, 2014

Respectfully submitted,

KAMALA D. HARRIS
Attorney General of California
JANICE K. LACHMAN
Supervising Deputy Attorney General

KRISTINA T. JANSEN
Deputy Attorney General
Attorneys for Complainant

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Exhibit A

Accusation No. 4929

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In the Matter of the Accusation Against: **GRANDPA'S COMPOUNDING PHARMACY** **7563 Green Valley Road** **Placerville, CA 95667** **Pharmacy License No. PHY 45878** **Sterile Compounding License No. LSC 99109** Respondents.	Case No. 4929 **ACCUSATION**

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 30, 2002, the Board of Pharmacy issued Pharmacy License Number PHY 45878 to Grandpa's Compounding Pharmacy (Respondent). The Pharmacy 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.

3. On or about July 14, 2003, the Board of Pharmacy issued Sterile Compounding License Number LSC 99109 to Grandpa's Compounding Pharmacy (Respondent). The Sterile

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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

8. 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.

"(c) The policy and procedure manual shall include the following:

"(1) Procedures for notifying staff assigned to compounding duties of any changes in processes or to the policy and procedure manual.

"(3) The procedures for maintaining, storing, calibrating, cleaning, and disinfecting equipment used in compounding, and for training on these procedures as part of the staff training and competency evaluation process.

13. CCR section 1735.8 states in pertinent part:

"(a) Any pharmacy engaged in compounding shall maintain, as part of its written policies and procedures, a written quality assurance plan designed to monitor and ensure the integrity, potency, quality, and labeled strength of compounded drug products.

"(b) The quality assurance plan shall include written procedures for verification, monitoring, and review of the adequacy of the compounding processes and shall also include written documentation of review of those processes by qualified pharmacy personnel.

"(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.

"..."

14. CCR section 1751.3 states in pertinent part:

"(a) Any pharmacy engaged in compounding sterile injectable drug products shall maintain a written policy and procedure manual for compounding that includes, in addition to the elements required by section 1735.5, written policies and procedures regarding the following:

"(1) Compounding, filling, and labeling of sterile injectable compounds.

"(2) Labeling of the sterile injectable product based on the intended route of administration and recommended rate of administration.

"(3) Equipment and supplies.

"(4) Training of staff in the preparation of sterile injectable products.

"(5) Procedures for handling cytotoxic agents.

"(6) Quality assurance program.

"(7) Record keeping requirements.

"...

"(d) Pharmacies compounding sterile injectable products from one or more non-sterile ingredients must have written policies and procedures that comply with the following:

"(3) Policies and procedures must address at least the following:

"...

"(G) Regular cleaning schedule for the controlled area and any equipment in the controlled area and the alternation of disinfectants. Pharmacies subject to an institutional infection control policy may follow that policy as it relates to cleaning schedules and the alternation of disinfectants in lieu of complying with this subdivision.

"..."

15. CCR section 1751.4 states in pertinent part:

"(a) No sterile injectable product shall be compounded if it is known, or reasonably should be known, that the compounding environment fails to meet criteria specified in the pharmacy's written policies and procedures for the safe compounding of sterile injectable drug products.

"..."

16. CCR section 1751.5 states in pertinent part:

"(b) When compounding sterile products from one or more non-sterile ingredients the following standards must be met:

"(1) Cleanroom garb consisting of a low-shedding coverall, head cover, face mask, and shoe covers must be worn inside the designated area at all times.

"(2) Cleanroom garb must be donned and removed outside the designated area.

"...

"(5) Gloves made of low-shedding materials are required..."

17. CCR section 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.

"(c) Records of training and demonstrated competence shall be available for each individual and shall be retained for three years beyond the period of employment.

"(d) The pharmacist-in-charge shall be responsible to ensure the continuing competence of pharmacy personnel engaged in compounding sterile injectable products.

"(e) Pharmacies that compound sterile products from one or more non-sterile ingredients must comply with the following training requirements:

"(1) The pharmacy must establish and follow a written program of training and performance evaluation designed to ensure that each person working in the designated area has the knowledge and skills necessary to perform their assigned tasks properly. This program of training and performance evaluation must address at least the following:

"(A) Aseptic technique.

"(B) Pharmaceutical calculations and terminology.

"(C) Sterile product compounding documentation.

"(D) Quality assurance procedures.

"(E) Aseptic preparation procedures.

"(F) Proper gowning and gloving technique.

"(G) General conduct in the controlled area.

"(H) Cleaning, sanitizing, and maintaining equipment used in the controlled area.

"(I) Sterilization techniques.

"(J) Container, equipment, and closure system selection.

"(2) Each person assigned to the controlled area must successfully complete practical skills training in aspetic technique and aseptic area practices. Evaluation must include written testing and a written protocol of periodic routine performance checks involving adherence to aspetic area policies and procedures. Each person's proficiency and continuing training needs must be reassessed every 12 months. Results of these assessments must be documented and retained in the pharmacy for three years."

18. CCR section 1751.7 states:

"(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.

"(c) Batch-produced sterile injectable drug products compounded from one or more non-sterile ingredients shall be subject to documented end product testing for sterility and pyrogens and shall be quarantined until the end product testing confirms sterility and acceptable levels of pyrogens.

"..."

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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

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.

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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 depyrogenation[1] 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 centigrade[2].

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.

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[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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1. Revoking or suspending Sterile Compounding License Number LSC 99109, issued to Grandpa's Compounding Pharmacy;

2. Ordering Grandpa's Compounding Pharmacy 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;

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

DATED: 1/8/14

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

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