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

In the Matter of the Accusation Against: **ADVANCED PHYSICIAN SOLUTIONS, INC. dba ADVANCED COMPOUNDING PHARMACY** 7225 Fulton Avenue North Hollywood, CA 91605 Pharmacy Permit No. PHY 48591 Permit to Compound Injectable Sterile Drug Products No. LSC 99426 Respondent.	Case No. 3251 OAH No. 2012031804

DECISION

The attached Proposed Decision of the Administrative Law Judge is hereby adopted by the Board of Pharmacy as the decision in the above-entitled matter, except that, pursuant to the provisions of Government Code section 11517, subdivision (c)(2)(C), third paragraph of term #17 of the order appearing on page 25 of the Proposed Decision, is hereby modified for technical reasons as follows:

> During the first year of Respondent's probation, should any of the eleven Allowed Compounds become commercially available, Respondent may request of the Board or the Board's designee that Respondent be allowed to substitute a different, non-commercially available compounded drug product for that non-commercially available Allowed Compound.

The technical change made above does not affect the factual or legal basis of the Proposed Decision, which shall become effective on July8, 2013.

IT IS SO ORDERED this 7th day of June, 2013.

BOARD OF PHARMACY
DEPARTMENT OF CONSUMER AFFAIRS
STATE OF CALIFORNIA

By _____
STANLEY C. WEISSER
Board President

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

In the Matter of the Second Amended Accusation Against: ADVANCED PHYSICIAN SOLUTIONS, INC. dba ADVANCED COMPOUNDING PHARMACY, Pharmacy Permit No. PHY 48591 Permit to Compound Injectable Sterile Drug Products No. LSC 99426, Respondent.	Case No. 3251 OAH No. 2010031804

PROPOSED DECISION

This matter was heard by Erlinda G. Shrenger, Administrative Law Judge, Office of Administrative Hearings (OAH), State of California, on March 6, 7, and 8, 2012, in Los Angeles.

Heather Hua and Susan Melton Wilson, Deputy Attorneys General, represented Virginia Herold (Complainant), as the Executive Officer of the Board of Pharmacy, Department of Consumer Affairs.

McGuire Woods LLP, by Noah E. Jussim and Herbert L. Weinberg, Attorneys at Law, represented Advanced Physician Solutions, Inc. dba Advanced Compounding Pharmacy.

During the hearing, Complainant amended the First and Second Causes for Discipline as set forth in Complainant's Exhibits 65 and 66, respectively. The Administrative Law Judge, by interlineation, indicated the changes on the Second Amended Accusation included in Complainant's Exhibit 1.

Oral, documentary, and stipulated evidence was received on March 6, 7, and 8, 2012. The record was held open for the filing of written closing briefs and reply briefs by the parties, as ordered by the Administrative Law Judge. Closing briefs were due by April 20, 2012. Reply briefs were due by May 4, 2012. OAH received timely filed briefs from the parties, which were marked for identification only. Complainant's

written closing brief was marked as Exhibit 69, and her reply brief was marked as Exhibit 70. Respondent's written closing brief was marked as Exhibit V, and its responsive brief was marked as Exhibit W.[1]

The record was closed and the matter was submitted for decision on May 4, 2012.

FACTUAL FINDINGS

Parties and Jurisdiction

1. On or about October 31, 2011, Complainant brought the Second Amended Accusation, case number 3251, in her official capacity.

2. On April 26, 2007, the Board of Pharmacy (Board) issued pharmacy permit number PHY 48591 to Advanced Physician Solutions, Inc. to do business as Advanced Compounding Pharmacy at 7225 Fulton Avenue, North Hollywood, California (Respondent Pharmacy or Pharmacy).

3. On July 3, 2007, the Board issued permit number LSC 99426 to Respondent Pharmacy to compound injectable sterile drug products.

4. Official notice is taken that the Board's website states the pharmacy permit, number PHY 48591, has been renewed through April 1, 2014, and the compounding permit, number LSC 99426, has been renewed through April 1, 2013. (Gov. Code, § 11515; Evid. Code, § 452, subd. (h).)

5. Tooraj Bereliani (Bereliani or PIC Bereliani) has been the president of Respondent Pharmacy since April 26, 2007. He was the pharmacist-in-charge (PIC) from April 26, 2007, through November 15, 2010. The Board records indicate Norman J. Jacobs was the pharmacist-in-charge starting on December 14, 2010.

6. Notices of Defense were filed by Respondent Pharmacy, Bereliani, and Jacobs. Prior to this hearing, stipulated settlements were reached by Complainant with Bereliani and Jacobs, respectively. As of December 21, 2011, Bereliani's pharmacist license was placed on five years' probation.

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[1] The parties filed papers in addition to the written closing and reply briefs ordered by the Administrative Law Judge. Respondent filed motions to add new exhibits S, T, and U and to strike portions of Complainant's closing reply. Complainant filed opposition and responsive papers. As no leave was granted for the filing of additional papers, the motions and opposition pleadings filed were not considered or included in the record.

7. The bulk of the violations alleged in the Second Amended Accusation are based on the Board's inspection of Respondent Pharmacy in June 2008. In analyzing the violations, the Administrative Law Judge used the statutes and regulations in effect at the time of the violations.

Compounding

8. Respondent Pharmacy holds a permit to compound sterile injectable drugs. Compounding is the process of mixing or combining ingredients to produce an end product that is used by the patient through oral intake, topically, or by injection.

9. A sterile injectable product can be made from combining two sterile ingredients. A sterile injectable product can also be made from combining a non-sterile ingredient with a sterile ingredient, in which case the end product must be evaluated to verify sterility and tested for pyrogens (bacteria). Testing can be done in-house or by a third party lab. The compounded drugs must be quarantined until the final lab results are received.

10. Respondent Pharmacy has a separate room for its compounding activities which contains a certified ISO Class 5 barrier isolator. Respondent Pharmacy compounds tablets, capsules, cream, suppositories, eye preps, and injectable products, including non-sterile to sterile drugs. Respondent Pharmacy made sterile injectable products by combining non-sterile and sterile ingredients.

11. Respondent Pharmacy is required to maintain certain records regarding its compounding activities. Those records include master formulas, which are the recipes for making the compounded drug, and logged formula worksheets. The logged formula worksheets identify the compounded drug, the date made, the expiration date, the lot number, the ingredients, and the process for mixing.

Board's Investigation

12. On June 19, 2008, the Board conducted an inspection at Respondent Pharmacy located at 7225 Fulton Avenue, North Hollywood, California. The inspection was prompted by a complaint received by the Board that Respondent Pharmacy was selling its compounded Medroxyprogesterone prefilled syringes through a wholesaler called Superior Medical Supply.

13. The inspection was conducted by Robert E. Kazebee, and Anna Yamada. Inspector Kazebee received his Doctorate of Pharmacy from the University of Southern California School of Pharmacy in 1973. He has been licensed in California as a pharmacist since 1973. He has been an inspector for the Board since December 2000. Inspector Yamada has been an inspector for the Board since February 2008. She received her Doctor of Pharmacy in 1999 from the University of Southern California School of Pharmacy

14. On June 19, 2008, Board inspectors Kazebee and Yamada inspected Respondent Pharmacy and reviewed available records. At the end of the approximately three to five hour inspection, PIC Bereliani was provided written notice of violations disclosed by the inspection. He was also requested to provide additional records and information to the Board, including master formulas for Medroxyprogesterone Acetate prefilled syringes, for all dosages of Methylprednisolone Acetate Suspension and the Trimix formulations, and all other non-sterile to sterile products. The Board also requested PIC Bereliani to review the pharmacy's injectable inventory and quarantine all sterile injectable products where the logged formula worksheets indicated the drug had expired.

15. On June 23, 2008, PIC Bereliani faxed some of the requested documents and information to the Board. The documents included documents pertaining to Respondent Pharmacy's recall of "Medroxy Progest. Acetate 150 mg/ml" from January 1, 2007 to June 22, 2008. The documents also included seven master formula worksheets.

16. On June 24, 2008, the Board investigators returned to Respondent Pharmacy and issued an order that the pharmacy cease and desist from compounding all non-sterile to sterile injectable drug compounds until compliance. On June 30, 2008, the Board received from PIC Bereliani, among other things, his compliance plan and response to the cease and desist order.

First and Second Causes for Discipline

17. The Board's investigation in June 2008 was prompted by a complaint that Respondent Pharmacy was selling its compounded Medroxyprogesterone prefilled syringes through a wholesaler called Superior Medical Supply, Inc. (SMS).

18. SMS is a wholesale company operating from Colorado. On March 24, 2006, the Board issued a permit to SMS as an out-of-state distributor. The permit was due to expire on March 1, 2012, unless renewed.

19. Respondent Pharmacy conducted business with SMS as follows. SMS sold sterile injectable drugs to its customers, which were doctors, clinics, and hospitals. SMS customers placed orders for drug products with SMS, and paid SMS for the products. SMS filled the customer orders by submitting a written bid (quote) to Respondent Pharmacy for the compounded drug product, which indicated the price SMS would pay Respondent Pharmacy for the product. Respondent Pharmacy shipped the product directly to SMS's customer. Respondent Pharmacy was not paid by the customer; instead, Respondent Pharmacy was paid by SMS, based on invoices it submitted to SMS. SMS paid Respondent Pharmacy for drugs shipped to SMS customers on a weekly or bi-weekly basis.

20. The Board's investigation found that the price SMS paid to Respondent Pharmacy for a compounded product was less than the amount paid by SMS's customer to SMS. For example, for Medoroxyprogesterone, SMS paid Respondent Pharmacy $13.00 per unit, but SMS charged its customers $17.67 per unit, with the difference being SMS's profit from the order.

21. According to Bereliani, SMS referred customers to Respondent Pharmacy for its sterile injectable products. Respondent Pharmacy contacted the physician to obtain a telephone prescription, and would dispense the product based on the telephone presecription. Respondent Pharmacy shipped the drug products directly to the customer and never shipped drug products to SMS.

22. The Board's investigation found that SMS did not have a DEA license to distribute controlled substances. The Board's investigation found that, from February 27, 2008, to August 4, 2008, Respondent Pharmacy and PIC Bereliani had a verbal agreement to furnish orders from SMS to SMS's customers for controlled substances and then bill SMS for the purchase of the controlled substance.

23. The controlled substances that Respondent Pharmacy shipped to SMS's customers were controlled substances not originally acquired from SMS.

24. Inspector Kazebee's testimony established that a drug manufacturer requires a manufacturing license obtained from the Federal Drug Administration (FDA). The FDA has stringent quality control requirements, checks and balances, etc., that apply to drug manufacturers. Respondent Pharmacy did not have an FDA issued drug manufacturing license.

Third Cause for Discipline

25. It was established by stipulation that "[o]n 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 none-sterile ingredients."

Fourth, Fifth, and Sixth Causes for Discipline

26. On June 19, 2008, Respondent Pharmacy maintained only a few of the required master formula work sheets for the pharmacy's compounding of sterile injectable drugs from non-sterile ingredients. When Inspector Kazebee asked Bereliani for the master formula for Medroxyprogesterone Acetate 150 mg/ml, Bereliani stated he did not have that master formula. Bereliani told Kazebee that he prepared compounded drugs from worksheets and did not have master formulas.

27. It was established by stipulation that "[o]n 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 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."

28. On June 19, 2008, Inspector Kazebee reviewed samples of logged formula worksheets and found no master formulas to justify the expiration dates given to the drugs. For example, the logged formula worksheet dated May 23, 2008, for Methylprednisolone Acetate 80 mg/ml was given a 180-day expiration date of November 23, 2008, even though one of the ingredients used, Benzyl Alcohol, expired in October 2008. There was no master formula to justify the 180-day expiration date. When asked to justify the 180-day expiration dates recorded on the worksheets, Bereliani said he relied on his experience and literature, which he did not provide to Inspector Kazebee.

29. Based on their review of Respondent Pharmacy's records on June 19, 2008, the Board investigators found Respondent Pharmacy did not have written justification for labeling the same drug with different expiration dates, depending on whether it was shipped in California (180-day expiration) or outside of California (one-year expiration). At hearing, Bereliani testified that he assigned different expiration dates because he believed that the true expiration date for compounds was one year under federal law. Since California had stricter requirements than other states, then California products were given six month expiration dates. Bereliani's belief about expiration dates, however, does not excuse the failure to maintain records justifying the different expiration dates given to the same drug.

30. During the June 19, 2008 inspection, Board investigators asked to review the pharmacy's compounding records. Bereliani provided a binder containing logged formula worksheets. Inspector Kazebee found other compounding worksheets on a shelf that were not initialed by the pharmacist as verification of the work of the pharmacy technician. Bereliani explained that he checked all compounded products before they were dispensed but he documented his verification on the worksheets when the worksheets were filed in the binder at a later time.

31. At hearing, Bereliani denied that pharmacy technician Zherair Aghakhan performed compounding duties without supervision. There was supervision, but the supervision was not documented on the logged formula worksheets until later. Bereliani testified he initialed the logged formula worksheets after hours or on his days off. But he asserted that the pharmacy did not dispense any drug that was not first reviewed by a pharmacist on duty.

Seventh and Eighth Causes for Discipline

32. During the June 19, 2008, inspection, Board investigators found that Respondent Pharmacy misbranded the drug Medroxyprogesterone Acetate 150 mg/ml and labeled it with false and misleading information. Inspector Kazebee testified the drug was misbranded when it was identified by the abbreviation "Medroxy Proge" or "Medroxy Progst PF" instead of the full name. Inspector Kazebee testified these abbreviations are not clear. The letters "PF" are misleading because PF can mean pre-filled, preservative free, or paraben free. The drug was also misbranded by the strength of the drug shown as "(75/.5) 75/0.5 mg" or "(75/0.5 mg) ml." Inspector Kazebee testified there is no such drug in this strength. The strength of the drug should be written as "150 mg/ml," as shown on the logged formula worksheet. Inspector Kazebee also testified that the drug was misbranded by showing an expiration date of 180-days when the master formula indicated a 90-day expiration.

33. From February 28, 2008, through June 4, 2008, Respondent Pharmacy shipped Medroxyprogesterone 150 mg/ml pre-filled syringes to doctors and clinics that were labeled as "Medroxy Progst PF (75/0.5 mg) ml" or "Medroxy Proge (75/.5) 75/0.5 mg," and were given a 180-day expiration if shipped in California or a one-year expiration if shipped outside of California. These drugs were misbranded, for the same reasons discussed in Finding 32, above, which Respondent Pharmacy knew or should have known when it sold and shipped the drugs.

34. It was established by stipulation that "[o]n June 19, 2008 and June 24, 2008, Board investigators found that Respondents misbranded the prescription labels with 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."

35. At hearing, Bereliani testified that abbreviations were used to label the Medroxyprogesterone Acetate because of the Etreby computer software used by Respondent Pharmacy. The Etreby system is used by pharmacies all over the United States. Etreby labels were too big for small vials. The Etreby software allows only a limited number of characters to be input for the drug name on the label. Respondent Pharmacy used the Dymo machine to create labels for smaller vials. The Etreby system is an automated system that maintains all types of pharmacy records, patient profiles and history, and billing and insurance data, and also prints labels. Bereliani pointed out that prefilled syringes were packed for shipping in a plastic bag, where the larger Etreby label was attached to the outside of the plastic bag and used the abbreviated name (Medroxy Progst or Medroxy Proge), but the smaller Dymo label was placed on each pre-filled syringe with the full name of the drug on the label.

36. Inspector Kazebee's testimony that Respondent Pharmacy misbranded and labeled drugs with false and misleading information was credible, given his education, experience and training. Bereliani's testimony was not sufficient to refute Inspector Kazebee's testimony.

Ninth Cause for Discipline

37. On June 24, 2008, the Board served Respondent Pharmacy with a cease and desist order to immediately cease and desist compounding non-sterile to sterile injectable drugs. The cease and desist order also required Respondent Pharmacy to immediately implement a recall of "all compounded injectable drugs in which the labeled expiration dates on the finished products exceeds the expiration dating on the master formulas," and "all misbranded injectable products in which the Medroxyprogesterone 150 mg/ml was labeled with the false or misleading information as 'Medroxy Progst PF (75/0.5 mg)ml' or 'Medroxy Proge (75/.5)75/0.5mg'." (Exh. 28.)

38. On June 27, 2008, Bereliani sent the Board a letter setting forth the steps taken by Respondent Pharmacy in response to the cease and desist order. Among the steps taken were to recall the drugs whose labeled expiration dates on the finished products exceeded the expiration dates on the master formuals, and to recall the "misbranded" and "inadvertently mislabeled" Medroxyprogesterone. (Exh. 29.) For each drug recalled, Respondent Pharmacy sent out a Notice of Drug Recall, which indicated that the product was being recalled as a result of "Insufficient evidence to substantiate the assignment of expiration dates." (Exh. 32.)

39. Respondent Pharmacy stipulated to the factual allegations of the Second Amended Accusation, Paragraph 37(a) through 37(e), except for the word "drop" in Paragraph 37(b), line 14, and in Paragraph 37(e), line 13. The following facts were established by that stipulation (with brackets indicating the omission of the word "drop"):

A. "Approximately on or after June 19, 2008, [Respondent Pharmacy] 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. "[Bereliani] identified on the pharmacy's Drug Recall Report a total of 1732 orders: 1,425 misbranded drug orders [] shipped to clinics and doctors' [sic] 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: [the drugs listed in paragraph 37(d) of the Second Amended Accusation]."

E. "The misbranded drugs [] shipped to California clinics and prescribers between January 1, 2008 to June 30, 2008 were: [the drugs listed in paragraph 37(e) of the Second Amended Accusation]."

40. Based on Respondent Pharmacy's stipulation to Paragraph 39(a) through 39(e), set forth above, it was established that the drugs that Respondent Pharmacy sold and subsequently recalled were misbranded.

Tenth Cause for Discipline

41. During the June 19, 2008, inspection, Inspector Kazebee reviewed the logged formula worksheet for Phentolamine Mesylate 50 mg/cc Injectable. Phentolamine Mesylate is one of the ingredients used for making Tri-Mix, which is a drug for erectile dysfunction that is injected into the penis. Phentolamine Mesylate 50 mg/cc Injectable is a stock solution that is made in advance for use in filling future prescriptions for Tri-Mix.

42. Based on his review of the logged formula worksheet for Phentolamine Mesylate 50 mg/cc Injectable made on May 1, 2007, Inspector Kazebee found that the worksheet showed a miscalculation and resulted in the final product being only one-third the strength it should be. (Exh. 21.) The logged formula worksheet listed two ingredients for making the stock solution, the first ingredient being Phentolamine Mesylate USP and the second ingredient being Bacteriostatic Water for Injection Injec. The logged formula work stated the quantity of the first ingredient as 500 mg, and the quantity of the second ingredient as 30 cc. The final product ("Phentolamine Mesylate 50 mg/cc Injectable") is to have a potency of 50 mg/cc. Kazebee's testimony established that the 50 mg/cc potency is not achieved if the amount of the first ingredient is only 500 mg. According to Kazebee, the amount of the first ingredient should be 1,500 mg to achieve a final product potency of 50 mg/cc (i.e., 1,500 mg divided by 30cc equals 50 mg/cc). Since only one-third of the first ingredient was used (500 mg), the final product's potency was only one-third of what it should have been.

43. Respondent Pharmacy filled six prescriptions for Tri-Mix using the Phentolamine Mesylate 50 mg/cc Injectable made on May 1, 2007, which, due to miscalculation, was only one-third the required potency.

44. During the June 19, 2008, inspection, Inspector Kazebee determined that Respondent Pharmacy failed to verify the accuracy of the logged formula worksheet for Tri-Mix (Phen/PGE/PAPA) 1 MG/20MCG/30MG/ML Injectable. (Exh. 21, Doc. E.) According to Inspector Kazebee, two of the ingredients are transposed and miscalculated so that patient R.T. received three times the dose of the first ingredient (Phentolamine Mesylate) and one-third the dose of the second ingredient (Prostaglandin) on his Tri-Mix injection. Further, Inspector Kazebee noted

that the Tri-Mix product was given a "Discard after" date of May 14, 2008, but the first ingredient (Phentolamine Mesylate) had an expiration date of April 2008.

45. The logged formula worksheet for Phentolamine Mesylate 50 mg/cc Injectable made on May 1, 2007, indicated a discard date of November 1, 2007. Respondent Pharmacy continued to use the Phentolamine Mesylate 50 mg/cc Injectable made on May 1, 2007, to make Tri-Mix products that were labeled with expiration dates in March 2008 and May 2008.

46. Bereliani testified that he does not believe Respondent Pharmacy dispensed incorrectly compounded Tri-Mix product. Several Tri-Mix customers remained customers of Respondent Pharmacy after being dispensed the Tri-Mix compounded from the Phentolamine Mesylate stock solution made on May 1, 2007. Based on the behavior of these customers, Bereliani believes the pharmacy did not dispense Tri-Mix with improper stock solution. If there was any problems with Tri-Mix that was dispensed, Bereliani would expect he would hear complaints from the doctors and patients, which he did not.

Eleventh Cause for Discipline

47. "Soluspan" is a registered trademark name of Schering-Plough's Celestone Soluspan 6 mg/ml, a betamethasone acetate injectable suspension. (Exh. 46.) It is used to reduce inflammation. Documents provided to the Board following the June 19, 2008 inspection established that Respondent Pharmacy identified its compounded product "betamethasone suspension" by labeling it "Betam Soluspan Inj 6 mg/ml." It did so on a prescription label, on a notice of drug recall, and on a Drugs Recall Report. (Exh. 26, pp. AGO 10-12; Exh. 32, pp. AGO 7, 79-82, 149.) Respondent Pharmacy's use of the tradename "Soluspan" was an improper use of a registered trade name and constituted misbranding, as use of the name Soluspan implied that Respondent Pharmacy's compounded drug would work the same as Schering-Plough's Celestone Soluspan. No evidence was presented that Respondent Pharmacy had permission from Schering-Plough to use its registered trademark name "Soluspan."

48. At hearing, Bereliani testified he did not know "Soluspan" was a registered trademark name. This testimony was not credible. Bereliani has been licensed in California as a pharmacist since August 2000. Product information for Celestone Soluspan shows copyright dates of 1969 and 2007. (Exh. 46.) In 2008, Bereliani knew or reasonably should have known that "Soluspan" was a registered trademark name for a sterile injectable product, which is his business. At the very least, he reasonably could be expected to have inquired about the name Soluspan.

49. At the conclusion of the June 19, 2008 inspection, the Board investigators requested Bereliani, among other things, to provide within three days the master formulas for Medroxyprogesterone Acetate prefilled syringes, for all dosages

of Methylprednisolone Acetate Suspension and for the Trimix formulations, and all other non-sterile to sterile products. On June 23, 2008, the Board received seven formula worksheets from Bereliani. (Exh. 27.)

50. The Pharmaceutical Compounding Centers of America (PCCA) is an organization that provides its members with master formulas that have been researched and tested. Pharmacists and pharmacies have to pay to become members of PCCA.

51. Respondent Pharmacy stipulated to the factual allegations of Paragraph 39(b) of the Second Amended Accusation, which reads, in pertinent part: "Respondents were not a member of the [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," which are enumerated in Paragraph 39(b) of the Second Amended Accusation. For example, the formula worksheet for Medroxyprogesterone Acetae (New) 150 mg/ml referenced PCCA Formula 7404 in items 6 and 7 of the mixing directions. (Exh. 27, p. AGO 2.)

52. The seven formula worksheets received by the Board on June 23, 2008, referenced PCCA formulas, but also stated, "This formula is a trade secret of Advanced Pharmacy." Respondent Pharmacy referenced the PCCA formula and then identified the formula as "a trade secret of Advanced Pharmacy." By so doing, Respondent Pharmacy knowingly and falsely represented the PCCA formulas referenced were a trade secret of the pharmacy.

Twelfth Cause for Discipline

53. Respondent Pharmacy stipulated to the factual allegations of Paragraph 40 of the Second Amended Accusation, which reads: "[O]n or about June 30, 2011, an inspection of [Respondent Pharmacy] revealed that on that date, three pharmacy technicians employed by [Respondent Pharmacy] routinely compounded sterile injectable and non-sterile preparations with only one pharmacist on duty at the pharmacy during the morning shift (approximately 9 a.m. to 1 p.m.)."

54. Inspector Yamada conducted an inspection at Respondent Pharmacy on June 30, 2011. During the inspection, she interviewed the three pharmacy technicians who were present and asked them about their duties at the pharmacy. The three technicians told Inspector Yamada that they performed compounding duties while only one pharmacist was present at the pharmacy. Based on the statements of the technicians, Inspector Yamada concluded that Respondent Pharmacy was in violation of Business and Professions Code section 4115, subdivision (f)(1), which sets a ratio of two pharmacy technicians to one pharmacist when the technicians are performing pharmacy technician duties.

55. Respondent Pharmacy's stipulation, as supplemented by Inspector Yamada's testimony and the statements she obtained from the technicians, established that, on June 30, 2011, the pharmacy was not in compliance with the staffing ratio requirements under Business and Professions Code section 4115. (Gov. Code, § 11514, subd. (d).)

Thirteenth Cause for Discipline

56. During Inspector Yamada's inspection at Respondent Pharmacy on June 30, 2011, she reviewed compounding worksheets, end product testing results, prescriptions, and shipping records for the following sample of batch produced sterile injectable products prepared from a non-sterile sources: testosterone propionate; nandrolone decanoate; hyaluronidase; hydroxyprogesterone caproate; and medroxyprogesterone. Inspector Yamada found that, according to the records, Respondent Pharmacy was shipping the products before receiving testing results confirming the sterility of the product, from approximately April 27, 2011, to June 28, 2011. For example, the records showed that medroxyprogesterone was made on May 11, 2011, the testing results were received by Respondent Pharmacy on May 23, 2011, but the product was shipped between May 12, 2011 to May 19, 2011.

57. At hearing, Bereliani testified that the only batch product in the sample reviewed by Inspector Yamada was medroxyprogesterone, and to his knowledge, the other four products were not batches. Bereliani testified that Respondent Pharmacy received test results for each of the products whose records Inspector Yamada reviewed (i.e., testosterone propionate; nandrolone decanoate; hyaluronidase; hydroxyprogesterone caproate; and medroxyprogesterone), and all were reported sterile and pyrogen free as far as he knows. Bereliani testified that, in the past, if a doctor ordered a sterile injectable product and lab results were not yet received, Respondent Pharmacy would ship the product and tell the doctor to quarantine the product. The Pharmacy has since changed its procedures and now quarantines the product at the pharmacy for 14 days until it receives the results of sterility and pyrogen testing.

Mitigation / Rehabilitation

58. Respondent Pharmacy presented a letter dated March 6, 2012, from Analytical Research Laboratories commending the quality of the pharmacy's compounding activities. The letter reads in part: "Since [Respondent Pharmacy] began working with Analytical Research Laboratories in 1997, we have performed over a thousand tests on your samples for potency, sterility, and endotoxin; as well as other more complicated assays to help you achieve your quality assurance goals. Your dedication to high quality compounding is evident in your test results."

59. At hearing, Bereliani admitted and acknowledged that mistakes were made at Respondent Pharmacy in 2008. He took responsibility for those mistakes and

resigned as the pharmacist-in-charge. Pursuant to the stipulated settlement with the Board, Bereliani's pharmacist license was placed on five years' probation starting in December 2011.

60. Respondent Pharmacy has taken steps to ensure its future and continued compliance with applicable pharmacy laws and regulations. In September 2011, the pharmacy hired Natalie Behfarin to be the pharmacist-in-charge. PIC Behfarin received her Doctorate of Pharmacy in May 2010 from the University of Southern California School of Pharmacy. In addition, in 2011, Respondent Pharmacy hired Dr. Jesse Martinez as a consultant to advise on the pharmacy's operations, especially its sterile compounding practices, and ensure compliance with applicable laws and regulations. Dr. Martinez is a licensed pharmacist. He is currently a clinical assistant professor and vice-dean at Western University of Health Sciences, College of Pharmacy, where he teaches a continuing education course that certifies licensed pharmacists and technicians in non-sterile contemporary compounding. He has founded pharmacies nationally that included sterile compounding infusion services.

61. Respondent Pharmacy now has a policy and procedure for creating a master formulas and using worksheets. The master formula worksheets have been changed to cut down on errors. The Pharmacy uses computer software to determine strength and quality of compounded product, and to calculate the amount of each ingredient used, and the PIC does a final check. Respondent Pharmacy no longer indicates a one-year expiration date for products shipped outside of California and 180 days for the same product shipped within California. Bereliani is currently a member of PCCA.

62. Bereliani is the president and a shareholder of Respondent Pharmacy. The pharmacy is his main source of income for supporting his two children.

63. No evidence was presented of any complaints made against Bereliani or Respondent Pharmacy by doctors, patients, clinics, etc., related to its compounding activities. No evidence was presented of any patients being harmed from using compounded products made by Respondent Pharmacy. Respondent Pharmacy nor Bereliani conducts any business with SMS.

Cost Recovery

64. The Board incurred reasonable costs investigating this matter of $8,695.50, and reasonable costs of prosecution in the amount of $70,446.

65. Bereliani's pharmacist license was placed on five years' probation with one of the probation terms being that he pay the Board $1,147 for the investigative and prosecution costs incurred in this matter.

LEGAL CONCLUSIONS

1. Business and Professions Code section 4301 provides, in part, that the Board shall take action against any holder of a license who is guilty of unprofessional conduct, which includes but is not limited to: "(j) The violation of any of the statutes of this state . . . or of the United States regulation controlled substances and dangerous drugs," and "(o) "Violating . . . directly or indirectly . . . 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."[2]

2. FIRST CAUSE. Cause exists to discipline Respondent Pharmacy's permits, pursuant to sections 4301, subdivisions (j) and (o), and 4033, subdivision (a), in that Respondent Pharmacy acted as a manufacturer within the meaning of section 4033, at a time when it only held a pharmacy permit and compounding permit, based on the matters in Factual Findings 2, 3, 6, 17-21, and 24.

A "manufacturer" is defined under section 4033, subdivision (a)(1), to include "every person who prepares, derives, produces, compounds, or repackages any drug or device *except* a pharmacy that manufactures on the immediate premises where the drug or device is sold to the ultimate consumer." (Emphasis added.)

In the transactions involving SMS, Respondent Pharmacy acted as a manufacturer within the meaning of section 4033. The exception under section 4033, subdivision (a)(1), does not apply because Respondent Pharmacy did not sell the compounded drug to the ultimate consumer (i.e., doctors, clinics, hospitals). Respondent Pharmacy "sold" drugs to SMS, in that SMS paid Respondent Pharmacy for the drugs which the pharmacy shipped to the ultimate consumer. Because of SMS's role in the transactions (i.e., acting as middle-man between Respondent Pharmacy and the ultimate consumer), and the fact that the price paid by the ultimate consumer to SMS was different than the amount SMS paid to Respondent Pharmacy for the drugs, it cannot be said that Respondent Pharmacy sold drugs to the ultimate consumer to come within the exception provided under section 4033, subdivision (a)(a). Respondent Pharmacy acted as a manufacturer without holding the appropriate license or license authorizing it to do so.

3. SECOND CAUSE. Cause exists to discipline Respondent Pharmacy's permits, pursuant to section 4301, subdivisions (j) and (o), in that Respondent Pharmacy violated section 4126.5 by furnishing controlled substances and compounded drugs to a wholesaler from whom the controlled substances were not acquired, based on the matters in Factual Findings 17-23.

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[2] All further statutory references are to the Business and Professions Code unless otherwise indicated.

Under Business and Professions Code section 4126.5, subdivision (a)(1), a pharmacy may furnish dangerous drugs only to, among others, a "wholesaler . . . from whom the dangerous drug was acquired." The term "furnish" is defined under section 4026 as "to supply by any means, by sale or otherwise." Here, Respondent Pharmacy "furnished" compounded drugs to SMS, in the sense that SMS paid Respondent Pharmacy for products that the pharmacy shipped directly to SMS's customers. The customers, in turn, paid SMS for the drugs received. SMS arranged the transaction as the middle-man. The transaction would not occur absent SMS's participation as middle-man. Under these circumstances, Respondent Pharmacy "furnished" compounded drugs SMS, which drugs it did not acquire from SMS.

4. THIRD CAUSE. Cause exists to discipline Respondent Pharmacy's permits, pursuant to section 4301, subdivisions (j) and (o), in that Respondent Pharmacy violated California Code of Regulations, title 16, section 1751.02, subdivision (c)(3)(I), by failing to maintain required written policies and procedures associated with its preparation and dispensing of sterile injectable products, based on the matters in Factual Finding 25. However, cause for discipline does not exist for a violation of section 4081. The written policies and procedures that are the subject of the Third Cause for Discipline are not the type of "records of manufacture and of sale, acquisition, or disposition of dangerous drugs or dangerous devices" governed by section 4081.

California Code of Regulations, title 16, section 1751.02, subdivision (c), requires that pharmacies compounding sterile injectable products from one or more non-sterile ingredients must have written policies and procedures that comply with certain requirements specified in the regulation. Subdivision (c)(3)(I) provides that, "[f]or sterile batch compounding, written policies and procedures must be established for the use of master formulas and work sheets and for appropriate documentation."

5. FOURTH CAUSE. Cause exists to discipline Respondent Pharmacy's permits, pursuant to section 4301, subdivisions (j) and (o), in that Respondent Pharmacy violated California Code of Regulations, title 16, section 1751.3, subdivision (b)(6), by failing to maintain, for three years, the preparation records, including Master Formula worksheets, when compounding sterile products from one or more non-sterile ingredients, based on the matters in Factual Findings 26-29. However, cause for discipline does not exist for a violation of section 4081. The preparation records that are the subject of the Fourth Cause for Discipline are not the type of "records of manufacture and of sale, acquisition, or disposition of dangerous drugs or dangerous devices" governed by section 4081.

California Code of Regulations, title 16, section 1751.3, subdivision (b)(6), requires that, for sterile products compounded from one or more non-sterile ingredients, certain records must be maintained for three years, including but not

limited to, "[p]reparation records including the master work sheet, the preparation work sheets, and records of end-production evaluation results."

6. FIFTH CAUSE. Cause exists to discipline Respondent Pharmacy's permits, pursuant to section 4301, subdivisions (j) and (o), in that Respondent Pharmacy violated California Code of Regulations, title 16, section 1716.2, by failing to maintain complete records required for compounding for future furnishing of drugs, based on the matters in Factual Findings 26-29. Specifically, Respondent Pharmacy failed to maintain records justifying different expiration dates for the same drug, the master formulas, and worksheets signed or initialed by a pharmacist performing the compounding. However, cause for discipline does not exist for a violation of section 4081. The records that are the subject of the Fifth Cause for Discipline are not the type of "records of manufacture and of sale, acquisition, or disposition of dangerous drugs or dangerous devices" governed by section 4081.

California Code of Regulations, title 16, section 1716.2, subdivision (a)(1)-(8), provides in pertinent part: "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:

(1) The date of preparation.

(2) The lot numbers. . . .

(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.

(6) The name(s) of the manufacturer(s) of the raw materials.

(7) The quantity in units of finished products or grams of raw materials.

(8) The package size and the number of units prepared."

7. SIXTH CAUSE. Cause exists to discipline Respondent Pharmacy's permits, pursuant to section 4301, subdivision (j) and (o), in that Respondent Pharmacy violated California Code of Regulations, title 16, section 1793.7, subdivision (a), by failing to document supervision and verification of duties performed by the pharmacy technicians, based on the matters in Factual Findings 30-31. However, cause for discipline does not exist for a violation of section 4081. The records that are the subject of the Sixth Cause for Discipline are not the type of "records of manufacture and of sale, acquisition, or disposition of dangerous drugs or dangerous devices" governed by section 4081.

California Code of Regulations, title 16, section 1793.7 sets forth the requirements for pharmacies employing pharmacy technicians. Subdivision (a) requires that "any function performed by a pharmacy technician in connection with the dispensing of a prescription . . . must be verified and documented in writing by a pharmacist. . . . [T]he pharmacist shall indicate verification of the prescription by initialing the prescription label before the medication is provided to the patient." Subdivision (b) states: "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.

Here, Bereliani's after-hours signing and initialing the worksheets did not constitute proper documenting of supervision and verification of duties of the pharmacy technician. Absent having a Board monitor stand in the pharmacy to verify supervision, documenting supervision by signing or initialing worksheets or labels is the only way for the Board to verify supervision and ensure public protection. It should not be left as an after-hours or off-day activity.

8. SEVENTH CAUSE. Cause exists to discipline Respondent Pharmacy's permits, pursuant to section 4301, subdivisions (j) and (o), in that Respondent Pharmacy violated section 4076, subdivisions (a)(7) and (9), and California Code of Regulations, title 16, section 1751.2, subdivision (b), when it misbranded and labeled drugs (Medroxyprogesterone Acetate) with false and misleading information about the name of the drug, its strength and concentration of ingredients, and expiration date, based on the matters in Factual Findings 32-36.

Under section 4076, subdivision (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 certain information including the "strength of the drug or drugs dispensed" (subdivision (a)(7)) and the "expiration date of the effectiveness of the drug dispensed" (subdivision (a)(9)). California Code of Regulations, title 16, section 1751.2, subdivision (b), requires that a pharmacy which compounds sterile injectable products shall include certain information on the label, including, but not limited to, "Name and concentrations of ingredients contained in the sterile injectable product."

9. EIGHTH CAUSE. Cause exists to discipline Respondent Pharmacy's permits, pursuant to section 4301, subdivisions (j) and (o), in that Respondent Pharmacy violated section 4169, subdivision (a)(3), and Health and Safety Code section 111335, when it sold dangerous drugs (Medroxyprogesterone 150 mg/ml pre-filled syringes) that it knew or reasonably should have known were misbranded, based on the matters in Factual Findings 32-36.

Section 4169, subdivision (a)(3), provides that a person or entity may not "[p]urchase, 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." Health and Safety Code section 111335 reads: "Any drug or device is misbranded if its labeling or packaging does not conform to the requirements of Chapter 4 (commencing with Section 110290)." Section 110290 reads: "In determining whether the labeling or advertisement of a food, drug, device, or cosmetic is misleading, all representations made or suggested by statement, word, design, device, sound, or any combination of these, shall be taken into account. The extent that the labeling or advertising fails to reveal facts concerning the food, drug, device, or cosmetic or consequences of customary use of the food, drug, device, or cosmetic shall also be considered."

10. NINTH CAUSE. Cause exists to discipline Respondent Pharmacy's permits, pursuant to section 4301, subdivisions (j) and (o), in that Respondent Pharmacy violated sections 4169, subdivision (a)(3), and 4342, and Health and Safety Code section 111330, when it sold dangerous drugs that it knew or reasonably should have known were misbranded, based on the matters in Factual Findings 37-40 and 32-36.

Health and Safety Code section 111330 states: "Any drug or device is misbranded if its labeling is false or misleading in any particular." The drugs that were the subject of the recall by Respondent Pharmacy were drugs that were sold and which Respondent Pharmacy stipulated were misbranded.

11. TENTH CAUSE. Cause does not exist to discipline Respondent Pharmacy's permits pursuant to section 4306.5, subdivision (a), which provides that unprofessional conduct "for a pharmacist" may include the inappropriate exercise of his or her education, training, or experience as a pharmacist. Respondent Pharmacy is not a "pharmacist," which is defined in section 4036 as "a natural person to whom a license has been issued by the board." Moreover, the acts upon which the Tenth Cause for Discipline are based (i.e., miscalculations and transposed information on worksheets, failing to document supervision and check lot numbers) seem to be another way to state general unprofessional conduct, simple negligence, or perhaps incompetence, but are not an "inappropriate exercise" of education, training, or experience. (Factual Findings 41-45.) The Tenth Cause for Discipline is dismissed.

12. ELEVENTH CAUSE. Cause exists to discipline Respondent Pharmacy's permits, pursuant to section 4301, subdivision (g), in that Respondent Pharmacy knowingly made or signed documents that falsely represented the existence or nonexistence of a state of facts, based on the matters in Factual Findings 47-52.

13. TWELFTH CAUSE. Cause exists to discipline Respondent Pharmacy's permits, pursuant to sections 4301, subdivision (o), and 4115, subdivision (f)(1), in that, on June 30, 2011, Respondent violated the pharmacist to pharmacy technician ratio requirements, based on the matters in Factual Findings 53-55.

Section 4115, subdivision (f)(1), provides, in pertinent part: "A pharmacy with only one pharmacist shall have no more than one pharmacy technician performing the tasks specified in subdivision (a). The ratio of pharmacy technicians performing the tasks specified in subdivision (a) to any additional pharmacist shall not exceed 2:1, except that this ratio shall not apply to personnel performing clerical functions pursuant to Section 4116 or 4117. The tasks specified in subdivision (a) are "packaging, manipulative, repetitive, or other nondiscretionary tasks, only while assisting, and while under the direct supervision and control of a pharmacist."

14. THIRTEENTH CAUSE. Cause exists to discipline Respondent Pharmacy's permits, pursuant to section 4301, subdivision (o), in that, between April 2011 and June 2011, Respondent Pharmacy violated California Code of Regulations, title 16, section 1751.7, subdivision (c), when it compounded sterile injectable batch products prepared from a non-sterile source and dispensed the products prior to quarantining the products and receiving acceptable end product pyrogen and sterility results, based on the matters set forth in Factual Finding 56.

California Code of Regulations, title 16, section 1751.7, subdivision (c), reads: "Batch produced sterile injectable drugs 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."

15. DISPOSITION. Respondent Pharmacy has shown sufficient rehabilitation to warrant retaining its permits subject to a period of probation under specified terms and conditions. Bereliani cooperated with the Board investigation. He has accepted responsibility for the mistakes made at the pharmacy. No evidence was presented of any patient harm or complaints arising from the pharmacy's compounding activities. Bereliani and Respondent Pharmacy stopped doing business with SMS. Bereliani stepped down as the pharmacist-in-charge. He has implemented changes in the pharmacy's operations, including the hiring of a new pharmacist in charge and a consultant, to ensure compliance with pharmacy laws and regulations. Bereliani's pharmacist license is on probation under appropriate terms and conditions. Under these circumstances, public protection is served by placing Respondent Pharmacy's permits on probation for five years under the terms and conditions set forth in the Order below.

The Board's model standard terms for premises are used for the terms and conditions in the Order below. However, the standard term entitled "Community Services Program" is omitted, as it would be impractical for a corporation to comply with this term. Moreover, the Respondent owner, Bereliani, is already obligated to perform 250 hours of free health-care related services to a community or charitable facility as part of the five-year probation for his pharmacist license. Complainant's closing reply brief included suggested optional probation terms, which were considered. The optional terms that were not included in the Order below were for

administrative fine, mandatory education, and documentation. Those optional terms were deemed not necessary or appropriate for this case.

16. COST RECOVERY. Grounds exist to direct Respondent Pharmacy to pay the reasonable costs of investigation and enforcement of this matter pursuant to section 125.3, in that Respondent Pharmacy committed violations of pharmacy law and regulations, based on Legal Conclusions 1-9 and 11-13 above. The reasonable costs of investigation and enforcement of this matter under section 125.3 are $8,695.50 (investigative) and $70,446 (enforcement), as set forth in Finding 64 above. However, a reduction in the cost recovery amount is warranted. No evidence was presented regarding Respondent Pharmacy's ability to pay costs. Bereliani is already obligated to pay $1,147 of costs as part of the probation for his pharmacist license. Ordering Respondent Pharmacy to pay the entire cost recovery of approximately $78,000 would be unduly harsh and punitive. However, more than just a nominal amount of cost recovery is appropriate in this case given the nature of the violations established. The Board's costs were incurred over a four-year period, from 2008 to 2012. Investigative costs per year were approximately $2,174 (calculated by dividing $8,695 by 4). Enforcement costs per year were approximately $17,612 (calculated by dividing $70,446 by 4). It is appropriate to order Respondent Pharmacy to pay one year's worth of the costs, which is $19,786. Respondent Pharmacy shall pay that amount as set forth in the Order below.

ORDER

Permit number PHY 48591 and permit number LSC 99426, issued to respondent Advanced Physician Solutions, Inc., dba Advanced Compounding Pharmacy, are revoked; however, the revocation is stayed and respondent is placed on probation for five years upon the following terms and conditions:

1. Obey All Laws

Respondent owner shall obey all state and federal laws and regulations. Respondent owner shall report any of the following occurrences to the board, in writing, within seventy-two (72) hours of such occurrence:

- 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 pharmacy permit or compounding permit or which is related to the practice of pharmacy or the manufacturing, obtaining, handling or distributing, billing, or charging for any drug, device or controlled substance. Failure to timely report any such occurrence shall be considered a violation of probation.

2. Report to the Board

Respondent owner 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 owner 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.

3. Interview with the Board

Upon receipt of reasonable prior notice, respondent owner 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.

4. Cooperate with Board Staff

Respondent owner 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 his or her probation. Failure to cooperate shall be considered a violation of probation.

5. Reimbursement of Board Costs

As a condition precedent to successful completion of probation, respondent owner shall pay to the board its costs of investigation and prosecution in the total amount of $19,786. Respondent owner shall make said payments pursuant to a payment plan approved by the Board or its designee. 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 owner shall not relieve respondent of his or her responsibility to reimburse the board its costs of investigation and prosecution.

6. Probation Monitoring Costs

Respondent owner 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.

7. Status of License

Respondent owner shall, at all times while on probation, maintain current licensure with the board. If respondent owner 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 retain continuing jurisdiction over the license, and the respondent shall remain on probation as determined by the board. Failure to maintain current licensure shall be considered a violation of probation.

If respondent license expires or is 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's license shall be subject to all terms and conditions of this probation not previously satisfied.

8. License Surrender While on Probation/Suspension

Following the effective date of this decision, should respondent owner discontinue business, respondent owner may tender the premises 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.

Upon acceptance of the surrender, respondent owner shall relinquish the premises wall and renewal license to the board within ten (10) days of notification by the board that the surrender is accepted. Respondent owner shall further submit a completed Discontinuance of Business form according to board guidelines and shall notify the board of the records inventory transfer. Respondent owner 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 owner 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 owner may not apply for any new licensure from the board for three (3) years from the effective date of the surrender. Respondent owner shall meet all requirements applicable to the license sought as of the date the application for that license is submitted to the board.

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

9. Notice to Employees

Respondent owner shall, upon or before the effective date of this decision, ensure that all employees involved in permit operations are made aware of all the terms and conditions of probation, either by posting a notice of the terms and conditions, circulating such notice, or both. If the notice required by this provision is posted, it shall be posted in a prominent place and shall remain posted throughout the probation period. Respondent owner shall ensure that any employees hired or used after the effective date of this decision are made aware of the terms and conditions of probation by posting a notice, circulating a notice, or both. Additionally, respondent owner shall submit written notification to the board, within fifteen (15) days of the effective date of this decision, that this term has been satisfied. Failure to submit such notification to the board shall be considered a violation of probation.

> "Employees" as used in this provision includes all full-time, part-time, volunteer, temporary and relief employees and independent contractors employed or hired at any time during probation.

10. Owners and Officers: Knowledge of the Law

Respondent 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 or respondent'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.

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11. Posted Notice of Probation

Respondent owner 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 owner 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.

12. Violation of Probation

If a respondent owner has not complied with any term or condition of probation, the board shall have continuing jurisdiction over respondent license, and probation shall be automatically 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 owner 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 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.

13. Completion of Probation

Upon written notice by the board or its designee indicating successful completion of probation, respondent license will be fully restored.

14. Separate File of Records

Respondent owner shall maintain and make available for inspection a separate file of all records pertaining to the acquisition or disposition of all controlled substances. Failure to maintain such file or make it available for inspection shall be considered a violation of probation.

15. Development and Approval of All Master Formulas

Before any sterile drug is compounded by the Respondent, a master formula shall be developed, and approved and validated by a compounding expert. The compounding expert shall be approved by the board. Such master formulas shall be immediately retrievable upon request of the board, along with the name of the approving expert and the date approved.

16. Process Validation

The end product of any batch of non-sterile to sterile injectable compound 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. The end product of any non-sterile to sterile injectable compound shall be examined on a periodic sample basis as determined by the pharmacist-in-charge to insure that it meets required specifications. The Board shall assess the process validation done by Respondent on a quarterly basis.

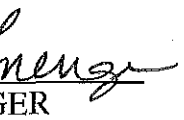
17. Restrictions on Compounding - First Year of Probation

For the first year of probation, Respondent is restricted from compounding for future use, and shall compound drugs only pursuant to a patient-specific prescription. Additionally, pursuant to Board approval, Respondent choose up to eleven drugs to be compounded for physician's office use, which will be referred to as "Allowed Compounds."

The Board reserves the right to cap quantity provided at any time for good cause shown based on potential risk to the safety of patients. After the first year of probation, Respondent has no limit or restrictions on compounding, except those established in law.

During the first year of Respondent's probation, should any of the five Allowed Compounds become commercially available, Respondent may request of the Board or the Board's designee that Respondent be allowed to substitute a different, non-commercially available compounded drug product for that non-commercially available Allowed Compound.

DATED: March 1, 2013



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

In the Matter of the Second 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 and **NORMAN JACOBS** **Pharmacist-in-Charge** P.O. Box 260044 Encino, CA 91426-0044 Pharmacist License No. RPH 22604 Respondents.	Case No. 3251 **SECOND 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, 2012, 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, 2012, unless renewed.

4. On or about August 30, 2000, the Board of Pharmacy issued Pharmacist License Number RPH 51817 to Tooraj Bereliani (Respondent Bereliani). Respondent Bereliani was pharmacist-in-charge of Advanced Compounding Pharmacy from April 26, 2007 through November 15, 2010. 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.[1]

5. On or about July 30, 1962, the Board of Pharmacy issued Pharmacist License Number RPH 22604 to Norman Jacobs (Respondent Jacobs). Respondent Jacobs is pharmacist-in-charge of Advanced Compounding Pharmacy from December 14, 2010 through the present. The Pharmacist License was in full force and effect at all times relevant to the charges brought herein and will expire on June 30, 2013, unless renewed.

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[1] Board approval of a proposed settlement of the First Amended Accusation against Respondent Tooraj Bereliani only is currently pending.

JURISDICTION

6. 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.

7. 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.

8. Section 4026 of the Code states as follows:

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

9. 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. . . ."

10. 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.

11. 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. . . ."

12. 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."

13. 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."

14. Section 4115 of the Code states:

"(a) A pharmacy technician may perform packaging, manipulative, repetitive, or other nondiscretionary tasks, only while assisting, and while under the direct supervision and control of a pharmacist.

. . .

(f) (1) A pharmacy with only one pharmacist shall have no more than one pharmacy technician performing the tasks specified in subdivision (a). The ratio of pharmacy technicians

performing the tasks specified in subdivision (a) to any additional pharmacist shall not exceed 2:1, except that this ratio shall not apply to personnel performing clerical functions pursuant to Section 4116 or 4117. This ratio is applicable to all practice settings, except for an inpatient of a licensed health facility, a patient of a licensed home health agency, as specified in paragraph (2), an inmate of a correctional facility of the Department of the Youth Authority or the Department of Corrections, and for a person receiving treatment in a facility operated by the State Department of Mental Health, the State Department of Developmental Services, or the Department of Veterans Affairs.

(2) The board may adopt regulations establishing the ratio of pharmacy technicians performing the tasks specified in subdivision (a) to pharmacists applicable to the filling of prescriptions of an inpatient of a licensed health facility and for a patient of a licensed home health agency. Any ratio established by the board pursuant to this subdivision shall allow, at a minimum, at least one pharmacy technician for a single pharmacist in a pharmacy and two pharmacy technicians for each additional pharmacist, except that this ratio shall not apply to personnel performing clerical functions pursuant to Section 4116 or 4117."

15. 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."

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

17. 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. . . ."

18. 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."

19. 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."

20. 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."

21. 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. . . ."

22. 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. . . ."

23. 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. . . ."

24. 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. . . ."

25. 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. . . ."

26. California Code of Regulations, Title 16, section 1751.7, subdivision (c), provides:

. . .

(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.

COST RECOVERY

27. 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.

28. 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	Anti-inflammatory corticosteroid
Celestone Soluspan	Betamethasone Soluspan	Yes	No	Anti-inflammatory corticosteroid
Depo Estradiol	Estradiol Cyprionate	Yes	No	HRT
Depo Medrol	Methylprednisolone Inj.	Yes	No	Anti-inflammatory 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	Anti-

				inflammatory 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	Anti-inflammatory 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
Demerol	Meperidine	Yes	CII HSC 11055(c)(17)	Severe pain
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]

29. 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 Medroxyprogesterone Acetate Suspension 150 mg/ml [2] 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.

SECOND CAUSE FOR DISCIPLINE

(Furnishing of Controlled Substance through Unlicensed Wholesaler)

[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 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.

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[2] 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.

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]

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 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]

32. 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]

33. 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]

34. 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]

35. 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]

36. 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]

37. 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]

38. 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]

39. 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 repósitory 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".

TWELFTH CAUSE FOR DISCIPLINE

(Failure to Comply with Pharmacy Technician Ratio Requirements)

[Respondents Advanced Compounding and Jacobs]

40. Respondents Advanced Compounding and Jacobs are subject to disciplinary action under section 4115, subdivision (f)(1), in that on or about June 30, 2011, an inspection of Respondent Advanced Compounding revealed that on that date, three pharmacy technicians employed by Respondent Advanced Compounding routinely compounded sterile injectable and non-sterile preparations with only one pharmacist on duty at the pharmacy during the morning shift (approximately 9 a.m. to 1 p.m.), in violation of pharmacist to pharmacy technician ratio requirements.

THIRTEENTH CAUSE FOR DISCIPLINE

(Failure to Provide Quality Assurance in Sterile Compounding)

[Respondents Advanced Compounding and Jacobs]

41. Respondents Advanced Compounding and Jacobs are subject to disciplinary action under Business and Professions Code section 4301, subdivision (o) in conjunction with Title 16, California Code of Regulations section 1751.7, subdivision (c), in that on or about June 30, 2011, an inspection of Respondent Advanced Compounding revealed that approximately between April 27, 2011 and June 28, 2011, the pharmacy compounded sterile injectable batch products prepared from a non-sterile source and dispensed the products prior to quarantining the products and receiving acceptable end product pyrogen and sterility results for the products in at least 25 instances, as follows:

Drug	Lot#	Date Prepared	Date Testing Results Received	Date Drug Dispensed	RX#
Testosterone Propionate 150mg/ml	06162011 @2	6/16/11	6/24/11	6/16/11	66757
Nandrolone Decanoate 200mg/ml	06132011 @17	6/13/11	6/27/11	6/20/11	68927
Nandrolone Decanoate 200mg/ml	06132011 @17	6/13/11	6/27/11	6/17/11	68870
Nandrolone Decanoate 200mg/ml	06132011 @17	6/13/11	6/27/11	6/20/11	69078
Hyaluronidase 150u/ml	04272011 @14	4/27/11	5/11/11	4/27/11	67655
Hyaluronidase 150u/ml	04272011 @14	4/27/11	5/11/11	5/10/11	65821
Hyaluronidase 150u/ml	04272011 @14	4/27/11	5/11/11	5/3/11	67769
Hydroxyprogesterone Caproate 250mg/ml	06222011 @15	6/22/11	6/29/11	6/23/11	69133
Hydroxyprogesterone Caproate 250mg/ml	06222011 @15	6/22/11	6/29/11	6/28/11	69135

Hydroxyprogesterone Caproate 250mg/ml	06222011 @15	6/22/11	6/29/11	6/27/11	60345
Medroxyprogesterone 150mg/ml	05112011 @2	5/11/11	5/23/11	5/12/11	65649
Medroxyprogesterone 150mg/ml	05112011 @2	5/11/11	5/23/11	5/12/11	66339
Medroxyprogesterone 150mg/ml	05112011 @2	5/11/11	5/23/11	5/12/11	65037
Medroxyprogesterone 150mg/ml	05112011 @2	5/11/11	5/23/11	5/13/11	64952
Medroxyprogesterone 150mg/ml	05112011 @2	5/11/11	5/23/11	5/13/11	65016
Medroxyprogesterone 150mg/ml	05112011 @2	5/11/11	5/23/11	5/16/11	66069
Medroxyprogesterone 150mg/ml	05112011 @2	5/11/11	5/23/11	5/16/11	68158
Medroxyprogesterone 150mg/ml	05112011 @2	5/11/11	5/23/11	5/16/11	65614
Medroxyprogesterone 150mg/ml	05112011 @2	5/11/11	5/23/11	5/17/11	64985
Medroxyprogesterone 150mg/ml	05112011 @2	5/11/11	5/23/11	5/17/11	65215
Medroxyprogesterone 150mg/ml	05112011 @2	5/11/11	5/23/11	5/17/11	66368
Medroxyprogesterone 150mg/ml	05112011 @2	5/11/11	5/23/11	5/18/11	65238
Medroxyprogesterone 150mg/ml	05112011 @2	5/11/11	5/23/11	5/19/11	68225
Medroxyprogesterone 150mg/ml	05112011 @2	5/11/11	5/23/11	5/18/11	65385
Medroxyprogesterone 150mg/ml	05112011 @2	5/11/11	5/23/11	5/19/11	68257

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.

4. Revoking or suspending Pharmacist License Number RPH 22604, issued to Respondent Norman Jacobs.

5. Ordering Respondents Advanced Physician Solutions, Inc. dba Advanced Compounding Pharmacy, Tooraj Bereliani, and Norman Jacobs 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.

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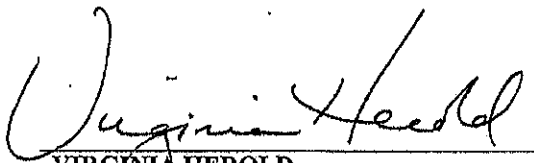
6. Taking such other and further action as deemed necessary and proper.

DATED: 10/31/11



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

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

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.

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

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

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 **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, 2010, 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, 2010, 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, 2010, unless renewed.

JURISDICTION

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

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

7. 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.

8. 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."

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9. 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:

. . .

(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. . . ."

10. 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."

11. 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. . . ."

12. 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.

13. 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. . . ."

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14. 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."

15. 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. . . ."

16. 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. . . ."

17. 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,

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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. . . ."

18. 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 prescription 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. . . ."

19. 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

20. 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.

FIRST CAUSE FOR DISCIPLINE

(Furnishing of Controlled Substance through Unlicensed Wholesaler)

[Respondents Advanced Compounding and Bereliani]

21. 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, 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 Advanced Compounding and Bereliani had a verbal agreement to furnish orders from Superior Medical Supply (located in the State of Colorado) to their 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.

SECOND CAUSE FOR DISCIPLINE

(Failure to Maintain Written Policies and Procedures)

[Respondents Advanced Compounding and Bereliani]

22. 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) During an investigation at Advanced Compounding Pharmacy on or about June 19, 2008, Respondent Bereliani stated he 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.

THIRD CAUSE FOR DISCIPLINE

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

[Respondents Advanced Compounding and Bereliani]

23. 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) During an investigation at Advanced Compounding Pharmacy on or about June 19, 2008, 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) During the June 19, 2008, investigation the preparation records for the compounding of sterile injectable drugs from non-sterile ingredients, showed expiration dating of 180 days extended to one year expiration dating for sterile injectable drugs shipped outside of California and no Master Formulas to substantiate any expiration dating.

FOURTH CAUSE FOR DISCIPLINE

(Failure to Maintain Complete Compounding Records)

[Respondents Advanced Compounding and Bereliani]

24. 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) During an investigation at Advanced Compounding Pharmacy on or about June 19, 2008, Respondents labeled sterile injectable products, with a 180 day expiration date, with a one year expiration date when the drug was shipped outside California without justifying either expiration date and in violation of Regulation section 1716.2(a)(3).

b) During an investigation at Advanced Compounding Pharmacy on or about June 19, 2008, Respondent Bereliani failed to sign or initial the Logged Formula Worksheet records in violation of Regulation section 1716.2(a)(4).

c) During an investigation at Advanced Compounding Pharmacy on or about June 19, 2008, 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).

FIFTH CAUSE FOR DISCIPLINE

(Failure to Document Supervision of Pharmacy Technician)

[Respondents Advanced Compounding and Bereliani]

25. 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) During the June 19, 2008 investigation at Advanced Compounding Pharmacy, Respondent Bereliani failed to initial or document many of the Logged Formula Worksheet records verifying the supervision and duties performed by compounding pharmacy technician Zherair Aghakhan.

SIXTH CAUSE FOR DISCIPLINE

(Misbranding of Drugs with False or Misleading Information)

[Respondents Advanced Compounding and Bereliani]

26. 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 Respondent misbranded and labeled drugs with false and misleading information. The circumstances are as follows:

a) During investigations conducted at Advanced Compounding Pharmacy on June 19, 2008 and June 24, 2008, it was 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) During investigations conducted at Advanced Compounding Pharmacy on June 19, 2008 and June 24, 2008, it was found that Respondents misbranded the prescription labels with false and misleading expiration dates typed as 180 days and one year.

SEVENTH CAUSE FOR DISCIPLINE

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

[Respondents Advanced Compounding and Bereliani]

17. Respondents Advanced Physician Solutions 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 sold 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 Advanced Compounding Pharmacy (ACP). ACP, which is located in North Hollywood, California, is a licensee permitted to compound injectable sterile drug products. The drugs were further misbranded in that the drugs were labeled by ACP with a one year expiration date when they were shipped outside of California and with a six month expiration date when they were shipped in California.

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 Advanced Physician Solutions, Inc. dba Advanced Compounding Pharmacy.

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

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

4. Ordering Advanced Physician Solutions, Inc. 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: 12/30/09

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

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