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

In the Matter of the First Amended Accusation Against: **ADVANCED PHYSICIAN SOLUTIONS, INC. Dba ADVANCED COMPOUNDING PHARMACY** 7225 Fulton Ave. North Hollywood, CA 91605 Pharmacy Permit No. PHY 48591 Permit to Compound Injectable Sterile Drug Products No. LSC 99426, and **TOORAJ BERELIANI** 7225 Fulton Ave. North Hollywood, CA 91605 Pharmacist License No. RPH 51817 Respondent.	Case No. 3251 **STIPULATED SETTLEMENT AND DISCIPLINARY ORDER AS TO TOORAJ BERELIANI ONLY**

DECISION AND ORDER

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

This decision shall become effective on December 21, 2011.

It is so ORDERED on November 21, 2011.

BOARD OF PHARMACY
DEPARTMENT OF CONSUMER AFFAIRS
STATE OF CALIFORNIA

By _____

STANLEY C. WEISSER
Board President

KAMALA D. HARRIS
Attorney General of California
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BEFORE THE
BOARD OF PHARMACY
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In the Matter of the First Amended Accusation Against: **ADVANCED PHYSICIAN SOLUTIONS, INC. dba ADVANCED COMPOUNDING PHARMACY** 7225 Fulton Ave. North Hollywood, CA 91605 Pharmacy Permit No. PHY 48591 Permit to Compound Injectable Sterile Drug Products No. LSC 99426, and **TOORAJ BERELIANI** 7225 Fulton Ave. North Hollywood, CA 91605 Pharmacist License No. RPH 51817 Respondents.	Case No. 3251 OAH No. L-2010031804 **STIPULATED SETTLEMENT AND DISCIPLINARY ORDER AS TO TOORAJ BERELIANI ONLY**

IT IS HEREBY STIPULATED AND AGREED by and between Complainant and Tooraj Bereliani 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 Heather Hua, Deputy Attorney General.

2. Tooraj Bereliani (Respondent Bereliani) is represented in this proceeding by attorney Noah Jussim, whose address is: 1800 Century Park East, 8th Floor, Los Angeles, CA. 90067.

3. On or about August 30, 2000, the Board of Pharmacy issued Pharmacist License Number RPH 51817 to Tooraj Bereliani. The Pharmacist License was in full force and effect at all times relevant to the charges brought herein and will expire on July 31, 2012, unless renewed.

JURISDICTION

4. Accusation No. 3251 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 27, 2010. Respondent timely filed its Notice of Defense contesting the Accusation. Subsequently, a First Amended Accusation was served on September 14, 2010. A copy of the First Amended Accusation No. 3251 is attached as Exhibit A and incorporated herein by reference.

This disciplinary action will also include any pending charges based on Board inspections of Respondent premises on March 9, 2011 and June 30, 2011.

ADVISEMENT AND WAIVERS

5. Respondent has carefully read, fully discussed with counsel, and understands the charges and allegations in Accusation No. 3251. Respondent has also carefully read, fully discussed with counsel, and understands the effects of this Stipulated Settlement and Disciplinary Order.

6. Respondent 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 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 his 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.

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

CULPABILITY

8. Respondent, by his authorized representative, admits that if the truth of each and every charge and allegation of the First Amended Accusation No. 3251 were established, cause would exist for discipline against Respondent's pharmacy license. For the purpose of resolving the First Amended Accusation without the expense and uncertainty of further proceedings, Respondent hereby gives up his right to contest the causes for discipline of the First Amended Accusation.

9. Respondent agrees that his pharmacist license is subject to discipline and he agrees to be bound by the Board of Pharmacy (Board)'s probationary terms as set forth in the Disciplinary Order below.

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 settlement, without notice to or participation by Respondent or his counsel. By signing the stipulation, Respondent understands and agrees that he may not withdraw the 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.

11. The parties understand and agree that facsimile copies of this Stipulated Settlement and Disciplinary Order, including facsimile signatures thereto, shall have the same force and effect as the originals.

12. 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.

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 Disciplinary Order:

DISCIPLINARY ORDER

IT IS HEREBY ORDERED that Pharmacist License No. RPH 51817 issued to Respondent is revoked. However, the revocation is stayed and Respondent is placed on probation for five (5) years on the following terms and conditions.

1. **Suspension**

As part of probation, Respondent is suspended from the practice of pharmacy for one hundred days (100) beginning the effective date of this decision.

During suspension, Respondent shall not enter any pharmacy area or any portion of the licensed premises of a wholesaler, veterinary food-animal drug retailer or any other distributor of drugs which is licensed by the Board, or any manufacturer, or where dangerous drugs and devices or controlled substances are maintained. Respondent shall not practice pharmacy nor do any act involving drug selection, selection of stock, manufacturing, compounding, dispensing or patient consultation; nor shall Respondent manage, administer, or be a consultant to any licensee of the Board, or have access to or control the ordering, manufacturing or dispensing of dangerous drugs and devices or controlled substances.

Respondent shall not engage in any activity that requires the professional judgment of a pharmacist. Respondent shall not direct or control any aspect of the practice of pharmacy. Respondent shall not perform the duties of a pharmacy technician or a designated representative for any entity licensed by the Board.

Subject to the above restrictions, respondent may continue to own or hold an interest in any licensed premises in which they holds an interest at the time this decision becomes effective unless otherwise specified in this order.

Failure to comply with this suspension shall be considered a violation of probation.

2. **Obey All Laws**

Respondent shall obey all state and federal laws and regulations.

Respondent shall report any of the following occurrences to the Board, in writing, within seventy-two (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 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.

3. **Report to the Board**

Respondent 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.

4. **Interview with the Board**

Upon receipt of reasonable prior notice, Respondent 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.

5. **Cooperate with Board Staff**

Respondent 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 their probation. Failure to cooperate shall be considered a violation of probation.

6. **Continuing Education**

Respondent shall provide evidence of efforts to maintain skill and knowledge as a pharmacist as directed by the Board or its designee.

7. **Notice to Employers**

During the period of probation, Respondent shall notify all present and prospective employers of the decision in case number 3251 and the terms, conditions and restrictions imposed on Respondent by the decision, as follows:

Within thirty (30) days of the effective date of this decision, and within fifteen (15) days of Respondent undertaking any new employment, Respondent shall cause their direct supervisor, pharmacist-in-charge (including each new pharmacist-in-charge employed during Respondent'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 3251, and terms and conditions imposed thereby. It shall be Respondent's responsibility to ensure that his employer(s) and/or supervisor(s) submit timely acknowledgment(s) to the Board.

If Respondent works for or is employed by or through a pharmacy employment service, Respondent 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 3251 in advance of Respondent commencing work at each licensed entity. A record of this notification must be provided to the Board upon request.

Furthermore, within thirty (30) days of the effective date of this decision, and within fifteen (15) days of Respondent undertaking any new employment by or through a pharmacy

employment service, Respondent shall cause their direct supervisor with the pharmacy employment service to report to the Board in writing acknowledging that they has read the decision in case number 3251 and the terms and conditions imposed thereby. It shall be Respondent'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.

8. **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.

9. **Reimbursement of Board Costs**

As a condition precedent to successful completion of probation, Respondent shall pay to the Board its costs of investigation and prosecution in the amount of one thousand one hundred forty-seven dollars ($1,147). Respondent shall coordinate a payment schedule with the Board.

There shall be no deviation from this schedule absent prior written approval by the Board or its designee. Failure to pay costs by the deadline(s) as directed shall be considered a violation of probation.

The filing of bankruptcy by Respondent shall not relieve Respondent of their responsibility to reimburse the Board its costs of investigation and prosecution.

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10. **Probation Monitoring Costs**

Respondent 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.

11. **Status of License**

Respondent 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'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 shall be subject to all terms and conditions of this probation not previously satisfied.

12. **License Surrender While on Probation/Suspension**

Following the effective date of this decision, should Respondent cease practice due to retirement or health, or be otherwise unable to satisfy the terms and conditions of probation, respondent may tender their 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 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's license history with the Board.

Upon acceptance of the surrender, Respondent shall relinquish their pocket and wall license to the Board within ten (10) days of notification by the Board that the surrender is accepted. Respondent may not reapply for any license from the Board for three (3) years from the effective date of the surrender. Respondent 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.

13. **Notification of a Change in Name, Residence Address, Mailing Address or Employment**

Respondent shall notify the Board in writing within ten (10) 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 shall further notify the Board in writing within ten (10) 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.

14. **Tolling of Probation**

Except during periods of suspension, Respondent shall, at all times while on probation, be employed as a pharmacist in California for a minimum of forty (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 must nonetheless comply with all terms and conditions of probation.

Should Respondent, regardless of residency, for any reason (including vacation) cease practicing as a pharmacist for a minimum of forty (40) hours per calendar month in California, Respondent must notify the Board in writing within ten (10) days of the cessation of practice, and must further notify the Board in writing within ten (10) 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's probation to remain tolled pursuant to the provisions of this condition for a total period, counting consecutive and non-consecutive months, exceeding thirty-six (36) months.

"Cessation of practice" means any calendar month during which respondent is not practicing as a pharmacist for at least forty (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 forty (40) hours as a pharmacist as defined by Business and Professions Code section 4000 et seq

15. **Violation of Probation**

If Respondent has not complied with any term or condition of probation, the Board shall have continuing jurisdiction over Respondent, 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 violates probation in any respect, the Board, after giving Respondent 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 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.

16. **Completion of Probation**

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

17. **Restricted Practice**

Respondent shall not prepare, oversee or participate in the preparation of injectable sterile products during the first year of probation, or until he completes thirty (30) hours of mandatory education approved by the Board in compounding drugs. 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.

18. **Community Services Program**

Within sixty (60) days of the effective date of this decision, Respondent shall submit to the Board or its designee, for prior approval, a community service program in which Respondent shall provide free health-care related services on a regular basis to a community or charitable facility or agency for at least 250 hours over the term of the probation period. Within thirty (30) days of Board approval thereof, Respondent shall submit documentation to the Board demonstrating commencement of the community service program. A record of this notification must be provided to the Board upon request. Respondent shall report on progress with the community service program in the quarterly reports. Failure to timely submit, commence, or comply with the program shall be considered a violation of probation.

19. **No New Ownership of Licensed Premises**

Respondent shall not acquire any new ownership, legal or beneficial interest nor serve as a manager, administrator, member, officer, director, trustee, associate, or partner of any additional business, firm, partnership, or corporation licensed by the board. If Respondent currently owns or has any legal or beneficial interest in, or serves 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 may continue to serve in such capacity or hold that interest, but only to the extent of that position or interest as of the effective date of this decision. Violation of this restriction shall be considered a violation of probation.

20. **Ethics Course**

Within sixty (60) calendar days of the effective date of this decision, Respondent shall enroll in a course in ethics, at Respondent's expense, approved in advance by the Board or its designee. Failure to initiate the course during the first year of probation, and complete it within the second year of probation, is a violation of probation.

Respondent shall submit a certificate of completion to the Board or its designee within five days after completing such course.

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21. **Tolling of Suspension**

During the period of suspension, Respondent shall not leave California for any period exceeding ten (10) days, regardless of purpose (including vacation). Any such absence in excess of the (10) days during suspension shall be considered a violation of probation. Moreover, any absence from California during the period of suspension exceeding ten (10) days shall toll the suspension, i.e., the suspension shall be extended by one day for each day over ten (10) days Respondent is absent from California. During any such period of tolling of suspension, Respondent must nonetheless comply with all terms and conditions of probation.

Respondent must notify the Board in writing within ten (10) days of departure, and must further notify the Board in writing within ten (10) days of return. The failure to provide such notification(s) shall constitute a violation of probation. Upon such departure and return, Respondent shall not resume the practice of pharmacy until notified by the Board that the period of suspension has been satisfactorily completed.

ACCEPTANCE

I have carefully read the above Stipulated Settlement and Disciplinary Order and have fully discussed it with my attorney, Noah Jussim. I understand the stipulation and the effect it will have on 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: _____ Signature page attached

TOORAJ BERELIANI
Respondent

I have read and fully discussed with Respondent Tooraj Bereliani the terms and conditions and other matters contained in the above Stipulated Settlement and Disciplinary Order. I approve its form and content.

DATED: _____ Signature page attached
NOAH JUSSIM
Attorney for Respondent

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: _____

Respectfully submitted,

KAMALA D. HARRIS
Attorney General of California
GREGORY SALUTE
Supervising Deputy Attorney General

HEATHER HUA
Deputy Attorney General
Attorneys for Complainant

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21. **Tolling of Suspension**

During the period of suspension, Respondent shall not leave California for any period exceeding ten (10) days, regardless of purpose (including vacation). Any such absence in excess of the (10) days during suspension shall be considered a violation of probation. Moreover, any absence from California during the period of suspension exceeding ten (10) days shall toll the suspension, i.e., the suspension shall be extended by one day for each day over ten (10) days Respondent is absent from California. During any such period of tolling of suspension, Respondent must nonetheless comply with all terms and conditions of probation.

Respondent must notify the Board in writing within ten (10) days of departure, and must further notify the Board in writing within ten (10) days of return. The failure to provide such notification(s) shall constitute a violation of probation. Upon such departure and return, Respondent shall not resume the practice of pharmacy until notified by the Board that the period of suspension has been satisfactorily completed.

ACCEPTANCE

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DATED: 9/7/11

TOORAJ BERELIANI
Respondent

I have read and fully discussed with Respondent Tooraj Bereliani the terms and conditions and other matters contained in the above Stipulated Settlement and Disciplinary Order. I approve its form and content.

DATED: 9/7/11

NOAH JUSSIM
Attorney for Respondent

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: September 7, 2011

Respectfully submitted,

KAMALA D. HARRIS
Attorney General of California
GREGORY SALUTE
Supervising Deputy Attorney General

HEATHER HUA
Deputy Attorney General
Attorneys for Complainant

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Exhibit A

First Amended Accusation No. 3251

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BEFORE THE
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In the Matter of the Accusation Against: **ADVANCED PHYSICIAN SOLUTIONS, INC. dba ADVANCED COMPOUNDING PHARMACY** 7225 Fulton Ave. North Hollywood, CA 91605 Pharmacy Permit No. PHY 48591 Permit to Compound Injectable Sterile Drug Products No. LSC 99426, and **TOORAJ BERELIANI** Pharmacist-in-charge 7225 Fulton Ave. North Hollywood, CA 91605 Pharmacist License No. RPH 51817 Respondents.	Case No. 3251 **FIRST AMENDED** **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 April 26, 2007, the Board of Pharmacy issued Pharmacy Permit Number PHY 48591 to Advanced Physician Solutions, Inc. dba Advanced Compounding Pharmacy (Respondent Advanced Compounding). The Pharmacy Permit was in full force and effect at all times relevant to the charges brought herein and will expire on April 1, 2011, unless renewed.

3. On or about July 3, 2007, the Board of Pharmacy issued a Permit to Compound Injectable Sterile Drug Products Number LSC 99426 to Respondent Advanced Compounding. The Permit to Compound Injectable Sterile Drug Products was in full force and effect at all times relevant to the charges brought herein and will expire on April 1, 2011, unless renewed.

4. On or about August 30, 2000, the Board of Pharmacy issued Pharmacist License Number RPH 51817 to Tooraj Bereliani, Pharmacist-in-Charge (Respondent Bereliani). The Pharmacist License was in full force and effect at all times relevant to the charges brought herein and will expire on July 31, 2012, unless renewed.

JURISDICTION

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

6. Section 118, subdivision (b), of the Code provides that the suspension, expiration, surrender, or cancellation of a license shall not deprive the Board of jurisdiction to proceed with a disciplinary action during the period within which the license may be renewed, restored, reissued or reinstated.

7. Section 4026 of the Code states as follows:

"Furnish" means to supply by any means, by sale or otherwise.

8. Section 4076 of the Code states, in part, as follows:

"(a) A pharmacist shall not dispense any prescription except in a container that meets the requirements of state and federal law and is correctly labeled with all of the following:

. . .

(7) The strength of the drug or drugs dispensed.

. . .

(9) The expiration date of the effectiveness of the drug dispensed. . . ."

9. Section 4077 of the Code states, in pertinent part, that except as provided in subdivisions (b) and (c) of this section, no person shall dispense any dangerous drug upon prescription except in a container correctly labeled with the information required by Section 4076.

10. Section 4081 of the Code states, in part:

"(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 a pharmacy, wholesaler, . . . shall be jointly responsible, with the pharmacist-in-charge or representative-in-charge, for maintaining the records and inventory described in this section. . . ."

11. Section 4113, subdivision (b) of the Code states:

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

12. Code section 4126.5, subdivision (a), provides:

"(a) A pharmacy may furnish dangerous drugs only to the following:

(1) A wholesaler owned or under common control by the wholesaler from whom the dangerous drug was acquired.

(2) The pharmaceutical manufacturer from whom the dangerous drug was acquired.

(3) A licensed wholesaler acting as a reverse distributor.

(4) Another pharmacy or wholesaler to alleviate a temporary shortage of a dangerous drug that could result in the denial of health care. A pharmacy furnishing dangerous drugs pursuant to this paragraph may only furnish a quantity sufficient to alleviate the temporary shortage.

(5) A patient or to another pharmacy pursuant to a prescription or as otherwise authorized by law.

(6) A health care provider that is not a pharmacy but that is authorized to purchase dangerous drugs.

(7) To another pharmacy under common control."

13. Section 4169 of the Code states:

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

...

(3) Purchase, trade, sell, or transfer dangerous drugs that the person knew or reasonably should have known were misbranded, as defined in Section 111335 of the Health and Safety Code."

14. Section 4300 of the Code states, in pertinent part, that every license issued by the Board is subject to discipline, including suspension or revocation.

15. Section 4301 of the Code states, in part, as follows:

"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:

(g) Knowingly making or signing any certificate or other document that falsely represents the existence or nonexistence of a state of facts.

...

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

...

(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. . . ."

16. Section 4306.5 of the Code states, in part, as follows:

"Unprofessional conduct for a pharmacist may include any of the following:

(a) Acts or omissions that involve, in whole or in part, the inappropriate exercise of his or her education, training, or experience as a pharmacist, whether or not the act or omission arises in the course of the practice of pharmacy or the ownership, management, administration, or operation of a pharmacy or other entity licensed by the board."

...

17. Section 4328 of the Code states;

"Except as otherwise provided in this chapter, any person who permits the compounding or dispensing of prescriptions, or the furnishing of dangerous drugs in his or her pharmacy, except by a pharmacist, is guilty of a misdemeanor."

18. Section 4342 of the Code states:

"(a) The board may institute any action or actions as may be provided by law and that, in its discretion, are necessary, to prevent the sale of pharmaceutical preparations and drugs that do not conform to the standard and tests as to quality and strength, provided in the latest edition of the United States Pharmacopoeia or the National Formulary, or that violate any provision of the Sherman Food, Drug and Cosmetic Law (Part 5 (commencing with Section 109875) of Division 104 of the Health and Safety Code).

(b) Any knowing or willful violation of any regulation adopted pursuant to Section 4006 shall be subject to punishment in the same manner as is provided in Sections 4336 and 4321."

19. California Code of Regulations, Title 16, section 1751.02, subdivision (c), provides, in part, as follows:

"(c) 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:

...

(i) For sterile batch compounding, written policies and procedures must be established for the use of master formulas and work sheets and for appropriate documentation. . . ."

20. California Code of Regulations, Title 16, section 1751.3, subdivision (b), provides, in part:

"(b) In addition to the records required by subdivisions (a), for sterile products compounded from one or more non-sterile ingredients the following records must be maintained for at least three years:

. . .

(6) Preparation records including the master work sheet, the preparation work sheet, and records of end-product evaluation results. . . ."

21. California Code of Regulations, Title 16, section 1716.2, provides, in pertinent part, as follows:

"(a) For the purpose of compounding in quantities larger than required for immediate dispensing by a prescriber or for future dispensing upon prescription, a pharmacy shall maintain records that include, but are not limited to:

. . .

(3) The expiration date of the finished product. This date must not exceed 180 days or the shortest expiration date of any component in the finished product unless a longer date is supported by stability studies in the same type of packaging as furnished to the prescriber. Shorter dating than set forth in this subsection may be used if it is deemed appropriate in the professional judgment of the responsible pharmacist.

(4) The signature or initials of the pharmacist performing the compounding.

(5) A formula for the compounded product. The formula must be maintained in a readily retrievable form. . . ."

22. California Code of Regulations, Title 16, section 1793.7, provides, in part:

"(a) Except as otherwise provided in section 1793.8, any function performed by a pharmacy technician in connection with the dispensing of a prescription, including repackaging from bulk

and storage of pharmaceuticals, must be verified and documented in writing by a pharmacist. Except for the preparation of prescriptions for an inpatient of a hospital and for an inmate of a facility, the pharmacist shall indicate verification of the prescription by initialing the presecription label before the medication is provided to the patient.

(b) Pharmacy technicians must work under the direct supervision of a pharmacist and in such a relationship that the supervising pharmacist is fully aware of all activities involved in the preparation and dispensing of medications, including the maintenance of appropriate records.

. . .

(e) A pharmacist shall be responsible for all activities of pharmacy technicians to ensure that all such activities are performed completely, safely and without risk of harm to patients. . . ."

23. California Code of Regulations, Title 16, section 1751.2, subdivision (b), provides:

"In addition to existing labeling requirements, a pharmacy which compounds sterile injectable products shall include the following information on the labels for those products:

. . .

(b) Name and concentrations of ingredients contained in the sterile injectable product. . . ."

COST RECOVERY

24. 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.

25. The classification for the dangerous drugs is listed below:

BRAND NAME	GENERIC NAME	DANGEROUS DRUG PER B & PC 4022	CONTROLLED SUBSTANCE PER H & SC	INDICATIONS FOR USE
Depo Provera	Medroxyprogesterone Acetate 150mg Susp	Yes	No	Contraceptive
Depo Testosterone	Testosterone Cyprionate Inj.	Yes	HSC 11056(f)(30)	Anabolic steroid /male sex hormone
Celestone	Betamethasone Sod. Phosphate Inj.	Yes	No	Antiinflammatory corticosteroid
Celestone Soluspan	Betamethasone Soluspan	Yes	No	Antiinflammatory corticosteroid

Depo Estradiol	Estradiol Cyprionate	Yes	No	HRT
Depo Medrol	Methylprednisolone Inj.	Yes	No	Antiinflammatory corticosteroid
Deca Durabolin	Nandrolone Decanoate Inj.	Yes	HSC 11056(f)(19)	Anabolic Steroid /male sex hormone
Unknown	Sodium Hydroxide Inj.	Yes	No	Unknown
Alprostadil	Prostaglandin PGE-1 Inj.	Yes	No	Used in Trimix for erectile dysfunction
Regitine	Phentolamine Inj.	Yes	No	Used in Trimix for erectile dysfunction
*Not FDA approved	*Polidocanol Inj.	*"Unapproved New Drug" Misbranded-Not Approved by FDA	No	Sclerotherapy
Prednisolone	Prednisolone Inj	Yes	No	Antiinflammatory corticosteroid
Progesterone	Progesterone in Oil Inj.	Yes	No	Progesterone replacement therapy
Sotradecol	Sodium Tetradecyl Sulfate Inj.	Yes	No	Vericose Vein therapy
Vitamin B-1	Thiamine Inj.	Yes	No	Vitamin B-1 deficiency
Kenolog Inj.	Triamincolone Acetonide Inj.	Yes	No	Antiinflammatory corticosteroid
Tri-Mix	PGE-1+ Papavarine + Phentolamine	Yes	No	Erectile Dysfunction
Depo Winstrol Inj	Depo Stanozolol	Yes	HSC 11056(f)(28)	Anabolic Steroid/ male sex hormone
Delestrogen	Estradiol Valerate Inj.	Yes	No	HRT
Healon or Hyaluronan	Hyaluronic Acid Inj.	Yes	No	Joint & skin repair, eye surgery
Wyadase	Hyaluronidase Inj.	Yes	No	Enzyme to help absorb medications
17-P	Hydroxyprogesterone Caproate Inj.	Yes	No	Preventing Pre-term Births
Xylocaine	Lidocaine PF Inj.	Yes	No	Numbing Agent
Vitamin B12	Methylcobalamine	Yes	No	Vitamin B 12 deficiency
Celestone Soluspan	Betamethasone Soluspan	Yes	No	Injectable anti-inflammatory
Astamorph	Morphine	Yes	CII HSC 11055(b)(1)(M)	Severe pain
				Severe pain

Demerol	Meperidine	Yes	CII HSC 11055(c)(17)	
Dilaudid	Hydromorphone	Yes	CII HSC 11055(b)(1)(K)	Severe pain
Duragesic	Fentanyl	Yes	CII HSC 1111055(c)(8)	Severe pain
Ketalar	Ketamine	Yes	CIII HSC 11056(g)	General Anesthetics
Valium	Diazepam	Yes	CIV HSC 11057(d)(9)	Anxiety
Versed	Midazolam	Yes	CIV HSC 11057(d)(21)	Pre-operative sedation
Perocet	Oxycodone w/APAP	Yes	CII HSC 11055(b)	Severe pain
Cocaine Top. Soln.	Cocaine Topical Solution	Yes	CII HSC 11055(b)(6)	Topical Anesthetic
Vicodin	Hydrocodone w/APAP 5/500	Yes	CIII HSC 11056(e)	Moderate to severe pain

FIRST CAUSE FOR DISCIPLINE

(Manufacturing Drugs Sold Through Wholesaler)

[Respondents Advanced Compounding and Bereliani]

26. Respondents Advanced Compounding and Bereliani are subject to disciplinary action under Business and Professions Code Section 4033(a) in that Respondents were a manufacturer when they compounded drugs that were not sold to the ultimate consumer.

On June 19, 2008, during an investigation of Advanced Compounding Pharmacy, Board investigators found that Respondents' records showed they were manufacturing sterile injectable compounded drugs for customers that were brokered through wholesaler Superior Medical Supply, Inc. For instance, the drug [1] Medroxyprogesterone Acetate Suspension 150 mg/ml prefilled syringes were drop shipped from Respondents directly to clinics and doctors' offices. Respondents were paid by the wholesaler Superior Medical Supply, Inc. for the drop shipped drugs rather than by the clinics or doctors' offices as the ultimate consumers.

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[1] Medroxyprogesterone Acetate Suspension 150mg/ml prefilled syringes are the generic name for the commercially available drug Depo Provera 150mg/ml prefilled syringes. The drug is a long acting birth control drug injected every 12 weeks.

SECOND CAUSE FOR DISCIPLINE

(Furnishing of Controlled Substance through Unlicensed Wholesaler)

[Respondents Advanced Compounding and Bereliani]

27. Respondents Advanced Compounding and Bereliani are subject to disciplinary action under section 4301, subdivisions (j) and (o), in conjunction with Code section 4126.5, in that Respondents furnished controlled substances and compounded drugs, as defined in Title 21, Code of Federal Regulations, sections 1301.11 and 1301.13(a), to a wholesaler from whom the controlled substance was not acquired. The circumstances are as follows:

a) Between February 27, 2008 and August 4, 2008, Respondents had a verbal agreement to furnish orders from Superior Medical Supply (located in the State of Colorado) to Superior Medical Supply's customers for controlled substances and then to bill Superior Medical Supply for the purchase of the controlled substances. Superior Medical Supply was not authorized by the Drug Enforcement Administration to engage in the distribution of controlled substances.

b) The furnishing of the controlled substances occurred as follows: Schedule II, III, IV, and V controlled substances were ordered through Superior Medical Supply for their customers; the controlled substances were drop shipped by Respondents to Superior Medical Supply customers; Respondents billed Superior Medical Supply for the controlled substances; Superior Medical Supply paid the billed invoices from Respondents; Superior Medical Supply then invoiced their customers directly for the drop shipped controlled substances.

c) The controlled substances Respondents shipped to Superior Medical Supply's customers were controlled substances not originally acquired from Superior Medical Supply.

THIRD CAUSE FOR DISCIPLINE

(Failure to Maintain Written Policies and Procedures)

[Respondents Advanced Compounding and Bereliani]

28. Respondents Advanced Compounding and Bereliani are subject to disciplinary action under section 4301, subdivisions (j) and (o), in conjunction with Code section 4081, subdivisions (a) and (b) and California Code of Regulations, Title 16, section 1751.02(c)(3)(I), in that Respondents failed to maintain required written policies and procedures associated with the pharmacy's preparation and dispensing of sterile injectable products. The circumstances are as follows:

a) On June 19, 2008, Board investigators determined that Respondent Bereliani did not have written policies and procedures established for the use of a master formula, worksheets and documentation when compounding sterile batch injectable drugs from non-sterile ingredients.

FOURTH CAUSE FOR DISCIPLINE

(Failure to Maintain Preparation Records and/or Master Formulas)

[Respondents Advanced Compounding and Bereliani]

29. Respondents Advanced Compounding and Bereliani are subject to disciplinary action under section 4301, subdivisions (j) and (o), in conjunction with Code section 4081, subdivisions (a) and (b) and California Code of Regulations, Title 16, section 1751.3(b)(6), in that Respondents failed to maintain, for three years, the preparation records, including Master Formula worksheets, when compounding sterile products from one or more non-sterile ingredients. The circumstances are as follows:

a) On June 19, 2008, Board investigators found that Respondent Bereliani maintained only a few of the required Master Formula worksheets for the pharmacy's compounding of sterile injectable drugs from non-sterile ingredients.

b) On June 19, 2008, Board investigators found that preparation records for the compounding of sterile injectable drugs from non-sterile ingredients showed different expiration dates. For instance, Respondents placed a 180-day expiration date for sterile injectable drugs shipped in California, while Respondents placed a one-year expiration date for the same sterile injectable drugs shipped outside of California. Investigators reviewing preparation records determined that no master

formula was present to substantiate the differing expiration dates for the same sterile injectable drugs.

FIFTH CAUSE FOR DISCIPLINE

(Failure to Maintain Complete Compounding Records)

[Respondents Advanced Compounding and Bereliani]

30. Respondents Advanced Compounding and Bereliani are subject to disciplinary action under section 4301, subdivisions (j) and (o), in conjunction with Code section 4081, subdivisions (a) and (b) and California Code of Regulations, Title 16, section 1716.2, in that Respondents failed to maintain complete records required for compounding for future furnishing of drugs. The circumstances are as follows:

a) On June 19, 2008, Board investigators determined that Respondents, as a routine practice, labeled sterile injectable products with a 180-day expiration date for drugs shipped in California and a one-year expiration date for the same drugs shipped outside of California without a written justification for either expiration dates chosen in violation of Regulation section 1716.2(a)(3).

b) On June 19, 2008, Board investigators found that Respondent Bereliani, as a routine practice, failed to sign or initial the Logged Formula Worksheet records in violation of Regulation section 1716.2(a)(4).

c) On June 19, 2008, Board investigators found that no Master Formulas were available to substantiate a one year or 180-day expiration for the same product in violation of Regulation section 1716.2(a)(5).

SIXTH CAUSE FOR DISCIPLINE

(Failure to Document Supervision of Pharmacy Technician)

[Respondents Advanced Compounding and Bereliani]

31. Respondents Advanced Compounding and Bereliani are subject to disciplinary action under section 4301, subdivisions (j) and (o), in conjunction with Code section 4081, subdivisions (a) and (b) and California Code of Regulations, Title 16, section 1793.7(a), in that Respondents

failed to document supervision and verification of duties performed by the pharmacy technician. The circumstances are as follows:

a) On June 19, 2008, Board investigators determined that Respondent Bereliani, as a routine practice, failed to initial or document many of the Logged Formula Worksheet records verifying the supervision and duties performed by compounding pharmacy technician Zherair Aghakhan.

SEVENTH CAUSE FOR DISCIPLINE

(Misbranding of Drugs with False or Misleading Information)

[Respondents Advanced Compounding and Bereliani]

32. Respondents Advanced Compounding and Bereliani are subject to disciplinary action under section 4301, subdivisions (j) and (o), in conjunction with Code section 4076, subdivisions (a)(7) and (a)(9) and California Code of Regulations, Title 16, section 1751.2(b), in that Respondents misbranded and labeled drugs with false and misleading information. The circumstances are as follows:

a) On June 19, 2008 and June 24, 2008, Board investigators found that Respondents allowed the compounded drug Medroxyprogesterone Acetate 150mg/ml to be misbranded by falsely labeling the drug with the misleading label as either "Medroxy Progst PF (75/0.5mg) ml" or "Medroxy Proge (75/.5) 75/0.5mg."

b) On June 19, 2008 and June 24, 2008, Board investigators found that Respondents misbranded the prescription labels with false and misleading expiration dates as 180 days for drugs shipped in California and one year expiration date for drugs shipped outside of California for the same drugs.

EIGHTH CAUSE FOR DISCIPLINE

(Sale, Purchase, Trade, or Transfer of Misbranded Drugs)

[Respondents Advanced Compounding and Bereliani]

33. Respondents Advanced Compounding and Bereliani are subject to disciplinary action under section 4301, subdivisions (j) and (o), in conjunction with Code section 4169, subdivision (a)(3) and Health and Safety Code section 111335, in that Respondents purchased, traded, sold or

transferred dangerous drugs that they knew, or reasonably should have known were misbranded. The circumstances are as follows:

a) From on or about February 28, 2008 through on or about June 4, 2008, Respondents drop shipped to doctors and clinics Medroxyprogesterone 150mg/ml pre-filled syringes that were misbranded with false or misleading labels that read "Medroxy Progst PF (75/0.5mg) ml" or "Medroxy Proge (75/.5) 75/0.5mg" that were manufactured by Respondent Advanced Compounding. The drugs were further misbranded in that Respondents placed a 180-day expiration date for drugs shipped in California, while Respondents placed a one-year expiration date for the same drugs shipped outside of California.

NINTH CAUSE FOR DISCIPLINE

(Sale, Purchase, Trade, or Transfer of Misbranded Drugs)

[Respondents Advanced Compounding and Bereliani]

34. Respondents Advanced Compounding and Bereliani are subject to disciplinary action under section 4169, subdivisions (a) and (3), in conjunction with Code section 4342, and Health and Safety Code section 111330, in that Respondents purchased, traded, sold or transferred dangerous drugs that they knew, or reasonably should have known were misbranded. The circumstances are as follows:

a) Approximately on or after June 19, 2008, Respondents Advanced Compounding and Bereliani initiated a drug recall of all compounded injectable drugs whose labeled expiration dates on the finish products exceeded the expiration dates on the Master Formulas.

b) Respondent Bereliani identified on the pharmacy's Drug Recall Report a total of 1732 orders: 1,425 misbranded drug orders drop shipped to clinics and doctors' outside of California and 307 misbranded drug orders shipped to California clinics and doctors.

c) The Drug Recall Report identified the drug, the total quantity of drug ordered, and the number of orders shipped that contained the misbranded labeled expiration dates that were false and misleading.

d) Based on Respondents' Drug Recall Report the misbranded drugs shipped out of California to clinics and doctors' offices between the period of July 1, 2007 through June 30, 2008 included:

1. Medroxy Proges. Acetate 150mg/ml with total quantity of 50mls from 3 orders
2. Medroxy Progest. Acetate 150mg/ml with total quantity of 11,501mls from 283 orders
3. Medroxy Progst AcetatePF. 150mg/ml with total quantity of 2,033mls from 113 orders
4. Polidocanol 0.5% with total quantity of 780 from 9 orders
5. Polidocanol 0.75% with total quantity of 40mls from 2 orders
6. Polidocanol 1% with total quantity of 3,400mls from 15 orders
7. Polidocanol 2% with total quantity of 280mls from 7 orders
8. Polidocanol 3% with total quantity of 4,230mls from 42 orders
9. Polidocanol 5% with total quantity of 360mls from 4 orders
10. Sodium Tetrad 1% with total quantity of 1120 from 12 orders
11. Sodium Tetrad 2% with total quantity of 230mls from 2 orders
12. Sodium Tetrad 3% with total quantity of 1,110mls from 9 orders
13. Sodium Tetradecyl with total quantity of 1,070mls from 3 orders
14. Triamcinolone Inj. 40mg/ml with total quantity of 15,680mls from 131 orders
15. Methyl Prednisolone with total quantity of 15,365mls from 169 orders
16. Nandrolone Decanoate (all strengths) with total quantity of 1,030mls from 17 orders
17. Sodium Hyaluronate (all strengths) with total quantity of 2,498mls from 43 orders
18. Sodium Hyaluronic Inj with total quantity of 80mls from 2 orders
19. Betam Soluspan Inj 6mg/ml with total quantity of 11,382mls from 105 orders
20. Betamethesone 6mg/ml Inj Sol with total quantity of 340mls from 3 orders
21. Hydroxy Progesterone with total quantity of 30mls from 2 orders
21. HydroxyP4 Caproate 250mg/ml with total quantity of 450mls from 28 orders
22. Winstrol Cmpd with total quantity of 30mls from 1 order
23. Estradiol Cypionate with total quantity of 375mls from 9 orders
24. Estradiol Valerate (all strengths) with total quantity of 455mls from 15 orders
25. Hyaluronidase 150u/m with total quantity of 20mls from 2 orders
26. DMSO 50% Sol with total quantity of 8,050mls from 15 orders
27. Thiamin Inj with total quantity of 10mls from 1 order
28. Methyl Cobalamine (all strengths) with total quantity of 340mls from 6 orders
29. HydroxyP4 Caproate 250mg/ml with total quantity of 20mls from 1 order
30. Testosterone Cyp 200mg/ml Inj with total quantity of 32,005mls from 371 orders

e) The misbranded drugs drop shipped to California clinics and prescribers between January 1, 2008 to June 30, 2008 were:

1. Medroxy Progest. Acetate 150mg/ml with total quantity of 3,585mls from 60 orders
2. Medroxy Progst AcetatePF. 150mg/ml with total quantity of 401mls from 27 orders
3. PGE 1*** with total quantity of 20mls from 4 orders
4. Polidocanol 0.5% with total quantity of 330 from 5 orders
5. Polidocanol 0.75% with total quantity of 50mls from 1 order

6. Polidocanol 1% with total quantity of 610mls from 6 orders
7. Polidocanol 2% with total quantity of 260mls from 3 orders
8. Polidocanol 3% with total quantity of 520mls from 4 orders
9. Polidocanol 5% with total quantity of 120mls from 3 orders
10. Sodium Tetrad 0.125% with total quantity of 70mls from 3 orders
11. Sodium Tetrad 0.25% with total quantity of 60mls from 3orders
12. Sodium Tetrad 0.5% with total quantity of 30mls from 1 orders
13. Sodium Tetrad 1% with total quantity of 170 from 4 orders
14. Sodium Tetrad 2% with total quantity of 120mls from 4 orders
15. Sodium Tetrad 3% with total quantity of 170mls from 4 orders
16. Methyl Prednisolone with total quantity of 1,120mls from 21 orders
17. Triamcinolone Inj. 40mg/ml with total quantity of 3470mls from 43 orders
18. Nandrolone Decanoate (all strengths) with total quantity of 140mls from 7 orders
19. Sodium Hyaluronate (all strengths) with total quantity of 20mls from 1 order
20. Sodium Hyaluronic Inj with total quantity of 40mls from 4 orders
21. Betam Soluspan Inj 6mg/ml with total quantity of 195mls from 4 orders
22. Betamethesone 6mg/ml Inj Sol with total quantity of 5mls from 1 order
23. HydroxyP4 Caproate 250mg/ml with total quantity of 20mls from 1 order
24. Winstrol Cmpd. with total quantity of 40mls from 2 orders
25. Estradiol Cypionate with total quantity of 350mls from 8 orders
26. Hyaluronidase 150u/m with total quantity of 280mls from 9 orders
27. DMSO 50% Sol with total quantity of 500mls from 5 orders
28. Thiamine Inj. with total quantity of 120mls from 4 orders
29. Methyl Cobalamin (all strengths) with total quantity of 565mls from 13 orders
30. Testosterone Cyp. 200mg/ml Inj. with total quantity of 2,805mls from 52 orders

TENTH CAUSE FOR DISCIPLINE

(Unprofessional Conduct – Misuse of Knowledge of Pharmacy Law)

[Respondents Advanced Compounding and Bereliani]

35. Respondents Advanced Compounding and Bereliani are subject to disciplinary action under section 4306.5, subdivision (a), in that Respondent committed unprofessional conduct for acting or omitting that involve, in whole or in part, the inappropriate exercise of his education, training or experience as a pharmacist. The circumstances are as follows:

a) On February 14, 2008, Respondents failed to verify the accuracy of the Logged Formula Worksheet for Tri-Mix (Phen/PGE/PAPA) 1mg/20mcg/30mg/ml Injection which showed two ingredients were miscalculated and transposed so that patient R. Thorne received 3 times the dose of Phentolamine and 1/3 the dose of Prostaglandin (PGE) on his Tri-Mix Injection.

b) Additionally, Respondent Bereliani, as a routine practice, failed to document on the worksheet his supervision of the compounding pharmacy technician Zherair Aghakhan.

c) On May 1, 2007, Respondents incorrectly calculated his stock solution of 30cc-Phentolamine 50mg/ml stock solution under lot #05012007@3. The active drug Phentolamine Mesylate powder was incorrectly calculated at 500mg instead of 1500mg. This incorrectly compounded stock solution was then used to mix 6 TriMix preparations on the following dates:

1. December 10, 2007
2. February 6, 2008
3. February 14, 2008
4. February 27, 2008
5. February 27, 2008
6. February 27, 2008

d) Respondent Bereliani, on a routine practice, failed to check the lot numbers on the ingredients used, which showed that the Phentolamine stock solution made on May 1, 2007 had already expired.

ELEVENTH CAUSE FOR DISCIPLINE

(Unprofessional Conduct – Misrepresentation)

[Respondents Advanced Compounding and Bereliani]

36. Respondents Advanced Compounding and Bereliani are subject to disciplinary action under section 4301, subdivision (g), in that Respondents knowingly made or signed a certificate or other document that falsely represented the existence or nonexistence of a state of facts. The circumstances are as follows:

a) The word "Soluspan" is a registered trademark name of Schering-Plough's Celestone Soluspan 6mg/ml, which describes their brand of rapid and repository injectable. On June 19, 2008, Board investigators discovered that Respondents falsely represented the compounded product of "betamethasone suspension" by labeling it "Betam Soluspan Inj 6mg/ml" without authorization from Schering-Plough.

b) Respondents were not a member of the Pharmaceutical Compounding Centers of America (hereinafter PCCA) and were not authorized to copy their formulas without PCCA's permission. Though they had not been given permission by PCCA to reference their formulas, Respondents did so in at least 7 formulas sent to the Board as follows:

1. The Medroxyprogesterone Acetae (New) 150mg/ml referenced PCCA Formula 7404 but stated "This formula is a trade secret of ADVANCED PHARMACY".

2. The Medroxyprogesterone Acetae Suspension Vehic referenced PCCA Formula 7405 but stated "This formula is a trade secret of ADVANCED PHARMACY".
3. The MethylPrednisolone 40mg/ml Injectable referenced PCCA Formula 5678 but stated "This formula is a trade secret of ADVANCED PHARMACY".
4. The MethylPrednisolone 80mg Injectabl referenced PCCA Formula 5678 but stated "This formula is a trade secret of ADVANCED PHARMACY".
5. The Triamcinolone Acetonide 40mg/ml referenced PCCA Formula 4359 but stated "This formula is a trade secret of ADVANCED PHARMACY".
6. The Tri-Mix 0.5mg/5.88mcg/30mg Injectable referenced PCCA Formula 4338 but stated "This formula is a trade secret of ADVANCED PHARMACY".
7. The Testosterone Cypionate 200mg/ml Injectable referenced PCCA Formula 7719 but stated "This formula is a trade secret of ADVANCED PHARMACY".

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 48591, issued to Respondent Advanced Physician Solutions, Inc. dba Advanced Compounding Pharmacy.

2. Revoking or suspending Permit Number LSC 99426, issued to Respondent Advanced Physician Solutions, Inc. dba Advanced Compounding Pharmacy.

3. Revoking or suspending Pharmacist License Number RPH 51817, issued to Respondent Tooraj Bereliani, Pharmacist-in-Charge.

4. Ordering Respondents Advanced Physician Solutions, Inc. dba Advanced Compounding Pharmacy and Tooraj Bereliani to pay the Board of Pharmacy the reasonable costs of the investigation and enforcement of this case, pursuant to Business and Professions Code section 125.3.

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

DATED: 9/13/10

Virginia Herold

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