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8 **BEFORE THE**
9 **BOARD OF PHARMACY**
10 **DEPARTMENT OF CONSUMER AFFAIRS**
11 **STATE OF CALIFORNIA**

11 In the Matter of the Accusation Against:

Case No. 3251

12 **ADVANCED PHYSICIAN SOLUTIONS,**
13 **INC. dba ADVANCED COMPOUNDING**
14 **PHARMACY**
7225 Fulton Ave.
North Hollywood, CA 91605

A C C U S A T I O N

15 Pharmacy Permit No. PHY 48591
16 Permit to Compound Injectable Sterile
Drug Products No. LSC 99426,

17 and

18 **TOORAJ BERELIANI**
19 **PHARMACIST-IN-CHARGE**
7225 Fulton Ave.
North Hollywood, CA 91605

20 Pharmacist License No. RPH 51817

21 Respondents.

22
23
24 Complainant alleges:

25 **PARTIES**

26 1. Virginia Herold (Complainant) brings this Accusation solely in her official capacity
27 as the Executive Officer of the Board of Pharmacy, Department of Consumer Affairs.
28

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

2 "The board shall take action against any holder of a license who is guilty of unprofessional
3 conduct or whose license has been procured by fraud or misrepresentation or issued by mistake.

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

5 ...

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

8 ...

9 (o) Violating or attempting to violate, directly or indirectly, or assisting in or abetting the
10 violation of or conspiring to violate any provision or term of this chapter or of the applicable
11 federal and state laws and regulations governing pharmacy, including regulations established by
12 the board or by any other state or federal regulatory agency. . . ."

13 10. Code section 4126.5, subdivision (a), provides:

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

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

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

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

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

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

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

28

1 (7) To another pharmacy under common control.”

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

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

5 ...

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

7 ...

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

9 12. Section 4077 of the Code states, in pertinent part, that except as provided in
10 subdivisions (b) and (c) of this section, no person shall dispense any dangerous drug upon
11 prescription except in a container correctly labeled with the information required by Section
12 4076.

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

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

23 (b) The owner, officer, and partner of a pharmacy, wholesaler, . . . shall be jointly
24 responsible, with the pharmacist-in-charge or representative-in-charge, for maintaining the
25 records and inventory described in this section. . . .”

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1 14. Section 4328 of the Code states:

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

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

7 “(c) Pharmacies compounding sterile injectable products from one or more
8 non-sterile ingredients must have written policies and procedures that comply
9 with the following:

10 ...

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

12 ...

13 (I) For sterile batch compounding, written policies and procedures must be
14 established for the use of master formulas and work sheets and for appropriate
15 documentation. . . .”

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

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

21 ...

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

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

26 “(a) For the purpose of compounding in quantities larger than required for
27 immediate dispensing by a prescriber or for future dispensing upon prescription,

28 ///

1 a pharmacy shall maintain records that include, but are not limited to:
2 ...
3 (3) The expiration date of the finished product. This date must not exceed
4 180 days or the shortest expiration date of any component in the finished
5 product unless a longer date is supported by stability studies in the same
6 type of packaging as furnished to the prescriber. Shorter dating than set forth
7 in this subsection may be used if it is deemed appropriate in the professional
8 judgment of the responsible pharmacist.
9 (4) The signature or initials of the pharmacist performing the compounding.
10 (5) A formula for the compounded product. The formula must be maintained in a
11 readily retrievable form. . . .”
12 18. California Code of Regulations, Title 16, section 1793.7, provides, in part:
13 “(a) Except as otherwise provided in section 1793.8, any function performed by
14 a pharmacy technician in connection with the dispensing of a prescription,
15 including repackaging from bulk and storage of pharmaceuticals, must be verified
16 and documented in writing by a pharmacist. Except for the preparation of
17 prescriptions for an inpatient of a hospital and for an inmate of a
18 facility, the pharmacist shall indicate verification of the prescription by
19 initialing the prescription label before the medication is provided to the
20 patient.
21 (b) Pharmacy technicians must work under the direct supervision of a
22 pharmacist and in such a relationship that the supervising pharmacist is fully
23 aware of all activities involved in the preparation and dispensing of
24 medications, including the maintenance of appropriate records.
25 ...
26 (e) A pharmacist shall be responsible for all activities of pharmacy
27 technicians to ensure that all such activities are performed completely, safely
28 and without risk of harm to patients. . . .”

1 19. California Code of Regulations, Title 16, section 1751.2, subdivision (b), provides:
2 “In addition to existing labeling requirements, a pharmacy which compounds
3 sterile injectable products shall include the following information on the
4 labels for those products:
5 ...
6 (b) Name and concentrations of ingredients contained in the sterile
7 injectable product. . . .”

8 **COST RECOVERY**

9 20. Section 125.3 of the Code states, in pertinent part, that the Board may request the
10 administrative law judge to direct a licentiate found to have committed a violation or violations of
11 the licensing act to pay a sum not to exceed the reasonable costs of the investigation and
12 enforcement of the case.

13 **FIRST CAUSE FOR DISCIPLINE**

14 **(Furnishing of Controlled Substance through Unlicensed Wholesaler)**

15 **[Respondents Advanced Compounding and Bereliani]**

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

- 21 a) Between February 27, 2008 and August 4, 2008, Respondents Advanced
22 Compounding and Bereliani had a verbal agreement to furnish orders from Superior
23 Medical Supply (located in the State of Colorado) to their customers for controlled
24 substances and then to bill Superior Medical Supply for the purchase of the
25 controlled substances. Superior Medical Supply was not authorized by the Drug
26 Enforcement Administration to engage in the distribution of controlled substances.
27 b) The furnishing of the controlled substances occurred as follows: Schedule II, III,
28 IV, and V controlled substances were ordered through Superior Medical Supply for

1 their customers; the controlled substances were drop shipped by Respondents to
2 Superior Medical Supply customers; Respondents billed Superior Medical Supply
3 for the controlled substances; Superior Medical Supply paid the billed invoices from
4 Respondents; Superior Medical Supply then invoiced their customers directly for
5 the drop shipped controlled substances.

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

9 **SECOND CAUSE FOR DISCIPLINE**

10 **(Failure to Maintain Written Policies and Procedures)**

11 **[Respondents Advanced Compounding and Bereliani]**

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

- 18 a) During an investigation at Advanced Compounding Pharmacy on or about June
19 19, 2008, Respondent Bereliani stated he did not have written policies and
20 procedures established for the use of a master formula, worksheets and
21 documentation when compounding sterile batch injectable drugs from non-sterile
22 ingredients.

23 **THIRD CAUSE FOR DISCIPLINE**

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

25 **[Respondents Advanced Compounding and Bereliani]**

26 23. Respondents Advanced Compounding and Bereliani are subject to disciplinary action
27 under section 4301, subdivisions (j) and (o), in conjunction with Code section 4081, subdivisions
28 (a) and (b) and California Code of Regulations, Title 16, section 1751.3(b)(6), in that

1 Respondents failed to maintain, for three years, the preparation records, including Master
2 Formula worksheets, when compounding sterile products from one or more non-sterile
3 ingredients. The circumstances are as follows:

- 4 a) During an investigation at Advanced Compounding Pharmacy on or about June 19,
5 2008, Respondent Bereliani maintained only a few of the required Master Formula
6 worksheets for the pharmacy's compounding of sterile injectable drugs from non-
7 sterile ingredients.
- 8 b) During the June 19, 2008, investigation the preparation records for the
9 compounding of sterile injectable drugs from non-sterile ingredients, showed
10 expiration dating of 180 days extended to one year expiration dating for sterile
11 injectable drugs shipped outside of California and no Master Formulas to
12 substantiate any expiration dating.

13 **FOURTH CAUSE FOR DISCIPLINE**

14 **(Failure to Maintain Complete Compounding Records)**

15 **[Respondents Advanced Compounding and Bereliani]**

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

- 21 a) During an investigation at Advanced Compounding Pharmacy on or about June 19,
22 2008, Respondents labeled sterile injectable products, with a 180 day expiration
23 date, with a one year expiration date when the drug was shipped outside California
24 without justifying either expiration date and in violation of Regulation section
25 1716.2(a)(3).
- 26 b) During an investigation at Advanced Compounding Pharmacy on or about June 19,
27 2008, Respondent Bereliani failed to sign or initial the Logged Formula Worksheet
28 records in violation of Regulation section 1716.2(a)(4).

- 1 c) During an investigation at Advanced Compounding Pharmacy on or about June 19,
2 2008, no Master Formulas were available to substantiate a one year or 180 day
3 expiration for the same product in violation of Regulation section 1716.2(a)(5).

4 **FIFTH CAUSE FOR DISCIPLINE**

5 **(Failure to Document Supervision of Pharmacy Technician)**

6 **[Respondents Advanced Compounding and Bereliani]**

7 25. Respondents Advanced Compounding and Bereliani are subject to disciplinary action
8 under section 4301, subdivisions (j) and (o), in conjunction with Code section 4081, subdivisions
9 (a) and (b) and California Code of Regulations, Title 16, section 1793.7(a), in that Respondents
10 failed to document supervision and verification of duties performed by the pharmacy technician.

11 The circumstances are as follows:

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

16 **SIXTH CAUSE FOR DISCIPLINE**

17 **(Misbranding of Drugs with False or Misleading Information)**

18 **[Respondents Advanced Compounding and Bereliani]**

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

- 24 a) During investigations conducted at Advanced Compounding Pharmacy on June 19,
25 2008 and June 24, 2008, it was found that Respondents allowed the compounded
26 drug Medroxyprogesterone Acetate 150mg/ml to be misbranded by falsely labeling
27 the drug with the misleading label as either "Medroxy Progst PF (75/0.5mg) ml" or
28 "Medroxy Proge (75/.5) 75/0.5mg."

1 b) During investigations conducted at Advanced Compounding Pharmacy on June 19,
2 2008 and June 24, 2008, it was found that Respondents misbranded the prescription
3 labels with false and misleading expiration dates typed as 180 days and one year.

4 **SEVENTH CAUSE FOR DISCIPLINE**

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

6 **[Respondents Advanced Compounding and Bereliani]**

7 17. Respondents Advanced Physician Solutions and Bereliani are subject to disciplinary
8 action under section 4301, subdivisions (j) and (o), in conjunction with Code section 4169,
9 subdivision (a)(3) and Health and Safety Code section 111335, in that Respondents purchased,
10 traded, sold or transferred dangerous drugs that they knew, or reasonably should have known
11 were misbranded. The circumstances are as follows:

12 a) From on or about February 28, 2008 through on or about June 4, 2008, Respondents
13 sold to doctors and clinics Medroxyprogesterone 150mg/ml pre-filled syringes that
14 were misbranded with false or misleading labels that read "Medroxy Progst PF
15 (75/0.5mg) ml" or "Medroxy Proge (75/.5) 75/0.5mg" that were manufactured by
16 Advanced Compounding Pharmacy (ACP). ACP, which is located in North
17 Hollywood, California, is a licensee permitted to compound injectable sterile drug
18 products. The drugs were further misbranded in that the drugs were labeled by ACP
19 with a one year expiration date when they were shipped outside of California and
20 with a six month expiration date when they were shipped in California.

21
22 **PRAYER**

23 WHEREFORE, Complainant requests that a hearing be held on the matters herein alleged,
24 and that following the hearing, the Board of Pharmacy issue a decision:

25 1. Revoking or suspending Pharmacy Permit Number PHY 48591, issued to Advanced
26 Physician Solutions, Inc. dba Advanced Compounding Pharmacy.

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

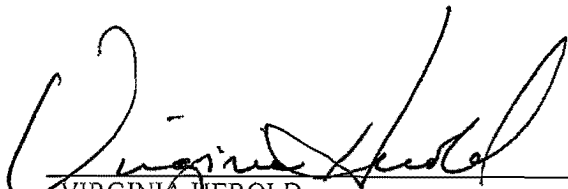
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3. Revoking or suspending Pharmacist License Number RPH 51817, issued to Tooraj Bereliani, Pharmacist-in-Charge.

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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