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

In the Matter of the Accusation Against: **CENTER PHARMACY, INC.,** **DBA FOUNTAIN VALLEY CANCER CENTER PHARMACY** 11190 Warner Avenue #11 Fountain Valley, CA 92708 Pharmacy Permit No. PHY 43274 Sterile Compounding Permit No. LSC 99020 AND **MARC LOUIS HORWITZ** 11190 Warner Avenue #11 Fountain Valley, CA 92708 Pharmacist License No. RPH 40786 Respondent.	Case No. 4551 OAH Case No. 2013080984

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 November 27, 2013.

It is so ORDERED on November 20, 2013.

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: **CENTER PHARMACY, INC.,** **DBA FOUNTAIN VALLEY CANCER CENTER PHARMACY** **11190 Warner Avenue #11,** **Fountain Valley, California 92708** **Pharmacy Permit No. PHY 43274** **Sterile Compounding Permit No. LSC 99020** **and** **MARC LOUIS HORWITZ** **11190 Warner Avenue #11,** **Fountain Valley, California 92708** **Pharmacist License No. RPH 40786** Respondents	Case No. 4551 OAH No. 2013080984 **STIPULATED SETTLEMENT AND DISCIPLINARY ORDER**

IT IS HEREBY STIPULATED AND AGREED by and between the parties in this proceeding that the following matters are true:

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PARTIES

1. Virginia Herold (Complainant) is the Executive Officer of the Board of Pharmacy (Board). 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 Antoinette B. Cincotta, Deputy Attorney General.

2. Marc Louis Horwitz, RPH and Fountain Valley Cancer Center Pharmacy (Respondents) are represented in this proceeding by attorney Herbert L. Weinberg, Esq., whose address is 1800 Century Park East, 8th Fl., Los Angeles, CA 90067.

3. On or about March 24, 1987, the Board issued Pharmacist License No. No. RPH 40786 to Marc Louis Horwitz (Respondent Horwitz). The Pharmacist License will expire on October 31, 2014, unless renewed.

4. On or about December 16, 1997, the Board issued Pharmacy Permit No. PHY 43274 to Center Pharmacy, Inc., to do business as Fountain Valley Cancer Center Pharmacy (Respondent Pharmacy). The Pharmacy Permit was in full force and effect at all times relevant to the charges brought in Accusation No. 4551, and will expire on December 1, 2013, unless renewed. Pharmacy Permit no. PHY 43274 was suspended by Order dated July 30, 2013. Marc Louis Horwitz, RPH 40786 is, and has been, the president of Center Pharmacy, Inc. since December 16, 1997, and Pharmacist-in-Charge of Center Pharmacy, Inc. since November 15, 2004.

5. On or about July 3, 2003, the Board issued Licensed Sterile Compounding Permit No. LSC 99020 to Center Pharmacy, Inc. to compound injectable sterile drug products. Sterile Compounding Permit No. LSC 99020 was suspended by Order dated July 30, 2013.

JURISDICTION

6. Accusation No. 4551 was filed before the Board, and is currently pending against Respondent. The Accusation and all other statutorily required documents were properly served on Respondent on August 13, 2013. Respondents timely filed their Notices of Defense contesting the Accusation. A copy of Accusation No. 4551 is attached as Exhibit A, and incorporated by reference.

ADVISEMENT AND WAIVERS

7. Respondent Horwitz has carefully read, fully discussed with counsel, and understands the charges and allegations in Accusation No. 4551. Respondent Horwitz also has carefully read, fully discussed with counsel, understands the effects of this Stipulated Settlement and Disciplinary Order, and has the full authority to act on behalf of Center Pharmacy, Inc., doing business as Fountain Valley Cancer Center Pharmacy.

8. Respondent Horwitz is fully aware of his legal rights in this matter, including the right to a hearing on the charges and allegations in the Accusation; 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.

9. Respondent Horwitz, individually and on behalf of Center Pharmacy, Inc., doing business as Fountain Valley Cancer Center Pharmacy, voluntarily, knowingly, and intelligently waives and gives up each and every right set forth above.

CULPABILITY

10. Respondent Horwitz, individually and on behalf of Center Pharmacy, Inc., doing business as Fountain Valley Cancer Center Pharmacy, understands and agrees that the charges and allegations in Accusation No. 4551, if proven at a hearing, constitute cause for imposing discipline upon the Pharmacist License and the Pharmacy and Sterile Compounding Permits.

8. For the purpose of resolving the Accusation without the expense and uncertainty of further proceedings, Respondent Horwitz, individually and on behalf of Respondent Center Pharmacy, Inc., agrees that, at a hearing, Complainant could establish a factual basis for the charges in the Accusation, and Respondents hereby give up the right to contest those charges.

11. Respondent Horwitz, individually and on behalf of Respondent Center Pharmacy, Inc., understands that by signing this stipulation he enables the Board to issue an order revoking the Pharmacy Permit and Licensed Sterile Compounding Permit without further process. Respondent Horwitz, individually and on behalf of Respondent Center Pharmacy, Inc., further

agrees that his Pharmacist License and the Pharmacy and Sterile Compounding Permits are subject to discipline, and he agrees to be bound by the Board's Disciplinary Order below.

CONTINGENCY

12. This stipulation shall be subject to approval by the Board. Respondent Horwitz, individually and on behalf of Center Pharmacy, Inc., understands and agrees that counsel for Complainant and the staff of the Board may communicate directly with the Board regarding this stipulation, without notice to or participation by Respondent or its counsel. By signing the stipulation, Respondents understand and agree that they may not withdraw this 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 Settlement 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.

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

14. This Stipulated Settlement and Disciplinary 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 Settlement and Disciplinary 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.

15. 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:

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ORDER

IT IS HEREBY ORDERED that Pharmacy Permit No. PHY 43274, and Licensed Sterile Compounding Permit No. LSC 99020 issued to Respondent Center Pharmacy, Inc., doing business as Fountain Valley Cancer Center Pharmacy are revoked; however, the revocations are stayed, and Respondent Center Pharmacy, Inc., doing business as Fountain Valley Cancer Center Pharmacy is placed on probation for a period of three (3) month beginning on the effective date of this decision or until January 1, 2014, whichever date occurs first.

After three (3) months from the effective date of this decision or on January 1, 2014, whichever date occurs first, the stay will be automatically lifted and Pharmacy Permit No. PHY 43274, and Licensed Sterile Compounding Permit No. LSC 99020, issued to Respondent Center Pharmacy, Inc., doing business as Fountain Valley Cancer Center Pharmacy will be permanently revoked, without further notice or formal hearing.

During the period of probation, Respondent Center Pharmacy, Inc., doing business as Fountain Valley Cancer Center Pharmacy, shall be subject to the following terms and conditions:

1. **Obey All Laws** - Respondent Center Pharmacy, Inc., doing business as Fountain Valley Cancer Center Pharmacy, through its authorized representative, shall obey all state and federal laws and regulations. Respondent Center Pharmacy, Inc., doing business as Fountain Valley Cancer Center Pharmacy, through its authorized representative, shall report any of the following occurrences to the Board, in writing, within seventy-two (72) hours of such an occurrence:

- An arrest or issuance of a criminal complaint for violation of any provision of Pharmacy Law, state and federal food and drug laws, or state and federal controlled substances law.

- A plea of guilty or nolo contendre in any state or federal criminal proceeding to any criminal complaint, information, or indictment.

- A conviction of any crime

- Discipline, citation, or other administrative action filed by any state or federal agency which involves Respondent Horwitz's pharmacist license and Respondent Center Pharmacy,

Inc.'s pharmacy permit and/or sterile compounding permit or which is related to the practice of pharmacy or the manufacturing, obtaining, handling, compounding, distributing, billing, or charging for any drug, device, or controlled substance.

Failure to timely report such occurrence shall be considered a violation of probation.

2. **Consulting Pharmacist -** Within thirty (30) days of the effective date of the decision, Respondent Center Pharmacy, Inc., through its authorized representative, shall employ a consulting pharmacist to assist with maintaining the pharmacy's compliance with all applicable pharmacy laws and regulations. Prior to the employment of this consultant, Respondent Center Pharmacy, Inc., through its authorized representative, shall submit the name of the candidate(s) for the position of consulting pharmacist, to the Board for approval. If Respondent Center Pharmacy, Inc.'s candidates are denied by the Board, then within seven (7) days of the denial, the Respondent Center Pharmacy, Inc., through its authorized representative, shall submit the name of another candidate for the position of consulting pharmacist.

3. **Report to the Board -** Respondent Center Pharmacy, Inc., through its authorized representative, shall report to the Board on a schedule as directed by the Board or its designee. The report shall be made either in person, through its authorized representative, or in writing as directed. Among other requirements, Respondent Center Pharmacy, Inc., through its authorized representative, shall state in each report under penalty of perjury whether there has been compliance with all terms and conditions of probation. Failure to submit timely reports in a form as directed shall be considered a violation of probation. Any period of delinquency in submission of reports as directed, shall be considered a violation of probation.

4. **Interview with Board -** Upon receipt of reasonable prior notice, Respondent Center Pharmacy, Inc., through its authorized representative, shall appear in person for interviews with the Board or its designee, at such intervals and locations as are determined by the Board or its designee. Failure to appear for any scheduled interview without prior notification to Board staff, or failure to appear for two (2) or more scheduled interviews with the Board or its designee during the period of probation, shall be considered a violation of probation.

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5. **Cooperate with Board Staff** - Respondent Center Pharmacy, Inc., through its authorized representative, shall cooperate with the Board's inspection program and with the Board's monitoring and investigation of Respondent's compliance with the terms and conditions of probation. Failure to cooperate shall be considered a violation of probation.

6. **Probation Monitoring Costs** - Respondent Center Pharmacy, Inc., through its authorized representative, shall pay any costs associated with probation monitoring as determined by the Board. Such costs shall be payable to the Board on a schedule as directed by the Board or its designee. Failure to pay such costs by the deadline as directed shall be considered a violation of probation.

7. **Status of License** - Respondent Center Pharmacy, Inc., through its authorized representative, shall at all times while on probation, maintain current licensure with the Board. If Respondent Center Pharmacy, Inc., through its authorized representative, submits an application to the Board, and the application is approved, for a change of location, change of permit or change of ownership, the Board shall continue jurisdiction over the license, and Respondent Center Pharmacy, Inc., through its authorized representative, shall remain on probation as determined by the Board. Failure to maintain current licensure shall be considered a violation of probation.

If Respondent Center Pharmacy, Inc.'s pharmacy permit and/or sterile compounding permit expires or are cancelled by operation of law or otherwise at any time during the period of probation, including any extensions thereof or otherwise, upon renewal or reapplication Respondent Center Pharmacy, Inc.'s permits shall be subject to all terms and conditions of this probation not previously satisfied.

8. **License Surrender While on Probation** - Following the effective date of this decision, should Respondent Center Pharmacy, Inc. discontinue business, Respondent Center Pharmacy, Inc., may tender the pharmacy and sterile compounding permits to the Board for surrender. The Board or its designee shall have the discretion whether to grant the request for surrender or take any other action it deems appropriate and reasonable. Upon formal acceptance

of the surrender of both permits, Respondent Center Pharmacy, Inc. will no longer be subject to the terms and conditions of probation.

Upon acceptance of the surrender, Respondent Horwitz shall relinquish the premises wall and renewal license to the board within ten (10) days of notification by the board that the surrenders are accepted. Respondent Horwitz shall further submit a completed Discontinuance of Business form according to board guidelines and shall notify the board of the records inventory transfer.

Respondent Horwitz shall also, by the effective date of this decision, arrange for the continuation of care for ongoing patients of the pharmacy by, at minimum, providing a written notice to ongoing patients that specifies the anticipated closing date of the pharmacy and that identifies one or more area pharmacies capable of taking up the patients' care, and by cooperating as may be necessary in the transfer of records or prescriptions for ongoing patients. Within five days of its provision to the pharmacy's ongoing patients, Respondent Horwitz shall provide a copy of the written notice to the board. For the purposes of this provision, "ongoing patients" means those patients for whom the pharmacy has on file a prescription with one or more refills outstanding, or for whom the pharmacy has filled a prescription within the preceding sixty (60) days.

Respondent Horwitz may not apply for any new licensure from the board for three (3) years from the effective date of the surrender. Respondent Horwitz shall meet all requirements applicable to the license sought as of the date the application for that license is submitted to the board.

Respondent Horwitz further stipulates that he shall reimburse the board for its costs of investigation and prosecution prior to the acceptance of the surrender.

9. **Owners and Officers: Knowledge of the Law -** Respondent Center Pharmacy, Inc., doing business as Fountain Valley Cancer Center Pharmacy shall provide, within thirty (30) days after the effective date of this decision, signed and dated statements from its owners, including any owner or holder of ten percent (10%) or more of the interest in Respondent Center Pharmacy, Inc. or Respondent Center Pharmacy, Inc.'s stock, and any officer, stating under penalty of

perjury that said individuals have read and are familiar with state and federal laws and regulations governing the practice of pharmacy. The failure to timely provide said statements under penalty of perjury shall be considered a violation of probation.

10. **Posted Notice of Probation** - Respondent Horwitz, shall prominently post a probation notice provided by the Board in a place conspicuous and readable to the public. The probation notice shall remain posted during the entire period of probation.

Respondent Horwitz shall not, directly or indirectly, engage in any conduct or make any statement which is intended to mislead or is likely to have the effect of misleading any patient, customer, member of the public, or other person(s) as to the nature of and reason for the probation of the licensed entity.

Failure to post such notice shall be considered a violation of probation.

11. **Violation of Probation** - If Respondent Center Pharmacy, Inc. has not complied with any term or condition of probation, the Board shall have continuing jurisdiction over Respondent Center Pharmacy, Inc., then the Board shall take other action as deemed appropriate to treat the failure to comply as a violation of probation, to terminate probation, and to impose the penalty that was stayed.

If Respondent Center Pharmacy violates probation in any respect, the board, after giving Respondent owner notice and an opportunity to be heard, may revoke probation and carry out the disciplinary order that was stayed. Notice and opportunity to be heard are not required for those provisions stating that a violation thereof may lead to automatic termination of the stay and/or revocation of the license. If a petition to revoke probation or an accusation is filed against Respondent Center Pharmacy, Inc. during probation, the board shall have continuing jurisdiction and the period of probation shall be automatically extended until the petition to revoke probation or accusation is heard and decided.

12. **Sale of Permits** - After the end of the three (3) month probation period or January 1, 2014, whichever date occurs first, Respondent Horwitz shall be prohibited from owning or having any ownership interest in any entity that owns or operates a pharmacy or any other entity that is required to be licensed by the Board of Pharmacy. On or before the end of the three (3) month

probation period or January 1, 2014, whichever date occurs first, Respondent Horwitz shall sell the corporation of Center Pharmacy, Inc. or sell all assets of Center Pharmacy, Inc. and take no security interest in any of said assets in connection with the sale.

If Respondent Horwitz retains the corporation after the three (3) month probation period or January 1, 2014, whichever date occurs first, he shall change the name of the corporation so that it no longer contains the terms "Medical" or "Pharmacy." Within ten (10) days of any change in ownership, title, or holding in Center Pharmacy, Inc., doing business as Fountain Valley Cancer Center Pharmacy, Respondent Horwitz shall notify the Board in writing, under penalty of perjury, of said changes. Whether or not the corporation or all of the corporation's assets are disposed of through sale, transfer, or other means, on or before the end of the three (3) month probation period or January 1, 2014, whichever date occurs first, the Respondent Center Pharmacy, Inc.'s pharmacy permit and sterile compounding permit shall be permanently revoked, without further notice or formal hearing.

13. **Reimbursement of Board Costs** - Respondent Center Pharmacy, Inc. shall reimburse the Board for its costs of investigation and prosecution in the amount of eight thousand, five hundred, eighty-five dollars and fifty cents ($8,585.50). The full amount shall be paid within sixty calendar days of the effective date of this decision. Respondents Center Pharmacy, Inc. and Respondent Horwitz shall be jointly and severally liable for the full payment of the cost of investigation and prosecution in this matter.

Respondent Center Pharmacy, Inc. shall make payment by cashier check or money order payable to "Board of Pharmacy." Payment shall be mailed to Board of Pharmacy, 1625 North Market Boulevard, Suite N219, Sacramento, CA 95834-1924 and indicate reference: "Center Pharmacy/Horwitz, Case No. 4551."

Failure to pay the full fine amount within the timeline indicated may result in further license discipline, including the denial of the Respondent Center Pharmacy, Inc.'s application for renewal of its permits, and any other license issued to Respondent Center Pharmacy, Inc. by the Board of Pharmacy.

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After three (3) months from the effective date of this decision or on January 1, 2014, whichever date occurs first, the stay will be automatically lifted and Pharmacy Permit No. PHY 43274, and Licensed Sterile Compounding Permit No. LSC 99020, issued to Respondent Center Pharmacy, Inc., doing business as Fountain Valley Cancer Center Pharmacy will be permanently revoked, without further notice or formal hearing, subject to the following terms and conditions:

14. The revocation of Respondent Center Pharmacy, Inc.'s Pharmacy Permit and Licensed Sterile Compounding Permit shall constitute the imposition of discipline against Respondent Center Pharmacy, Inc. This stipulation constitutes a record of the discipline and shall become a part of Respondent's license history with the Board.

15. Respondent Center Pharmacy, Inc., doing business as Fountain Valley Cancer Center Pharmacy, shall lose all rights and privileges as a pharmacy, and shall also lose all rights and privileges to perform sterile compounding in California as of the effective date of the Board's Decision and Order.

16. Respondent Horwitz shall cause to be delivered to the Board all pocket permits and, if issued, wall certificates for the Pharmacy Permit and Licensed Sterile Compounding Permit on or before the effective date of the Decision and Order.

17. Respondent Center Pharmacy, Inc., doing business as Fountain Valley Cancer Center Pharmacy, shall pay the agency its costs of investigation and enforcement in the amount of $8,585.50.

18. Respondent Horwitz shall, within ten (10) days of the effective date, arrange for the destruction of, the transfer to, sale of or storage in a facility licensed by the board of all controlled substances and dangerous drugs and devices. Respondent Horwitz shall further provide written proof of such disposition and submit a completed Discontinuance of Business form according to board guidelines.

19. Respondent Horwitz shall also, by the effective date of this decision, arrange for the continuation of care for ongoing patients of the Respondent Center Pharmacy, Inc., doing business as Fountain Valley Cancer Center Pharmacy, by, at minimum, providing a written notice

to ongoing patients that specifies the anticipated closing date of the pharmacy and that identifies one or more area pharmacies capable of taking up the patients' care, and by cooperating as may be necessary in the transfer of records or prescriptions for ongoing patients. Within five days of its provision to the pharmacy's ongoing patients, Respondent Horwitz shall provide a copy of the written notice to the board. For the purposes of this provision, "ongoing patients" means those patients for whom the pharmacy has on file a prescription with one or more refills outstanding, or for whom the pharmacy has filled a prescription within the preceding sixty (60) days.

20. Respondent Horwitz may not reapply for any license from the board for three (3) years from the effective date of this decision. Respondent Horwitz stipulates that should he apply for any license from the board on or after the effective date of this decision, all allegations set forth in the Accusation shall be deemed to be true, correct and admitted by respondent when the board determines whether to grant or deny the application. Respondent shall satisfy all requirements applicable to that license as of the date the application is submitted to the board. Respondent Horwitz is required to report this surrender as disciplinary action.

IT IS FURTHER HEREBY ORDERED that Pharmacist License No. RPH 40786 issued to Respondent Horwitz is revoked. However, the revocation of Pharmacist License No. RPH 40786 is stayed, and Respondent Horwitz is placed on probation for five (5) years on the following terms and conditions.

22. **Obey All Laws** – Respondent Horwitz shall obey all state and federal laws and regulations.

Respondent Horwitz shall report any of the following occurrences to the Board, in writing, within 72 hours of such occurrence:

- an arrest or issuance of a criminal complaint for violation of any provision of the Pharmacy Law, state and federal food and drug laws, or state and federal controlled substances laws
- a plea of guilty or nolo contendre in any state or federal criminal proceeding to any criminal complaint, information or indictment
- a conviction of any crime

- discipline, citation, or other administrative action filed by any state or federal agency which involves Respondent's Pharmacist license and Pharmacy Permit or which is related to the practice of pharmacy or the manufacturing, obtaining, handling, distributing, billing, or charging for any drug, device or controlled substance.

Failure to timely report such occurrence shall be considered a violation of probation.

23. **Report to the Board** – Respondent Horwitz shall report to the Board quarterly, on a schedule as directed by the Board or its designee. The report shall be made either in person or in writing, as directed. Among other requirements, Respondent shall state in each report under penalty of perjury whether there has been compliance with all the terms and conditions of probation. Failure to submit timely reports in a form as directed shall be considered a violation of probation. Any period(s) of delinquency in submission of reports as directed may be added to the total period of probation. Moreover, if the final probation report is not made as directed, probation shall be automatically extended until such time as the final report is made and accepted by the Board.

24. **Interview with the Board** – Upon receipt of reasonable prior notice, Respondent Horwitz shall appear in person for interviews with the Board or its designee, at such intervals and locations as are determined by the Board or its designee. Failure to appear for any scheduled interview without prior notification to Board staff, or failure to appear for two or more scheduled interviews with the Board or its designee during the period of probation, shall be considered a violation of probation.

25. **Cooperate with Board Staff** – Respondent Horwitz shall cooperate with the Board's inspection program and with the Board's monitoring and investigation of Respondent's compliance with the terms and conditions of probation. Failure to cooperate shall be considered a violation of probation.

26. **Continuing Education** – Respondent Horwitz shall provide evidence of efforts to maintain skill and knowledge as a pharmacist as directed by the Board or its designee.

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27. **Notice to Employers** – During the period of probation, Respondent Horwitz shall notify all present and prospective employers of the decision in case number 4551, and the terms, conditions and restrictions imposed on Respondent by the decision, as follows:

Within 30 days of the effective date of this decision, and within 15 days of Respondent Horwitz's undertaking any new employment, Respondent Horwitz shall cause his direct supervisor, pharmacist-in-charge (including each new pharmacist-in-charge employed during Respondent Horwitz's tenure of employment) and owner to report to the Board in writing acknowledging that the listed individual(s) has/have read the decision in case number 4551, and terms and conditions imposed thereby. It shall be Respondent Horwitz's responsibility to ensure that his employer(s) and/or supervisor(s) submit timely acknowledgment(s) to the Board.

If Respondent Horwitz works for or is employed by or through a pharmacy employment service, Respondent Horwitz must notify his direct supervisor, pharmacist-in-charge, and owner at every entity licensed by the Board of the terms and conditions of the decision in case number 3423 in advance of the Respondent commencing work at each licensed entity. A record of this notification must be provided to the Board upon request.

Furthermore, within 30 days of the effective date of this decision, and within 15 days of Respondent Horwitz's undertaking any new employment by or through a pharmacy employment service, Respondent Horwitz shall cause his direct supervisor with the pharmacy employment service to report to the Board in writing acknowledging that he has read the decision in case number 4551 and the terms and conditions imposed thereby. It shall be Respondent Horwitz's responsibility to ensure that his employer(s) and/or supervisor(s) submit timely acknowledgment(s) to the Board.

Failure to timely notify present or prospective employer(s) or to cause that/those employer(s) to submit timely acknowledgments to the Board shall be considered a violation of probation.

"Employment" within the meaning of this provision shall include any full-time, part-time, temporary, relief or pharmacy management service as a pharmacist or any position for which a

pharmacist license is a requirement or criterion for employment, whether the Respondent is an employee, independent contractor or volunteer.

28. **No Supervision of Interns, Serving as Pharmacist-in-Charge (PIC), Serving as Designated Representative-in-Charge, or Serving as a Consultant** – During the period of probation, respondent shall not supervise any intern pharmacist, be the pharmacist-in-charge or designated representative-in-charge of any entity licensed by the board nor serve as a consultant unless otherwise specified in this order. Assumption of any such unauthorized supervision responsibilities shall be considered a violation of probation.

29. **Reimbursement of Board Costs** – Respondent Horwitz shall be jointly and severally responsible with Respondent Center Pharmacy, Inc., doing business as Fountain Valley Cancer Center Pharmacy, to pay the agency its costs of investigation and enforcement in the amount of $8,585.50, and shall pay these costs within sixty (60) calendar days from the effective date of this decision. Failure to reimburse the Board's cost of its investigation and prosecution shall constitute a violation of the probationary order, unless the Board or its designee agrees in writing to payment by an installment plan because of financial hardship. Any and all requests for a payment plan shall be submitted in writing by Respondent Horwitz to the Board. However, full payment of any and all costs required by this condition must be received by the Board no later than one (1) year prior to the scheduled termination of probation.

30. **Probation Monitoring Costs** – Respondent Horwitz shall pay any costs associated with probation monitoring as determined by the Board each and every year of probation. Such costs shall be payable to the Board on a schedule as directed by the Board or its designee. Failure to pay such costs by the deadline(s) as directed shall be considered a violation of probation.

31. **Status of License** – Respondent Horwitz shall, at all times while on probation, maintain an active, current license with the Board, including any period during which suspension or probation is tolled. Failure to maintain an active, current license shall be considered a violation of probation.

If Respondent Horwitz's license expires or is cancelled by operation of law or otherwise at any time during the period of probation, including any extensions thereof due to tolling or

otherwise, upon renewal or reapplication Respondent's license and permit shall be subject to all terms and conditions of this probation not previously satisfied.

32. **License Surrender While on Probation/Suspension** – Following the effective date of this decision, should Respondent Horwitz cease practice due to retirement or health, or be otherwise unable to satisfy the terms and conditions of probation, Respondent Horwitz may tender his license to the Board for surrender. The Board or its designee shall have the discretion whether to grant the request for surrender or take any other action it deems appropriate and reasonable. Upon formal acceptance of the surrender of the license, Respondent Horwitz will no longer be subject to the terms and conditions of probation. This surrender constitutes a record of discipline and shall become a part of the Respondent Horwitz's license history with the Board.

Upon acceptance of the surrender, Respondent Horwitz shall relinquish his pocket and/or wall license and permit to the Board within ten days of notification by the Board that the surrender is accepted. Respondent Horwitz may not reapply for any license or permit from the Board for three years from the effective date of the surrender. Respondent Horwitz shall meet all requirements applicable to the license sought as of the date the application for that license is submitted to the Board, including any outstanding costs.

33. **Notification of a Change in Name, Residence Address, Mailing Address or Employment** – Respondent Horwitz shall notify the Board in writing within ten days of any change of employment. Said notification shall include the reasons for leaving, the address of the new employer, the name of the supervisor and owner, and the work schedule if known. Respondent Horwitz shall further notify the Board in writing within ten days of a change in name, residence address, mailing address, or phone number.

Failure to timely notify the Board of any change in employer(s), name(s), address(es), or phone number(s) shall be considered a violation of probation.

34. **Tolling of Probation** – Except during periods of suspension, Respondent Horwitz shall, at all times while on probation, be employed as a pharmacist in California for a minimum of 40 hours per calendar month. Any month during which this minimum is not met shall toll the period of probation, i.e., the period of probation shall be extended by one month for each month

during which this minimum is not met. During any such period of tolling of probation, Respondent Horwitz must nonetheless comply with all terms and conditions of probation.

Should Respondent Horwitz, regardless of residency, for any reason (including vacation) cease practicing as a pharmacist for a minimum of 40 hours per calendar month in California, Respondent Horwitz must notify the Board in writing within ten days of the cessation of practice, and must further notify the Board in writing within ten days of the resumption of practice. Any failure to provide such notification(s) shall be considered a violation of probation.

It is a violation of probation for Respondent Horwitz's probation to remain tolled pursuant to the provisions of this condition for a total period, counting consecutive and non-consecutive months, exceeding 36 months.

"Cessation of practice" means any calendar month during which Respondent Horwitz is not practicing as a pharmacist for at least 40 hours, as defined by Business and Professions Code section 4000 et seq. "Resumption of practice" means any calendar month during which Respondent is practicing as a pharmacist for at least 40 hours as a pharmacist as defined by Business and Professions Code section 4000 et seq.

35. **Violation of Probation** – If Respondent Horwitz has not complied with any term or condition of probation, the Board shall have continuing jurisdiction over him, and probation shall automatically be extended, until all terms and conditions have been satisfied or the Board has taken other action as deemed appropriate to treat the failure to comply as a violation of probation, to terminate probation, and to impose the penalty that was stayed.

If Respondent Horwitz violates probation in any respect, the Board, after giving him notice and an opportunity to be heard, may revoke probation and carry out the disciplinary order that was stayed. Notice and opportunity to be heard are not required for those provisions stating that a violation thereof may lead to automatic termination of the stay and/or revocation of the license. If a petition to revoke probation or an accusation is filed against Respondent Horwitz during probation, the Board shall have continuing jurisdiction and the period of probation shall be automatically extended until the petition to revoke probation or accusation is heard and decided. If an accusation or petition to revoke probation is filed against Respondent Horwitz pursuant to

this paragraph, all allegations and charges in Accusation No. 4551 are deemed admitted for the purposes of such proceedings.

36. **Completion of Probation** – Upon written notice by the Board or its designee indicating successful completion of probation, Respondent Horwitz's license will be fully restored.

37. **Restricted Practice** - Respondent Horwitz shall not prepare, oversee or participate in the preparation of compound sterile products during the first 3 years of probation. Respondent shall submit proof satisfactory to the board of compliance with this term of probation. Failure to abide by this restriction or to timely submit proof to the board of compliance therewith shall be considered a violation of probation.

38. **Remedial Education** -Within ninety (90) days of the effective date of this decision, Respondent Horwitz shall submit to the board or its designee, for prior approval, an appropriate program of remedial education related to sterile compounding. The program of remedial education shall consist of at least 15 hours per year for each year of probation, and shall be completed at Respondent's own expense. All remedial education shall be in addition to, and shall not be credited toward, continuing education (CE) courses used for license renewal purposes.

Failure to timely submit or complete the approved remedial education shall be considered a violation of probation. The period of probation will be automatically extended until such remedial education is successfully completed and written proof, in a form acceptable to the board, is provided to the board or its designee.

Following the completion of each course, the board or its designee may require the Respondent Horwitz, at his own expense, to take an approved examination to test the Respondent's knowledge of the course. If Respondent Horwitz does not achieve a passing score on the examination, this failure shall be considered a violation of probation. Any such examination failure shall require Respondent Horwitz to take another course approved by the board in the same subject area.

39. **No Ownership of Licensed Premises** - Respondent Horwitz shall not own, have any legal or beneficial interest in, or serve as a manager, administrator, member, officer, director,

trustee, associate, or partner of any business, firm, partnership, or corporation currently or hereinafter licensed by the board. Respondent Horwitz shall sell or transfer any legal or beneficial interest in any entity licensed by the board within ninety (90) days following the effective date of this decision and shall immediately thereafter provide written proof thereof to the board. Failure to timely divest any legal or beneficial interest(s) or provide documentation thereof shall be considered a violation of probation.

ACCEPTANCE

I have carefully read the above Stipulated Settlement and Disciplinary Order and have fully discussed it with my attorney, Herbert L. Weinberg, Esq.. I understand the stipulation and the effect it will have on the Pharmacy Permit and Licensed Sterile Compounding Permit issued to Respondent Center Pharmacy, Inc., doing business as Fountain Valley Cancer Center Pharmacy, and my Pharmacist License. I enter into this Stipulated Settlement and Disciplinary Order voluntarily, knowingly, and intelligently, and agree to be bound by the Decision and Order of the Board of Pharmacy.

DATED: 10/3/2013

MARC LOUIS HORWITZ, individually and on behalf of CENTER PHARMACY, INC., D.B.A. FOUNTAIN VALLEY CANCER CENTER PHARMACY
Respondents

I have read and fully discussed with Marc Louis Horwitz the terms and conditions and other matters contained in this Stipulated Settlement and Disciplinary Order. I approve its form and content.

DATED: 10/3/2013

HERBERT L. WEINBERG, ESQ.
Attorney for Respondent

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ENDORSEMENT

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

Dated: 10/7/2013

Respectfully submitted,

KAMALA D. HARRIS
Attorney General of California
LINDA K. SCHNEIDER
Supervising Deputy Attorney General

ANTOINETTE B. CINCOTTA
Deputy Attorney General
Attorneys for Complainant

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Exhibit A

Accusation No. 4551

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Attorneys for Complainant

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

In the Matter of the Accusation Against: **CENTER PHARMACY, INC.,** **DBA FOUNTAIN VALLEY CANCER CENTER PHARMACY** **11190 Warner Avenue #11,** **Fountain Valley, California 92708** **Pharmacy Permit No. PHY 43274** **Sterile Compounding Permit No. LSC 99020** **and** **MARC LOUIS HORWITZ, RPH AND PRESIDENT** **FOUNTAIN VALLEY CANCER CENTER PHARMACY** **11190 Warner Avenue #11,** **Fountain Valley, California 92708** **Pharmacist License No. RPH 40786** Respondents.	Case No. 4551 **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 (Board), Department of Consumer Affairs.

2. On or about March 24, 1987, the Board issued Pharmacist License No. RPH 40786 to Marc Louis Horwitz (Respondent Horwitz). The license will expire on October 31, 2014 unless renewed.

3. On December 16, 1997, the Board issued Pharmacy Permit No. PHY 43274 to Center Pharmacy, Inc. to do business as Fountain Valley Cancer Center Pharmacy. Pharmacy Permit No. PHY 43274 was suspended by Order dated July 30, 2013.

4. On July 3, 2003, the Board issued Sterile Compounding Permit Number LSC 99020 to Center Pharmacy, Inc. to do business as Fountain Valley Cancer Center Pharmacy to compound injectable sterile drug products. Mark L. Horwitz, RPH 40786 is and has been the president of Center Pharmacy, Inc. since December 16, 1997, and Pharmacist-in-Charge since November 15, 2004. Sterile Compounding Permit No. LSC 99020 was suspended by Order dated July 30, 2013.

JURISDICTION

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

6. 6. Section 4300 of the Code states in relevant 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.

". . . .

"(e) The proceedings under this article shall be conducted in accordance with Chapter 5 (commencing with Section 11500) of Part 1 of Division 3 of the Government Code, and the board shall have all the powers granted therein. The action shall be final, except that the propriety of the action is subject to review by the superior court pursuant to Section 1094.5 of the Code of Civil Procedure."

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."

STATUTORY AUTHORITIES

8. Section 4301 of the Code states in relevant 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:

". . .

"(j) The violation of any of the statutes of this state, of any other state, or of the United States regulating controlled substances and dangerous drugs.

". . .

"(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 4022 of the Code states

"Dangerous drug" or "dangerous device" means any drug or device unsafe for self-use in humans or animals, and includes the following:

"(a) Any drug that bears the legend: "Caution: federal law prohibits dispensing without prescription," "Rx only," or words of similar import.

"(b) Any device that bears the statement: "Caution: federal law restricts this device to sale by or on the order of a _____," "Rx only," or words of similar import, the blank to be filled in with the designation of the practitioner licensed to use or order use of the device.

"(c) Any other drug or device that by federal or state law can be lawfully dispensed only on prescription or furnished pursuant to Section 4006."

10. Section 4081 of the Code states:

"(a) All records of manufacture and of sale, acquisition, or disposition of dangerous drugs or dangerous devices shall be at all times during business hours open to inspection by authorized officers of the law, and shall be preserved for at least three years from the date of making. A current inventory shall be kept by every manufacturer, wholesaler, pharmacy, veterinary food-animal drug retailer, physician, dentist, podiatrist, veterinarian, laboratory, clinic, hospital, institution, or establishment holding a currently valid and unrevoked certificate, license, permit, registration, or exemption under Division 2 (commencing with Section 1200) of the Health and Safety Code or under Part 4 (commencing with Section 16000) of Division 9 of the Welfare and Institutions Code who maintains a stock of dangerous drugs or dangerous devices.

"(b) The owner, officer, and partner of any pharmacy, wholesaler, or veterinary food-animal drug retailer shall be jointly responsible, with the pharmacist-in-charge or representative-in-charge, for maintaining the records and inventory described in this section.

"(c) The pharmacist-in-charge or representative-in-charge shall not be criminally responsible for acts of the owner, officer, partner, or employee that violate this section and of which the pharmacist-in-charge or representative-in-charge had no knowledge, or in which he or she did not knowingly participate."

11. Section 4169 of the Code states in relevant part:

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

". . .

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"(2) Purchase, trade, sell, or transfer dangerous drugs that the person knew or reasonably should have known were adulterated, as set forth in Article 2 (commencing with Section 111250) of Chapter 6 of Part 5 of Division 104 of the Health and Safety Code.

". . .

"(5) Fail to maintain records of the acquisition or disposition of dangerous drugs or dangerous devices for at least three years.

". . . ."

12. Health and Safety Code section 111255 states:

"Any drug or device is adulterated if it has been produced, prepared, packed, or held under conditions whereby it may have been contaminated with filth, or whereby it may have been rendered injurious to health."

REGULATIONS

13. California Code of Regulations (CCR), title 16, section 1751.7 states:

"**Sterile Injectable Compounding Quality Assurance and Process Validation.**

"(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.

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"(b) Each individual involved in the preparation of sterile injectable products must first successfully complete a validation process on technique before being allowed to prepare sterile injectable products. The validation process shall be carried out in the same manner as normal production, except that an appropriate microbiological growth medium is used in place of the actual product used during sterile preparation. The validation process shall be representative of all types of manipulations, products and batch sizes the individual is expected to prepare. The same personnel, procedures, equipment, and materials must be involved. Completed medium samples must be incubated. If microbial growth is detected, then the sterile preparation process must be evaluated, corrective action taken, and the validation process repeated. Personnel competency must be revalidated at least every twelve months, whenever the quality assurance program yields an unacceptable result, when the compounding process changes, equipment used in the compounding of sterile injectable drug products is repaired or replaced, the facility is modified in a manner that affects airflow or traffic patterns, or whenever improper aseptic techniques are observed. Revalidation must be documented.

"(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.

"(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."

14. CCR, title 16, section 1735.3 provides:

"**Records of Compounded Drug Products.**

"(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.

"(b) Pharmacies shall maintain records of the proper acquisition, storage, and destruction of chemicals, bulk drug substances, drug products, and components used in compounding.

"(c) Chemicals, bulk drug substances, drug products, and components used to compound drug products shall be obtained from reliable suppliers. The pharmacy shall acquire and retain any available certificates of purity or analysis for chemicals, bulk drug substances, drug products, and components used in compounding. Certificates of purity or analysis are not required for drug products that are approved by the Food and Drug Administration.

"(d) Pharmacies shall maintain and retain all records required by this article in the pharmacy in a readily retrievable form for at least three years from the date the record was created."

COSTS

15. 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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FIRST CAUSE FOR DISCIPLINE

(Unprofessional Conduct: Failure to Validate the Competency of Individuals Compounding Drugs)

16. Respondents are subject to disciplinary action under Code section 4301, subdivision (o), in that they failed to produce records of validation of the competency of each individual involved in the preparation of sterile injectable products in violation of CCR, title, 16, section 1751.7, subdivision (b), the circumstances are as follows:

17. On or about November 8, 2012, the Board's investigators performed an annual Licensed Sterile Compounding (LSC) inspection of Center Pharmacy, Inc., doing business as Fountain Valley Cancer Pharmacy. Respondent Horwitz was present during the inspection.

18. During the inspection, the Board's investigator requested records of training and demonstrated competency for performing sterile compounding. Respondents produced no records of compliance.

19. During the inspection, Respondent Horwitz advised the investigator that he as the only person at the pharmacy involved in compounding drugs. Respondent Horwitz demonstrated his method of performing a self-evaluation for aseptic technique to the inspector using Tryptic Soy Broth as the growth media, which was inconsistent with the methodology described in the pharmacy's policy and procedure. Respondents' policy and procedure read, "a practical test will be a demonstration of aseptic technique and performance of Q.T. Medical's PATT-2 test that involves aliquot manipulations of a test agent per manufacturer procedure."

SECOND CAUSE FOR DISCIPLINE

(Unprofessional Conduct: Failure to Maintain Complete Records of Compounded Drugs)

20. Respondents are subject to disciplinary action for unprofessional conduct under Code section 4301, subdivision (o), in that from November 4, 2010 to October 8, 2012, they failed to maintain complete records for 76 compounded drugs in violation of CCR, title 16, section 1735.3, subdivision (a)(6). The circumstances are set forth in paragraph 17, above, which is incorporated here by this reference, and include the following:

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21. On November 8, 2012, during the inspection of Respondent Center Pharmacy, Inc., the Board's inspector reviewed compounding logs which revealed: (1) numerous logs were incomplete, missing the manufacturer lot numbers and/or the expiration date of one or more ingredients; (2) the pharmacy compounded stock solutions from one or more non-sterile ingredients, and then used the stock solution in medications for more than one patient; and (3) although Respondents' compounding logs had a preprinted section for sterility testing, pyrogens testing and quarantine start and end dates, numerous stock solutions used in making batches did not undergo proper end product testing or quarantine prior to use. After this discovery, the inspector requested the Respondents' compounding logs for the last 3 years for any product that included a non-sterile ingredient.

22. From November 4, 2010 to October 8, 2012, every one of Respondents' compounding logs for Sterile Injectable Solutions showed one or more ingredients missing the manufacturer lot number and/or expiration date as follows:

Table 1[1]

Sterile Injectable Solution Compounded	Date Compounded	Pharmacy Lot #	Ingredient(s) Missing MFG Lot# and Exp. Date*	Exhibit 5 Page Number
Clonidine	03/21/2011	CLO110321	clonidine, Water PF INJ	1
Baclofen	02/13/2012	1362517120213	NaCl 0.9% PF	2
fentanyl citrate	09/20/2012	FEN120920	fentanyl, NaOH, sterile water	3
fentanyl Base/clonidine	01/02/2012	312780	fentanyl, clonidine, NaCl	4
morphine/bupivicaine/baclofen	02/23/2011	310905110211	baclofen	5
TriMix	08/12/2011	1335054110722B	papaverine, phentolamine, alprostadil, NaCl	6
TriMix	05/27/2011	1336642110527	papaverine, phentolamine, alprostadil	7
TriMix/atropine	04/15/2011	308590101104	phentolamine, alprostadil	8

[1] TriMix = Papaverine/Phentolamine/Alprostadil (PGE), MFG = manufacturer, EXP. = expiration, *unless otherwise noted in table.

Sterile Injectable Solution Compounded	Date Compounded	Pharmacy Lot #	Ingredient(s) Missing MFG Lot# and Exp. Date*	Exhibit 5 Page Number
TriMix	04/13/2011	312051110412	papaverine, phentolamine, alprostadil	9
TriMix	04/12/2011	307615110412	papaverine, phentolamine, alprostadil	10
TriMix/atropine	04/14/2011	308615110414	papaverine, phentolamine, alprostadil, atropine, NaCl	11
TriMix	05/24/2011	1336630052411	papaverine, phentolamine, alprostadil	12
TriMix	08/29/2011	1335054110722B	papaverine, phentolamine, alprostadil, NaCl	13
TriMix	07/11/2011	TM11072011	papaverine, phentolamine, alprostadil	14
TriMix/lidocaine	08/02/2011	311881110802	papaverine, phentolamine, alprostadil, lidocaine, NaCl	15
TriMix	06/01/2011	1336414110601	papaverine, phentolamine, alprostadil	16
TriMix	05/24/2011	13364141105	papaverine, phentolamine, alprostadil	17
TriMix	02/17/2011	310841110217	papaverine, alprostadil	18
TriMix	02/14/2011	TM110214	papaverine, phentolamine, alprostadil, NaCl	19
TriMix/lidocaine	10/28/2011	134356111028	alprostadil, NaCl 0.9	20
TriMix/atropine	10/31/2011	None	phentolamine, alprostadil	21
TriMix/lidocaine	10/07/2011	1343561111007	Alprostadil	22
TriMix	10/07/2011	1350091111007	Alprostadil	23
TriMix	10/19/2011	1350130111019	papaverine, phentolamine, alprostadil, water, NaCl	24
TriMix/lidocaine	10/25/2011	134356111025	papaverine, phentolamine, alprostadil, lidocaine, NaCl 23.4% and 0.9	25

Sterile Injectable Solution Compounded	Date Compounded	Pharmacy Lot #	Ingredient(s) Missing MFG Lot# and Exp. Date*	Exhibit 5 Page Number
TriMix/lidocaine	04/05/2011	311881110504	phentolamine, alprostadil	26
TriMix/lidocaine	12/16/2010	309418101213	alprostadil, NaCl	27
TriMix	02/08/2011	310598110208	phentolamine, alprostadil	28
TriMix	10/08/2012	1383190121008	papaverine, phentolamine, alprostadil	29
TriMix/lidocaine	07/24/2012	1376947120724	papaverine, phentolamine, alprostadil, lidocaine, water	30
TriMix	07/26/2012	1352550120725	papaverine, phentolamine, alprostadil, water	31
TriMix	08/20/2012	1354074120820	papaverine, phentolamine, alprostadil	32
TriMix/lidocaine	10/01/2012	1376947120724	alprostadil, lidocaine, water	33
TriMix/lidocaine	02/24/2012	1356206120224	papaverine, phentolamine, alprostadil, lidocaine, water	34
TriMix	09/11/2012	Tm3015120911	papaverine, phentolamine, alprostadil	35
TriMix	09/11/2012	1380978120911	Alprostadil	36
TriMix	02/21/2012	1336630052411	papaverine, phentolamine, alprostadil	37
TriMix	12/27/2011	1357336111227	Alprostadil	38
TriMix	03/20/2012	1335054120320	papaverine, phentolamine, alprostadil, NaCl	39
TriMix	09/27/2012	1380978120911	Alprostadil	40
TriMix	04/03/2012	1367493120403	papaverine, phentolamine, alprostadil	41
TriMix	03/02/2012	1364470120302	papaverine, phentolamine, alprostadil	42
TriMix	03/02/2012	1364470120302	papaverine, phentolamine, alprostadil	43
TriMix	04/10/2012	1367493120403	papaverine, phentolamine, alprostadil	44

Sterile Injectable Solution Compounded	Date Compounded	Pharmacy Lot #	Ingredient(s) Missing MFG Lot# and Exp. Date*	Exhibit 5 Page Number
TriMix	04/03/2012	1367493120403	papaverine, phentolamine, alprostadil	45
TriMix	02/07/2012	1362088120207	phentolamine, alprostadil	46
TriMix	04/23/2012	1369116120423	Alprostadil	47
papaverine/alprostadil	12/10/2010	309411101210	NaCl, papaverine* missing either lot or exp. Date	49
TriMix	11/11/2010	308615101105	Water	50
TriMix	12/02/2011	1336646111202	Alprostadil	51
TriMix	11/08/2011	1353269110811	Alprostadil	52
TriMix	12/13/2011	1356304111212	papaverine, phentolamine, alprostadil	53
TriMix	06/12/2012	1373547120612	papaverine, phentolamine, alprostadil	54
TriMix	06/12/2012	1373507120612	papaverine, alprostadil. Phentolamine* missing only exp. Date	55
Alprostadil	06/02/2011	1337696110602	alprostadil, NaCl	56
Alprostadil	06/01/2011	CLA110601	alprostadil, NaCl	57
Alprostadil	05/19/2011	Alp11059	alprostadil, NaCl	58
Alprostadil	05/19/2011	1336315110519	alprostadil, NaCl	59
Alprostadil	11/15/2011	ALP111511	Alcohol	60
Alprostadil	05/14/2012	1361733120514	alprostadil, NaCl	61
Alprostadil	11/04/2010	ALP101104	alprostadil, NaCl	62
Alprostadil	08/09/2012	1361733120809	alprostadil, NaCl	63
Alprostadil	08/09/2012	1378247	alprostadil, NaCl	64
Alprostadil	07/03/2012	1375418120703	alprostadil, NaCl	65
Alprostadil	05/24/2012	1337486120524	alprostadil, NaCl	66
Alprostadil	02/03/2012	1361733120203	alprostadil, NaCl	67
Alprostadil	12/23/2011	1357425122311	alprostadil, NaCl	68
Alprostadil	12/02/2011	1337486110819	alprostadil, NaCl	69

Sterile Injectable Solution Compounded	Date Compounded	Pharmacy Lot #	Ingredient(s) Missing MFG Lot# and Exp. Date*	Exhibit 5 Page Number
Alprostadil	10/28/2011	1352463111028	alprostadil, NaCl	70
Alprostadil	10/28/2011	1337696111028	alprostadil, NaCl	71
Alprostadil	09/22/2011	1337696110922	alprostadil, NaCl	72
Alprostadil	07/05/2011	1340648110705	alprostadil, NaCl	73
Alprostadil	07/01/2011	Alp110701	alprostadil, NaCl	74
Alprostadil	06/06/2011	1337898110606	alprostadil, NaCl	75
TriMix/atropine	08/12/2011	1344326110809	alprostadil, NaCl	76

THIRD CAUSE FOR DISCIPLINE

(Failure to Document End Product Testing of Compounded Drugs and to Maintain Compounded Drugs in Quarantine until End Product Testing)

23. Respondents are subject to disciplinary action for unprofessional conduct under Code section 4301, subdivision (o), in that from September 7, 2010 to December 9, 2012, he failed to document end product testing for 58 batch-produced sterile injectable drug products compounded from one or more non-sterile ingredients, and failed to maintain them in quarantine until the end product testing confirmed sterility and acceptable levels of pyrogens in violation of CCR, title 16, section 1751.7, subdivision (c). The circumstances are set forth in paragraph 17, above, which is incorporated here by this reference and includes the following:

24. After collecting records on the day of the inspection, the inspector reviewed the compounding logs and compiled a list of compounds where a stock solution was used in compounding for multiple patients. For some compounds, the compounding log for the stock solution was available and showed no end product testing or quarantine was performed to determine sterility and acceptable levels of pyrogens. For other compounds, the compounding log for the stock solution was unavailable; therefore proof of end product testing and quarantine was unavailable. The following table shows compounded medications which used a stock solution for at least one of its ingredients. These products are considered batch-produced sterile

injectable drug products. For each of the stock solutions listed, the compounding log showed no evidence of end product testing.

Table 2[2]

Sterile Injectable Solution Compounded	Date Compounded	Pharmacy Lot #	Made from Stock Sol. Lot #	Stock Sol. tested for sterility or pyrogens?	Stock Sol. Cmpd Log Available?	Exhibit 6: Page Numbers
Alprostadil	08/09/2011	1337486110819	ALP110722	No	Yes	1
Alprostadil	08/25/2011	1345856110825	ALP110722	No	Yes	2
Alprostadil	11/11/2011	ALP111111	ALP110722	No	Yes	3
Alprostadil	11/29/2011	1340639111129	ALP110722	No	Yes	4
TriMix	11/18/2011	1354074111811	ALP110722	No	Yes	5
TriMix	11/29/2011	1335054111129	ALP110722	No	Yes	6
Alprostadil STOCK	07/22/2011	ALP110722	STOCK	No	Yes	7
TriMix	11/29/2011	1335054111129	PHE110527	No	Yes	8
TriMix	11/18/2011	1354074111811	PHE110527	No	Yes	9
TriMix	11/08/2011	1353269110811	PHE110527	No	Yes	10
TriMix	12/02/2011	1336646111202	PHE110527	No	Yes	11
TriMix/Lidocaine	12/09/2011	134356111209	PHE110527	No	Yes	12
TriMix	10/04/2011	1335054111004	PHE110527	No	Yes	13
TriMix	10/07/2011	1350091111007	PHE110527	No	Yes	14
TriMix/Lidocaine	10/07/2011	1343561111007	PHE110527	No	Yes	15
TriMix/Lidocaine	10/28/2011	134356111028	PHE110527	No	Yes	16
TriMix	08/12/2011	1344291110812	PHE110527	No	Yes	17
Phentolamine STOCK	05/27/2011	PHE110527	STOCK	No	Yes	18+19
TriMix	12/27/2011	1357336111227	PHE122711	?	No	20
TriMix	01/23/2012	1335054120123	PHE122711	?	No	21
Morphine	06/25/2010	305341100625	MOR100604	?	No	22
Morphine	06/25/2010	305340100625	MOR100604	?	No	23
Morphine/Clonidine	09/08/2010	307131	MOR100907	No	Yes	24
Morphine/Clonidine	09/08/2010	307111	MOR100907	No	Yes	25
Morphine	09/08/2010	307109100907	MOR100907	No	Yes	26
Morphine	09/08/2010	307110	MOR100907	No	Yes	27
Morphine STOCK	09/08/2010	MOR100907	STOCK	No	Yes	28
Morphine	04/29/2011	312359110429	MOR110429	No	Yes	29
Morphine	04/29/2011	312360110429	MOR110429	No	Yes	30
Morphine STOCK	04/29/2011	MOR110429	Stock	No	Yes	31

[2] TriMix=Papaverine/Phentolamine/Alprostadil(PGE), ?= unknown since no compounding log as available. The color highlighting is used to show where stock compounds were used.

Sterile Injectable Solution Compounded	Date Compounded	Pharmacy Lot #	Made from Stock Sol. Lot #	Stock Sol. tested for sterility or pyrogens?	Stock Sol. Cmpd Log Available?	Exhibit 6: Page Numbers
Fentanyl	09/23/2010	307555100923	FEN100923	No	Yes	32
Fentanyl	09/23/2010	307566100923	FEN100923	No	Yes	33
Fentanyl STOCK	09/23/2010	FEN100923	STOCK	No	Yes	34
Baclofen	07/05/2012	312823	BAC120622	No	Yes	35
Baclofen	06/22/2012	312821	BAC120622	No	Yes	36
Baclofen STOCK	06/22/2012	BAC120622	STOCK	No	Yes	37
Baclofen	12/27/2010	309686	BAC101227	No	Yes	38
Baclofen	02/07/2011	310399110207	BAC101227	No	Yes	39
Baclofen STOCK	12/27/2010	BAC101227	STOCK	No	Yes	40
Baclofen	09/08/2010	307133	BAC100823	?	No	41
Baclofen	09/08/2010	307132	BAC100823	?	No	42
Baclofen	09/07/2010	307107100907	BAC100823	?	No	43
Baclofen	09/13/2010	307233	BAC100823	?	No	44
Alprostadil	04/13/2011	305593110412	ALP110201	No	Yes	45
Alprostadil	03/29/2011	310829110329	ALP110201	No	Yes	46
Alprostadil	03/25/2011	311623110325	ALP110201	No	Yes	47
Alprostadil	03/25/2011	305005110325	ALP110201	No	Yes	48
Alprostadil	03/07/2011	310313110307	ALP110201	No	Yes	49
Alprostadil STOCK	02/28/2011	ALP110201	STOCK	No	Yes	50
Alprostadil	09/22/2010	304450100820	ALP100604	?	No	51
Alprostadil	02/01/2011	305005110201	ALP100604	?	No	52
Alprostadil	01/25/2011	310313110125	ALP100604	?	No	53
Alprostadil	02/16/2011	ALP110216	ALP100604	?	No	54
Alprostadil	11/24/2010	ALP101124	ALP100604	?	No	55
Alprostadil	11/17/2010	ALP101117	ALP100604	?	No	56
TriMix	10/12/2010	PPPT101012	ALP100604/ PHE100702	?	No	57
TriMix	11/01/2010	308469101101	ALP100604/ PHE100702	?	No	58
TriMix/Atropine	11/17/2010	308907101117	ALP100604/ PHE100702	?	No	59
Papaverine/PGE1	12/10/2010	309411101210	ALP100604	?	No	60
TriMix	01/07/2011	307615110107	ALP100604	?	No	61
TriMix	02/01/2011	305112110131	ALP100604	?	No	62
TriMix	11/11/2010	308615101105	PHE100702	?	No	63
TriMix	01/07/2011	307615110107	PHE101216	No	Yes	64
TriMix	02/08/2011	310598110208	PHE101216	No	Yes	65
TriMix/Lidocaine	12/16/2010	309418101213	PHE101216	No	Yes	66
TriMix/Atropine	01/27/2011	308615110127	PHE101216	No	Yes	67
Phentolamine STOCK	12/16/2010	PHE101216	STOCK	No	Yes	68+69

FOURTH CAUSE FOR DISCIPLINE

(Unprofessional Conduct: Selling, Holding or Offering for Sale Adulterated Drugs)

25. Respondents are subject to disciplinary action under section 4301, subdivision (j), in that from September 7, 2010 to July 5, 2012, Respondents sold, held, or offered for sale 58

dangerous drugs that Respondent Horwitz knew or should have known were adulterated as defined in Health and Safety Code section 111255, in violation of Code section 4169, subdivision (a). The circumstances are set forth in paragraphs 17 and 23-24, above, which are incorporated here by this reference and include the following:

26. Without proper documentation for end product testing, there was no evidence to support the safe use of the stock compounds listed in Table 2. The final product issued to patients may have been rendered injurious to health.

DISCIPLINARY CONSIDERATIONS

27. On or about February 23, 2012, Respondents were issued a Letter of Admonishment by the Board pursuant to Code sections 4005 and 4315, et seq. for the failure to comply with laws and regulations that govern the practice of pharmacy in California. The circumstances are as follows: on July 22, 2011, Respondent Horwitz, while Pharmacist-In-Charge of Center Pharmacy, Inc., doing business as Fountain Valley Medical Center Pharmacy located at 11100 Warner Avenue in Fountain Valley, California, did not have certain dangerous drugs in stock, ordered them from Mckesson, a wholesaler and resold them to Priority Pharmaceutical located at 4040 Sorrento Valley Blvd., Suite D, San Diego, Ca 92121. Fountain Valley Medical Center Pharmacy did not have independent knowledge of any temporary shortage. Fountain Valley Medical Center Pharmacy depended on Priority Pharmaceutical to identify the shortages, know what quantity of dangerous drugs was needed to alleviate specific shortages, if a temporary shortage actually existed, or if lack of the drug would result in a denial of health care, thus increasing the shortage. Respondents did not contest the Letter of Admonishment.

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 Pharmacy Permit Number PHY 43274 issued to Center Pharmacy, Inc., doing business as Fountain Valley Cancer Center Pharmacy.

2. Revoking or suspending Sterile Compounding Permit Number LSC 99020 issued to Center Pharmacy, Inc., doing business as Fountain Valley Cancer Center Pharmacy;

3. Revoking or suspending Pharmacy License Number RPH 40786 issued to Respondent Horwitz;

4. Ordering Marc L. Horwitz to pay the Board 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: 8/9/13

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