

1 03-15-C

2 BEFORE THE ARIZONA STATE BOARD OF PHARMACY

3 In the Matter of:

) Case Number 03-15-PHR

4 APOTHECARY SHOP OF PHOENIX, INC.  
5 Holder of Pharmacy Permit Number 3155  
6 In the State of Arizona,

)  
) **AMENDED COMPLAINT AND NOTICE**  
) **OF HEARING**

7 Respondent.  
\_\_\_\_\_ )

8 **DIRECTED TO:** Apothecary Shop of Phoenix, Inc.  
9 1300 N. 12<sup>th</sup> Street, Suite 555  
Phoenix, AZ 85006

10 **JURISDICTION**

11 1. This Complaint and Notice of Hearing are prepared, and these proceedings are instituted,  
12 under A.R.S. § 32-1928 and A.A.C. R4-23-104. The Arizona State Board of Pharmacy ("Board") will  
13 conduct a hearing at 9:00AM, the 5<sup>th</sup> day of November 2003, at the Board of Pharmacy Offices, 4425  
14 W. Olive Avenue, Suite 140, Glendale, Arizona to determine whether Pharmacy Permit Number 3155  
15 should be revoked, suspended, placed on probation or fined.

16 **PARTIES**

17 2. Under A.R.S. § 32-1904, the Board is created and empowered to administer the laws  
18 of the State of Arizona relating to the practice of pharmacy and the supplying of drugs, devices, poisons  
19 or hazardous substances.

20 3. Under A.R.S. § 32-1929, Respondent is the holder of Pharmacy Permit Number 3155,  
21 which permits the holder to operate a pharmacy in the state of Arizona. Respondent did and does  
22 operate the Apothecary Shop of Phoenix, Inc., located at 1300 N. 12<sup>th</sup> Street, Suite 555, Phoenix,  
23 Arizona.

24 **FACTUAL ALLEGATIONS**

25 4. On April 29, 2003, Timothy T. Kapsala, a United States Food & Drug Administration  
26 (FDA) investigator was contacted by Dr. David J. Watts, a toxicologist at Good Samaritan Medical

1 Center, regarding patient R.K. who had blood levels of thyroid hormone T3 that were eight hundred  
2 (800) times the normal range of ten (10) nanograms/deciliter.

3 5. On May 5, 2003, Timothy T. Kapsala, an FDA investigator was contacted by Dr. Len  
4 Katz, a toxicologist for Good Samaritan Medical Center, regarding patient S.R. who also exhibited blood  
5 levels of thyroid hormone T3 that were eight hundred (800) times the normal range of ten (10)  
6 nanograms/deciliter.

7 6. Mr. Kapsala and Dean Wright, a Board Compliance Officer visited the Apothecary Shop,  
8 Inc., located at 1300 N. 12<sup>th</sup> Street, Ste. 555, Phoenix, Arizona. After interviewing pharmacy personnel,  
9 it was disclosed to them that patients R.K. and S.R. had received compounded prescriptions for  
10 liothyronine that were compounded, filled and dispensed by personnel at the Apothecary Shop of  
11 Phoenix. On March 13, 2003, patient R.K. received prescription number 0173718 and on April 28,  
12 2003, patient S.R. received prescription number 0179175.

13 7. Messrs. Kapsala and Wright reviewed pharmacy invoices and conducted interviews with  
14 pharmacy technician A.K, who is solely responsible for ordering prescription drugs and raw materials  
15 for the pharmacy. On or about February 3, 2003, pharmacy technician, A.K., ordered three (3) bottles  
16 containing twenty-five (25) grams, total of seventy-five (75) grams, of liothyronine sodium.

17 8. From pharmacy records and an analysis by the FDA lab in Denver that the liothyronine  
18 compounded prescriptions provided to patients R.K. and S.R. came from lot # 20002707, which the  
19 investigators discovered was actually a container of raw material, not a diluted aliquot of liothyronine  
20 as labeled. The lab results disclosed that lot # 20002707 was 795.6 mcg. per mg. instead of the labeled  
21 quantity of 1 mcg. per mg., in violation of A.A.C. R4-23-410(I)(2) and (3), to wit:

- 22 a. A pharmacy permittee shall ensure that the pharmacist-in-charge  
23 establishes and implements drug compounding controls that conform  
24 with the standards in this subsection.  
25 b. Components for drug compounding are accurately weighed, measured,  
26 or subdivided. To ensure that each weight, measure, or subdivision is  
correct as stated in the compounding procedures, a pharmacist checks and  
rechecks, or assumes responsibility for checking and rechecking, the  
operations at each stage of the compounding process.

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c. When a component is removed from its original container and transferred to another container, the new container label contains, in full text or an abbreviated code system, the following:

- i. The component name
- ii. The lot or control number
- iii. The weight or measure
- iv. The beyond-use-date, and
- v. The transfer date

9. The unused capsules from patient R.K.'s prescription (#0173718), which were compounded, filled and dispensed by personnel at the Apothecary Shop of Phoenix, Inc., were analyzed by the FDA lab in Denver and were determined to contain over eight hundred (800) times the labeled quantity.

10. The unused capsules from patient S.R.'s prescription (#0179175), which were compounded, filled and dispensed by personnel at the Apothecary Shop of Phoenix, Inc., were analyzed by the FDA lab in Denver and were determined to contain over nine hundred (900) times the labeled quantity.

11. In a report dated May 30, 2003, FDA investigator Kapsala stated, "the common thread between the two patients ([R.K.] & [S.R.]) was the compounded medication Liothyronine 7.5 mcg. per capsule, which were compounded, filled and dispensed at the Apothecary Shop of Phoenix, Inc., located at 1300 N. 12<sup>th</sup> Street, Suite 555, Phoenix, AZ 85006." The report also stated that "the analysis of the suspect capsules revealed the capsules contained potency similar to the raw ingredients instead of the labeled strength which is achieved by diluting the raw ingredient."

12. Respondent is the permittee of, and has for the past four (4) years, held the permit for the Apothecary Shop of Phoenix, Inc., located at 1300 N. 12<sup>th</sup> Street, Suite 555, Phoenix, AZ, 85006.

**CAUSE OF ACTION**

13. The conduct and circumstances described in paragraphs four (4) through twelve (12) above constitute grounds for disciplinary action as defined in A.R.S. § 32-1932(A)(1) and A.A.C. R4-23-410(I)(2) and (3).

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14. A.R.S. § 32-1932(A)(1) provides that the board, after notice and hearing, may impose a civil penalty of not more than one thousand dollars for each offense and deny, suspend or revoke any permit issued under this chapter or place a permittee on probation if at any time any of the following occurs:

- a. On examination or inspection it is found that the place is not being conducted according to the federal act and this chapter relating to the manufacturing, sale and distribution of drugs, devices, poisons or hazardous substances.

15. A.A.C. R4-23-410(I)(2) and (3) provides that a pharmacy permittee shall ensure that the pharmacist-in-charge establishes and implements drug compounding controls that confirm with the standards stated in these rules.

16. Respondent is directed to mail to the Board no later than the 17<sup>th</sup> day of October, 2003, a written response to the allegations described above. Respondent's failure to file a timely response may result in the allegations being deemed admitted under A.A.C. R4-23-104(I).

17. Respondent is hereby notified that he may appear with or without the assistance of an attorney, on the date and at the time specified in this Complaint and Notice of Hearing and present testimony and argument. If the Respondent fails to appear, the Board may proceed in his absence.

18. Respondent is further notified that no continuance will be granted unless a request for continuance is submitted to the Board in writing, detailing the reasons for the requested continuance, and the request is granted by the Board. Except in the event of an emergency, a request for continuance shall be submitted to the Board no later than seven (7) days prior to the date of hearing.

DATED this 17<sup>th</sup> day of October, 2003.

THE ARIZONA STATE BOARD OF PHARMACY



By \_\_\_\_\_  
Hal Wand  
Executive Director

SEAL

1 Copies of the foregoing Notice of Hearing  
hand delivered this 17<sup>th</sup> day of October, 2003 to:  
2 *MAILED*

3 John Musil  
4 Apothecary Shop of Phoenix  
8133 N. Ridgeview Drive  
Paradise Valley, Arizona 85253

5 Copy of the foregoing mailed by US mail this  
17<sup>th</sup> day of October, 2003, to:

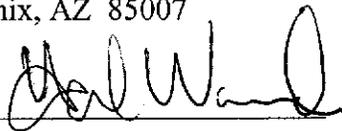
6 Roger N. Morris  
7 Quarles & Brady Streich Lang  
Two N. Central  
8 Phoenix, AZ 85004  
Attorneys for Respondent

9 And by courier mail to:

10 Roberto Pulver  
11 Assistant Attorney General  
Office of the Attorney General  
12 Civil Division  
1275 W. Washington  
13 Phoenix, AZ 85007

14 and

15 Victoria Mangiapane  
Assistant Attorney General  
16 Solicitor General's Office  
Office of the Attorney General  
17 1275 W. Washington  
Phoenix, AZ 85007

18 By:   
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